



Changing tomorrow

For the Year Ended March 31, 2020

ANNUAL REPORT

2020



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Editorial Policy

To enable deeper stakeholder understanding of Astellas' efforts to continue to create VALUE for sustainable growth, the Company has published this annual report as an integrated report.

In order to provide timely information, from fiscal year ended March 2019, we have started publishing the Annual Report on our website. The information in the online version "Annual Report" will be updated to the latest information as needed.

This report is a copy of the online version "Annual Report" made on October 9, 2020 to improve corporate transparency by providing regularly recorded information.

In this report, we have attempted to provide disclosure while taking note of the Guiding Principles and Content Elements of the international integrated reporting framework of the International Integrated Reporting Council (IIRC). We have also referred to the Sustainability Reporting Standard* published by the Global Reporting Initiative (GRI).

Astellas has adopted the International Financial Reporting Standards (IFRS), effective from fiscal 2013. Information in this report is based on IFRS unless otherwise indicated. The monetary amounts stated in this report have been rounded off to the nearest unit, and the number of shares has been rounded down to the nearest whole number. Unless otherwise noted, percentage changes and other ratios involving the previous fiscal year have been rounded off to the second decimal place.

* For the GRI Standards Content Index, please visit the following website:
<https://www.astellas.com/jp/en/investors/annual-report/archives>

Scope of the Report

Period covered

Fiscal year ended March 2020 (April 1, 2019 - March 31, 2020)

* As much as possible, we have included the latest information available at the time of publication.

* The period and scope of coverage may vary depending on the subject. We have noted each such case individually.

Organizations covered

Astellas Pharma Inc. and its consolidated subsidiaries in Japan and overseas (referred to in this report as "Astellas")

Cautionary Note

In this annual report, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this annual report is not intended to constitute an advertisement or medical advice.

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CEO Message



Steady Results also for the Second Year of the Corporate Strategic Plan 2018 Working to Achieve the Corporate Strategic Plan 2018's Objectives Upon Making Active Investments for Medium- to Long-Term Growth

We give our deepest sympathies to those who have passed away as a result of the Coronavirus Disease (COVID-19) and pray, from the bottom of our hearts, for the recovery of those who have been infected. As part of our mission as a pharmaceutical company, Astellas will contribute to overcoming this pandemic through [various actions and measures](#).

Corporate Strategic Plan 2018 and Progress

For Astellas, the three years of the [Corporate Strategic Plan 2018](#), which started in April 2018, are the years in which our product portfolio significantly changed due to the end of market exclusivity for several of our main products. As an important strategic goal of the Corporate Strategic Plan, in order to survive this transitional period and attain sustainable growth, we are launching new products as planned and maximizing their values. In implementing this strategy, we have been able to surpass expectations by concentrating management resources in expanding the sales of core products and to develop post-POC pipeline projects. In spite of the forecast which originally estimated a decrease of revenue and core operating profit for the fiscal year ended March 2020, we were able to offset the negative impact from the end of market

exclusivity for our main products by increasing the market penetration of XTANDI through the expanding of its indication for earlier stages of prostate cancer and the stronger than expected initial sales of our new product EVENITY. As a result, [revenue and profit for the fiscal year ended March 2020](#) were in the same range as those for the fiscal year ended March 2019, and an increase was seen in both when the foreign exchange rate impact was excluded from the calculation. In addition to this, we were able to invest in new technology in preparation for the future.

The three strategic goals outlined in the Corporate Strategic Plan are steadily progressing, and we are demonstrably advancing towards realizing our [VISION](#) of “on the forefront of healthcare change to turn innovative science into VALUE for patients.”

Corporate Strategic Plan 2018: Strategic Goal 1 **Maximizing Product VALUE and Operational Excellence**

Our key products [XTANDI and mirabegron](#) grew faster than expected in the fiscal year ended March 2020, which was one of the factors our revenue and core operating profit exceed the forecasts. Sales of XTANDI grew not only in the United States, Europe and Japan, but also in Russia, Brazil, etc. due to the expansion of its indications across the world. Sales of mirabegron continued to grow in each region due to market expansion through disease awareness activities and further penetration of product features in healthcare professionals. Many milestones have also been achieved in the development of [key post-POC pipeline projects](#), such as the obtaining of study results, regulatory submissions and approvals, and in these two years we were able to launch the three global products, [XOSPATA](#), [PADCEV](#) and [Evrenzo](#). In some cases, we were able to achieve ahead-of-schedule launches by utilizing the accelerated approval pathways that regulatory authorities have begun to introduce.

In order to maximize the VALUE of products and key post-POC pipeline projects, it is also important to realize an organizational structure that matches our product portfolios and external environment. In April 2019, we established a new sales and marketing structure and enhanced strategic planning and execution capabilities for key products by product, region and country. In China, where the market is expected to further expand going forward, we have strategically positioned the market as one of the top-tier markets like Japan, US and Europe, and accordingly started to strengthen not only the sales structure, but also the development and regulatory functions.

In terms of the allocation of management resources, we are sufficiently investing in new products and growing products based on clear prioritization. On the other hand, we are continuing to pursue Operational Excellence by reviewing selling expenses, transferring the rights to sell products to third parties, etc.

Corporate Strategic Plan 2018: Strategic Goal 2 **Evolving How We Create VALUE** **– With Focus Area Approach –**

Astellas is taking an approach called “[Focus Area Approach](#)” as its research and development strategy, and the Primary Focus that was selected based on this strategy is what we focus our management resources to develop innovative healthcare solutions.

In January 2020, Astellas acquired Audentes Therapeutics, Inc, and gained capabilities for gene therapy, including technology platforms, manufacturing capabilities, and the achievement and experience to develop new drug candidates into the clinical stage. By obtaining these assets, Astellas has made a significant first step toward becoming a top runner in this area. As a result of this, as an addition to the other four areas of, “[Antigen-specific Immune Modulation \(ASIM\)](#),” “[immuno-oncology targeting lymphocytes with low permeability](#),” “[regeneration and blindness](#)” and “[mitochondria biology](#),” “[genetic regulation](#)” became the 5th Primary Focus.

Moreover, links are now beginning to form between the Primary Focus areas that were originally independent of one another. For example, universal donor cell technology, which advances “regeneration and blindness,” is utilized also in “immuno-oncology.” By integrating technologies in the different fields, our initiatives will be strengthened and expanded,

and will grow into a unique Primary Focus. It is expected to become the key to the future growth of Astellas, and a source of competitive advantage that is second to none.

Corporate Strategic Plan 2018: Strategic Goal 3

Developing Rx+ Programs

Astellas set, as its third strategic goal, “to develop new products and services (Rx+ business) which is out of Astellas’ core prescription pharmaceutical products (Rx) by combining Astellas’ expertise and experience in medical drugs with technology and knowledge from different fields,” and has been seeking new business opportunities. Consequently, many projects have been developed thus far, and we have mapped out “Rx+ Story™” as a strategic direction in order to evolve the Rx+ business. We expect that connecting and creating synergy effects among business ideas which tend to be established based on single opportunity and be sporadic, are enhanced and the development of the Rx+ business accelerated by this strategic direction.

Each program aiming to create the Rx+ business is progressing steadily toward commercialization. Going forward, we plan to realize “a world where people can live mentally and physically healthy lives and be true to themselves through healthcare solutions based on scientific evidence.”

Improving the Sustainability of Society and Astellas

Astellas contributes to the improvement of a sustainable society by fulfilling its social responsibility as a pharmaceutical company through its business activities, such as providing pharmaceutical products that satisfy unmet medical needs. We earn the trust of society toward our products through such efforts, and we believe that this trust will enhance our own sustainability as a company.

In line with this belief, with the continuing spread of COVID-19, we are, as a part of our mission as a pharmaceutical company, taking various actions and measures to contribute to securing the safety of patients and alleviating strain on healthcare resources. We have, thus far, conducted initiatives in areas that include the stable supply of products, contribution to the R&D of drugs, and assistance to regions where infection is spreading.

Through improving Access to Health, Astellas will contribute to the attainment of the Sustainable Development Goals (SDGs) adopted by the United Nations, focusing primarily on “Goal 3: Good Health and Well-Being.” In addition to this, Astellas is working to achieve other goals related to the environment, society, etc. through various business activities, with the aim of developing a sustainable society.

Strengthening Human Resource Development and Organizational Capabilities

In order to realize the Corporate Strategic Plan, the “people” and the “organization” that support it are indispensable, and it is crucial that every employee working at Astellas takes ownership of their duties based on the understanding of the Astellas’ sense of values, the “Astellas Way,” as well as the Astellas’ approach to human resources and organization, the “HR Vision.” Astellas’ human resources and organization management has been structured in such a way as to focus on the three areas of attracting, developing, and retaining talent, so that it can maximize the performance of the “people” and the “organization”. In the fiscal year ended March 2020, we introduced a new global system that standardizes all the employees’ data and integrates the performance evaluation system. This allows us to assign the right person in the right position at the right time with a fair evaluation. Going forward, we will carry out new initiatives in due course and create a working environment where every employee is motivated to work.

As a consistent supporter of the United Nations Global Compact, Astellas conducts its daily business activities based on the 10 principles advocated by the United Nations, covering the four fields of human rights, labor, the environment, and anti-corruption.

To Our Stakeholders

Two years have passed since the implementation of the Corporate Strategic Plan 2018, and the fiscal year ending March 2021 will be its final year. The initiatives for each strategic goal are steadily making headway, and some are even performing better than expected. We were also able to make new investments for sustainable growth.

Though revenue and [core operating profit for the fiscal year ending March 2021](#) is projected to decrease compared to those for the fiscal year ending March 2020, mainly because of the spread of COVID-19, sales of XTANDI and PADCEV, which are our core products driving our growth, are expected to solidly grow. We are confident that we are advancing significantly towards our VISION in terms of more than what we see in the just financial figures, considering the fact that we have been able to begin further strengthening our business foundation and make active future investments by acquiring Audentes Therapeutics, Inc and Xyphos Biosciences, Inc.

We will proceed with our plan to achieve results for each strategic goal as soon as possible and continue to advance into the future.

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Corporate Strategy



Philosophy

The Astellas Group's business philosophy has three elements- Raison D'etre, Mission and Beliefs. We achieve continuous improvement in...

[Read More](#)

VISION & Strategy

Based on our business philosophy, we aim to achieve our VISION.

[Read More](#)

Strategic Plan 2018

Our Corporate Strategic Plan provide a path to realizing VISION in the coming years. By executing our corporate strategic plan, we will...

[Read More](#)

CSR-Based Management

Astellas' CSR-Based management basic concept

[Read More](#)

Materiality in CSR Activities

CSR Materiality Matrix which shows the material issues in Astellas' CSR activities

[Read More](#)

Contributions to the Sustainable Development Goals

Astellas' contribution to the SDGs

[Read More](#)

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Philosophy

The Astellas Group's business philosophy has three elements — raison d'être, mission and beliefs.

Raison D'être

Contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products

- To go beyond all others in exploring and tapping the potential of the life sciences.
- To continue tackling new challenges and creating innovative pharmaceutical products.
- To deliver quality products along with accurate information and retain solid credibility among customers.
- To support healthy living for people around the world.
- To continue shining on the global pharmaceutical field.

Mission

Sustainable enhancement of enterprise value

- Astellas will seek to enhance its enterprise value in a sustainable manner.
- Astellas will seek to be the company of choice among all its stakeholders, including its customers, shareholders, employees, and the global community.
- Astellas will strive to gain the trust of all stakeholders and thereby enhance its enterprise value.

Beliefs

Our "beliefs" provide the code of conduct we prize at all times. Astellas will always be a group of people who act upon these beliefs.

High Sense of Ethics

We will always manage our business with the highest sense of ethics.

Customer Focus

We will always seek to understand customer needs and our focus will always be on achieving customer satisfaction.

Creativity

We will not be complacent and will always seek to innovate to create new value.

Competitive Focus

Our eyes will always be directed to the outside world, and we will continue to create better value faster.

Astellas promises to perform its obligations toward all stakeholders by acting ethically and seeking to actively disclose information.

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VISION & Strategy

On the forefront of healthcare change to turn innovative science into value for patients

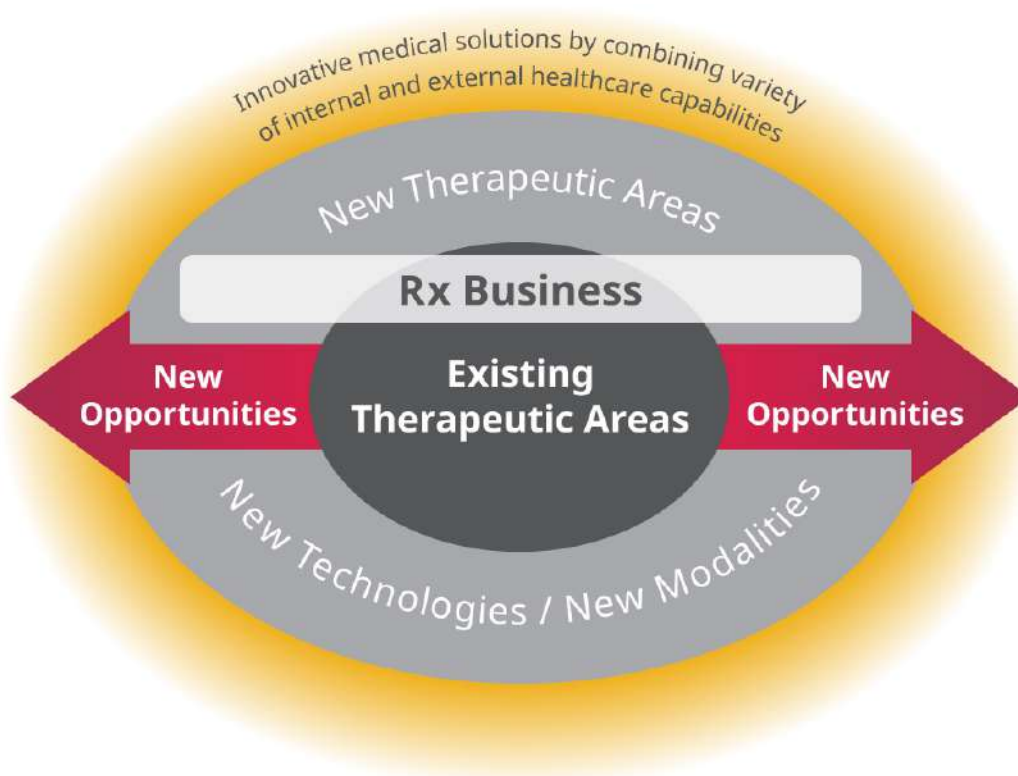
Turn changes into opportunities

Create innovative new drugs and medical solutions by leveraging our core capabilities

Go beyond GCL*

View business opportunities from multiple perspectives, and embrace change

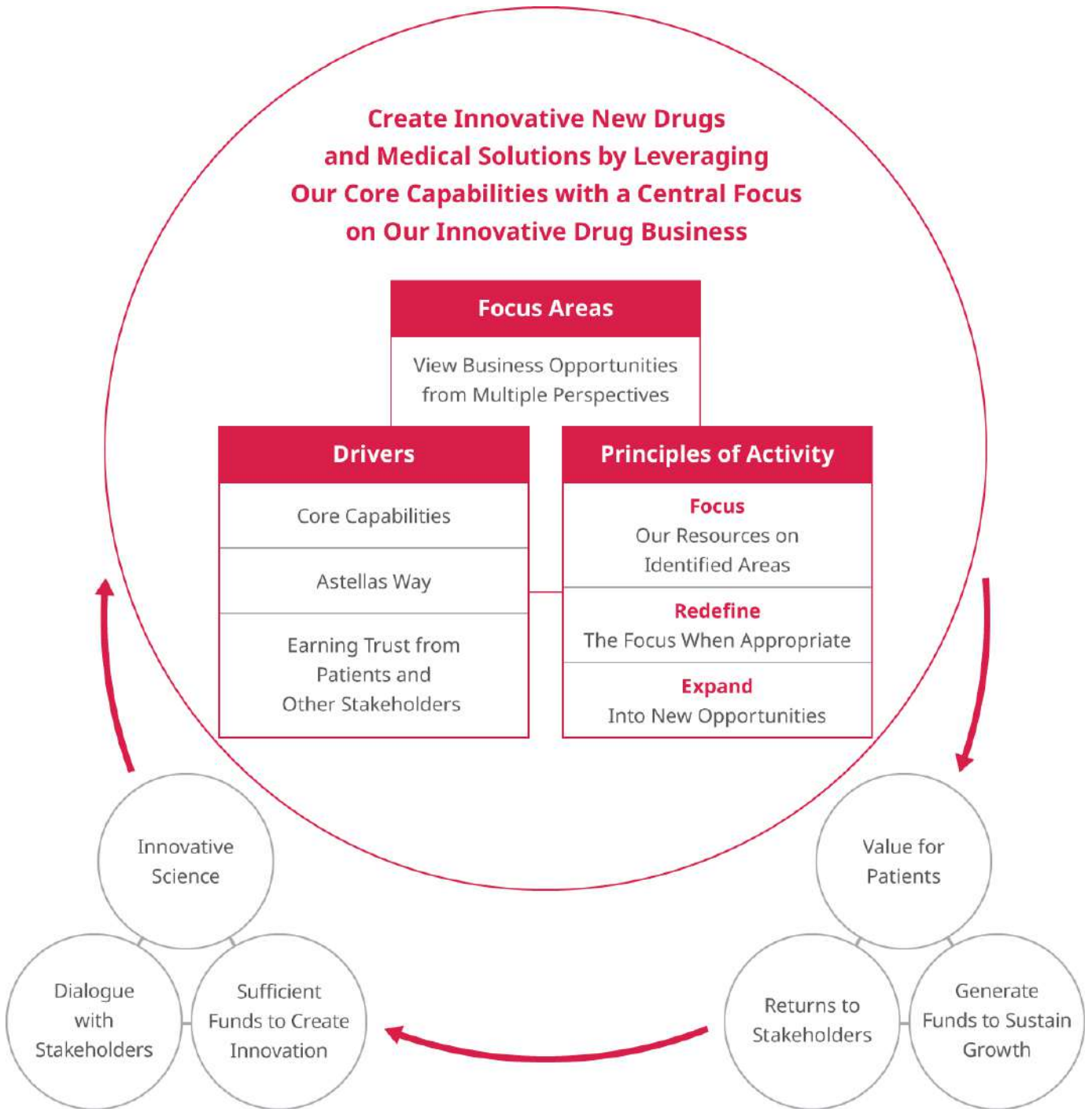
*GCL: Global Category Leader



Innovative medical solutions by combining variety
of internal and external healthcare capabilities

Astellas Value Creation Process

Astellas stands on the forefront of healthcare change, turning innovative science into value for patients. By repeating this cycle continuously, we are pursuing the sustainable growth of corporate value.



Our Approach to the Value Creation Process

Astellas' raison d'être is to "contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products."

Based on this, we aim to stand on the forefront of healthcare change, turning innovative science into value for patients. The keys to our success will be our Focus Areas, Principles of Activity, and Drivers, which describe where we should create value and how we should act to realize that value. Guided by this approach, we will create innovation with a central focus on the innovative drug business.

This process originates with advances in science, and Astellas then allocates sufficient funds and implements measures to satisfy the requests and expectations of stakeholders. By creating value for patients, through this process, we will generate funds to sustain the next phase of growth and provide returns to stakeholders.

Astellas will continue to follow this cycle to achieve sustainable growth of corporate value.

Focus Areas

Amid continuing evolution in the healthcare industry, Astellas needs to identify business opportunities more flexibly and efficiently than ever in order to achieve further growth. We will define our Focus Areas by adding multiple perspectives to our conventional viewpoint of therapeutic areas. We will factor in a consideration of new technologies and treatment approaches, product development feasibility and new possibilities for commercialization, market trends and changes in pharmaceutical laws and regulations. Our goal is to identify areas of unmet need and find new business opportunities.

Principles of Activity

In a fast-changing business environment, it is crucial to have the flexibility to reexamine business fields as needed—even those that have been carefully selected as opportunities at some point in the past. Astellas aims to drive further evolution by having all employees remain mindful of the three-step process of Focus our resources on identified areas, Redefine the focus when appropriate, and Expand the focus for the next generation of activity, as they carry out their activities.

Drivers

One of the drivers for Astellas to achieve sustainable growth is its core capabilities, which constitute the source of its competitive edge. It is vital to carefully identify our essential capabilities and enhance them until they are among the world's best. At the same time, when there are outstanding capabilities outside the Company, we will proactively form partnerships. By combining optimal capabilities, both internal and external, we enhance our productivity and creativity to maximize our value creation capabilities. Moreover, in the Astellas Way*, we have defined a shared set of values and actions to be embraced by all our employees as part of efforts to foster a corporate culture to help realize our Business Philosophy. At the same time, we remain committed to understanding the requests and expectations of a multitude of stakeholders, including patients, and transforming that understanding into value.

*For details on the Astellas Way, Five Messages for One Astellas—Patient Focus, Ownership, Results, Openness, and Integrity

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Strategic Plan 2018

Basic Policy

In its VISION formulated in 2015, Astellas made a commitment to stand “on the forefront of healthcare change to turn innovative science into VALUE for patients.” Guided by this VISION, Astellas seeks to create medical solutions that deliver VALUE to patients through the pursuit of cutting-edge science.

Under Strategic Plan 2018, Astellas will work to overcome the impact of the expiry of patents for core products that it will face from 2019 to 2020 to achieve sustainable growth. To this end, Astellas will strive to achieve three strategic goals: (1) Generate profit by maximizing product VALUE and operational excellence, along with using the funds generated through this process for (2) Evolving how we create VALUE through the Focus Area approach. Moreover, Astellas will (3) tackle the challenge of developing new businesses (Rx+™ programs) that go beyond conventional prescription pharmaceuticals (Rx).

Strategic Goal 1 Maximizing Product VALUE and Operational Excellence

Maximizing Product VALUE

Astellas will work to maximize product VALUE by intensively allocating resources to XTANDI, mirabegron and six key post-POC pipeline projects.

With regard to XTANDI, particularly its current indication, Astellas will strive to further increase penetration of XTANDI amongst urologists, along with establishing it as the first choice of therapy by utilizing extensive data based on the clinical experience accumulated since its launch. Moreover, we aim to expand the patient base and duration of therapy for XTANDI by expanding indications to earlier stages of prostate cancer.

In the OAB franchise, Astellas will work to mitigate the impact of the loss of exclusivity of VESicare by shifting sales resources to mirabegron. We will continue to educate the public on mirabegron’s clinical profile featuring a balance of efficacy and safety, with the aim of expanding market share.

In addition to maximizing the VALUE of these products, we will preferentially direct management resources to six key post-POC pipeline projects in order to obtain approval of these products as planned and support growth from fiscal 2020 onward.

Six Key Post-POC Pipeline Projects

- enfortumab vedotin
- enzalutamide (label expansion) ● fezolinetant
- gilteritinib ● zolbetuximab
- roxadustat

Potential Size of Key Post-POC Pipeline

Potential size ^{*1} (at peak, billion yen)	Key post-POC pipeline ^{*2}
400 – 500	● XTANDI (enzalutamide)
200 – 300	● fezolinetant
100 – 200	● zolbetuximab ● PADCEV (enfortumab vedotin) ^{*3}
50 – 100	● XOSPATA (gilteritinib)

*Not disclosed for roxadustat

*1 Sales amount in the case of successful development in the patient segments currently being evaluated. Some patient segments under evaluation may not be included in the potential size because development is still in an early stage.

*2 Target diseases listed in the current pipeline list are included in the projection. XTANDI also includes sales for indications that have already been approved.

*3 Potential size was revised as of the Q2/FY2019 Financial results.

Pursuing Operational Excellence

Astellas will review all activities from a zero-basis from many different angles, without relying on past precedent.

Specifically, Astellas will preferentially allocate management resources to functions and activities that establish its competitive advantage over other companies, while terminating investment in areas that will not lead to growth or the establishment of competitiveness. In addition, Astellas will work to further evolve the operating model by leveraging cutting-edge technologies such as robotic process automation (RPA) and artificial intelligence (AI), and through globalization of organizations and functions and the standardization of operating processes.

Astellas anticipates an improvement of more than ¥30.0 billion in core operating profit to be generated from new initiatives in fiscal 2020.

Our Approach to Operational Excellence



Close

Strategic Goal 2 Evolving How We Create VALUE - With Focus Area Approach -

Evolving How We Create VALUE - With Focus Area Approach -

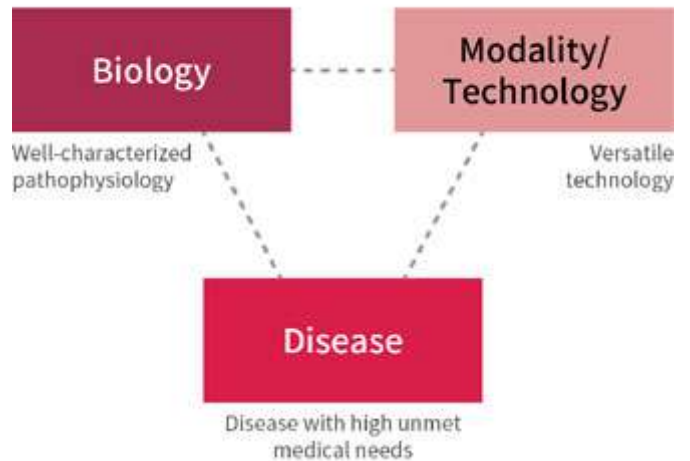
In order to achieve further growth, Astellas will need to identify business opportunities even more flexibly and efficiently than before. With this in mind, in its VISION, Astellas has established Focus Areas that reflect many different perspectives, without limiting itself to therapeutic areas, and has set out to find business opportunities in each of these areas.

Under Strategic Plan 2018, Astellas will evolve how it creates VALUE from the Therapeutic Area approach to the Focus Area approach. The goal of the Focus Area approach is to create innovative pharmaceuticals for diseases with high unmet medical needs by allocating management resources to fields that have been carefully narrowed from many different perspectives, including elucidation of pathophysiology through advances in science (biology) and the utilization of treatment modalities and technologies (modality/technology). Astellas will identify unique combinations of biology and modality/technology based on emerging science and translate this into innovative solutions for patients with high unmet medical needs through continuous efforts to ensure development progress and market access. By doing so, Astellas will continuously identify innovative new drug candidates as it upgrades and expands its development pipeline.

In order to promote the Focus Area approach, Astellas will establish research sites that incorporate outstanding external innovation and bolster collaboration with biotechnology startups and academia, based on the concepts of Best Science, Best Talent and Best Place. At the same time, Astellas will also focus on developing human resources with a discerning eye for innovative science.

Astellas will generate high-quality programs by promoting the Focus Area approach, which seeks to drive innovation by flexibly combining biology, modality/technology and disease, while constantly embracing innovative science.

Focus Area Approach (Research to Pre-POC)



Pipeline Assets Based on the Focus Area Approach

Biology	Modality/Technology	Disease	Examples (clinical)
Cancer immunology	Antibody	Oncology	ASP8374/PTZ-201, ASP1951/PTZ-522, ASP1948/PTZ-329 (Cancer) ASP0892 (Peanut allergy) ASP7317 (Dry AMD*) MA-0211 (Duchenne muscular dystrophy)
ASIM*	New generation vaccine	Immunology	
Regeneration	Cell therapy	Ophthalmology	
Mitochondria	Small molecule	Muscle disease	
	Gene therapy		

* ASIM: Antigen-specific immuno-modulation, AMD: Age-related macular degeneration

Close

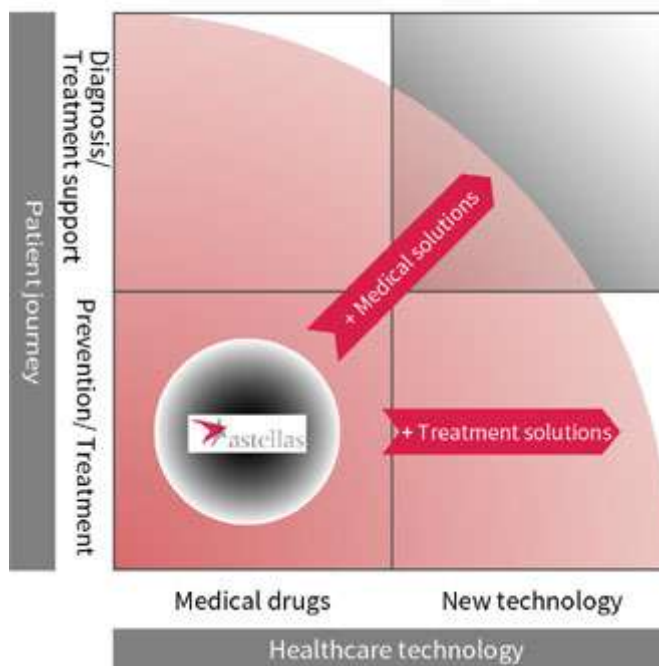
Developing Rx+™ Programs

In addition to growth in the prescription pharmaceutical (Rx) business, Astellas recognizes that it is crucial to constantly look for new business opportunities where it can leverage its current strengths.

Mindful of this, Astellas has commenced initiatives to develop Rx+™ programs. Rx+™ programs refer to new products and services that create new revenue streams separate from Astellas' core prescription pharmaceutical products. Rx+™ programs will be developed by combining Astellas' expertise and experience in medical drugs with technology and knowledge from different fields.

Through the Rx+™ programs, Astellas will create new treatment solutions that replace conventional therapy or add new VALUE, and medical solutions that contribute positively to the entire patient journey, encompassing prevention, diagnosis, treatment and post-treatment care and management.

Healthcare Solutions Beyond Rx Business



Close

Financial Guidance for Fiscal 2020

Financial Guidance for Fiscal 2020

Astellas aims to return to a medium- to long-term core operating profit growth trend after fiscal 2019.

Revenue in fiscal 2020 are forecast to remain at mostly the same level as fiscal 2017. Astellas plans to allocate more than ¥200.0 billion a year to R&D investments for medium- and long-term growth, after setting clear priorities for those investments. In order to ensure both a certain level of profit and adequate R&D investment, we will thoroughly review the cost structure from a zero-basis, in addition to maximizing product VALUE. Through these measures, we are targeting a core operating profit margin of 20% in fiscal 2020. At the same time, we aim to achieve core EPS exceeding the fiscal 2017 level by working to enhance capital efficiency.

Fiscal 2020 Financial Guidance

Indicators	Fiscal 2020 Guidance
Revenue	Fiscal 2017 level
R&D investment	More than ¥200.0 billion
Core operating profit	Core Operating Profit margin 20%
Core EPS	Exceed Fiscal 2017 level



Close

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CSR-Based Management

Astellas' CSR-based Management

At Astellas, we recognize our Corporate Social Responsibility (CSR) as our responsibility for any impacts that our decisions and the business activities have on society and the environment.

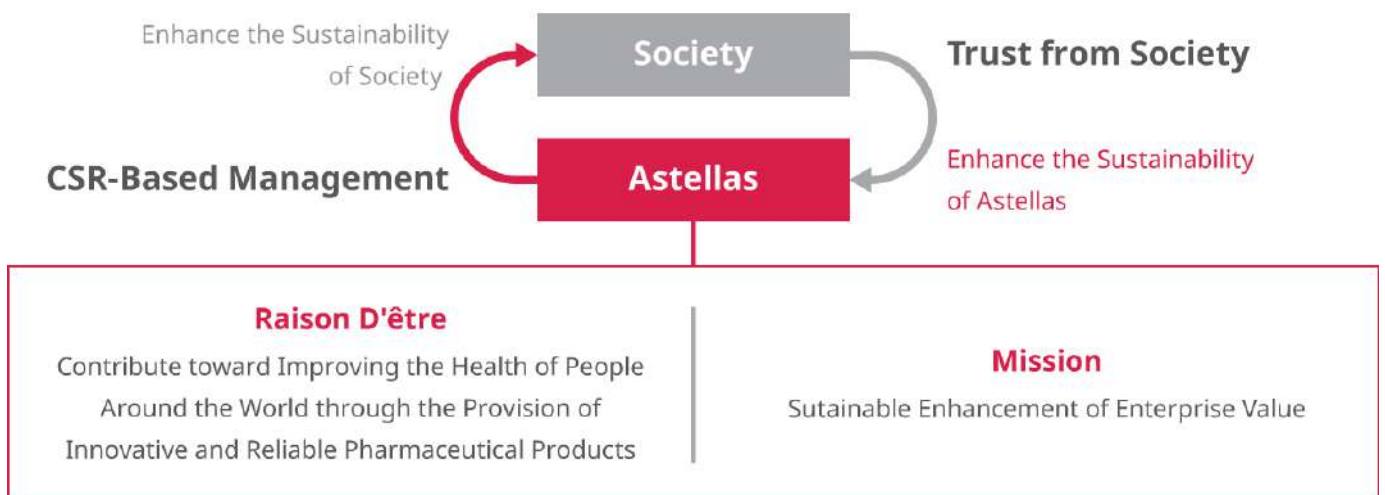
We are helping to enhance the sustainability of society by fulfilling our social responsibilities as a pharmaceutical company: for example, providing pharmaceutical products that satisfy unmet medical needs. As a result, we earn trust from society for both the Company and our products, which enhances our sustainability.

This positive cycle will lead to the realization of our mission, "sustainable enhancement of enterprise value" through fulfillment of our raison d'etre "contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products." In summary, for Astellas, fulfilling our social responsibility means the realization of its business philosophy.

The activities we have carried out under the aforementioned philosophy have been receiving very positive external evaluation.

For example, Astellas has been named to the FTSE4Good Index Series for ninth consecutive year, which is one of representative investment indexes. Also, Astellas is included as a constituent in all the ESG investment indexes adopted by the Government Pension Investment Fund (GPIF) in Japan, which are FTSE Blossom Japan Index, MSCI Japan ESG Select Leaders Index, MSCI Japan Empowering Women Index (WIN) and S&P/JPX Carbon Efficient Index.

Astellas' Interaction with Society



Two Aspects of CSR for Astellas

CSR for Astellas has two aspects: value creation and value protection.

Value Creation

Through its business activities, Astellas is creating value for society by addressing social issues such as unmet medical needs, and by rewarding stakeholders.

By reinvesting the profit we gain through business activities, we strengthen our capabilities in research and development. In addition, by winning trust from government and business partners in each country, we create new business opportunities. That is to say, value for Astellas is created.

Value Protection

Astellas seeks to reduce its environmental burden and preserve biodiversity, ensures compliance, and takes measures to prevent corruption. In addition to the social value of these activities, they contribute to mitigating reputation risk and elevating Astellas' corporate brand, thereby protecting our enterprise value.

Value Creation & Protection for Society & Astellas

	Value for Society	Value for Astellas
Value Creation	Supporting Healthy Living for People All Over the World through the Creation of Innovative Drugs Return to Stakeholders	Strengthening R&D Capabilities by Reinvesting Profits Creating New Business Opportunities
Value Protection	Mitigating Impact on Climate Change and Preserving Biodiversity by Reducing Environmental Burden Maintaining Social Order by Ensuring Compliance and Taking Measures to Prevent Corruption	Mitigating Reputation Risk Elevating Corporate Brand

Organizational Structure to Promote CSR

Astellas Pharma Inc. (Astellas) has established the CSR (Corporate Social Responsibility) Committee and CSR, Corporate Advocacy, and promotes long-term, strategic and global CSR activities by all departments.

CSR Committee

Astellas has established the CSR Committee with the aim of coordinating and promoting CSR activities globally. The CSR Committee discusses policies and plans for important activities in fulfilling the Company's social responsibilities.

CSR, Corporate Advocacy

In addition to the role of the secretariat for CSR Committee, the CSR, Corporate Advocacy is responsible for responding to CSR issues throughout the entire Astellas Group, raising CSR awareness internally and externally, distributing CSR-related information, and communicating with stakeholders.

Organizational Structures



* EHS : Environment, Health and Safety

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Materiality in CSR Activities

Identification and Prioritization of Material Issues

Materiality in CSR activities guides our CSR-based management. Astellas has identified material issues to be addressed based on the issues regarded as prerequisites of its business activities. These include global issues related to medical care and health and other broader social issues.

Making reference to expectations and requests from a broad range of stakeholders, we classified and prioritized the material issues into three categories by evaluating their societal significance and relevance to our business (CSR Materiality Matrix.) In order to tackle these material issues, we are executing a concrete action plan.

Materiality Determination Process

Step 1

Identify Issues

Astellas' material issues are identified with reference to various principles and guidelines (such as ISO 26000, the UN Global Compact's ten principles and the SASB* Materiality Map), communications with stakeholders, and evaluation items for Socially Responsible Investment (SRI) indices, etc.

* SASB: Sustainability Accounting Standards Board.

A U.S. non-profit organization exploring industry-specific standards for corporate sustainability disclosure. SASB has prepared industry-specific materiality maps by evaluating the materiality of sustainability topics.

Step 2

Prioritize

We will prioritize Astellas' material issues from the dual perspectives of societal significance and relevance to our business.

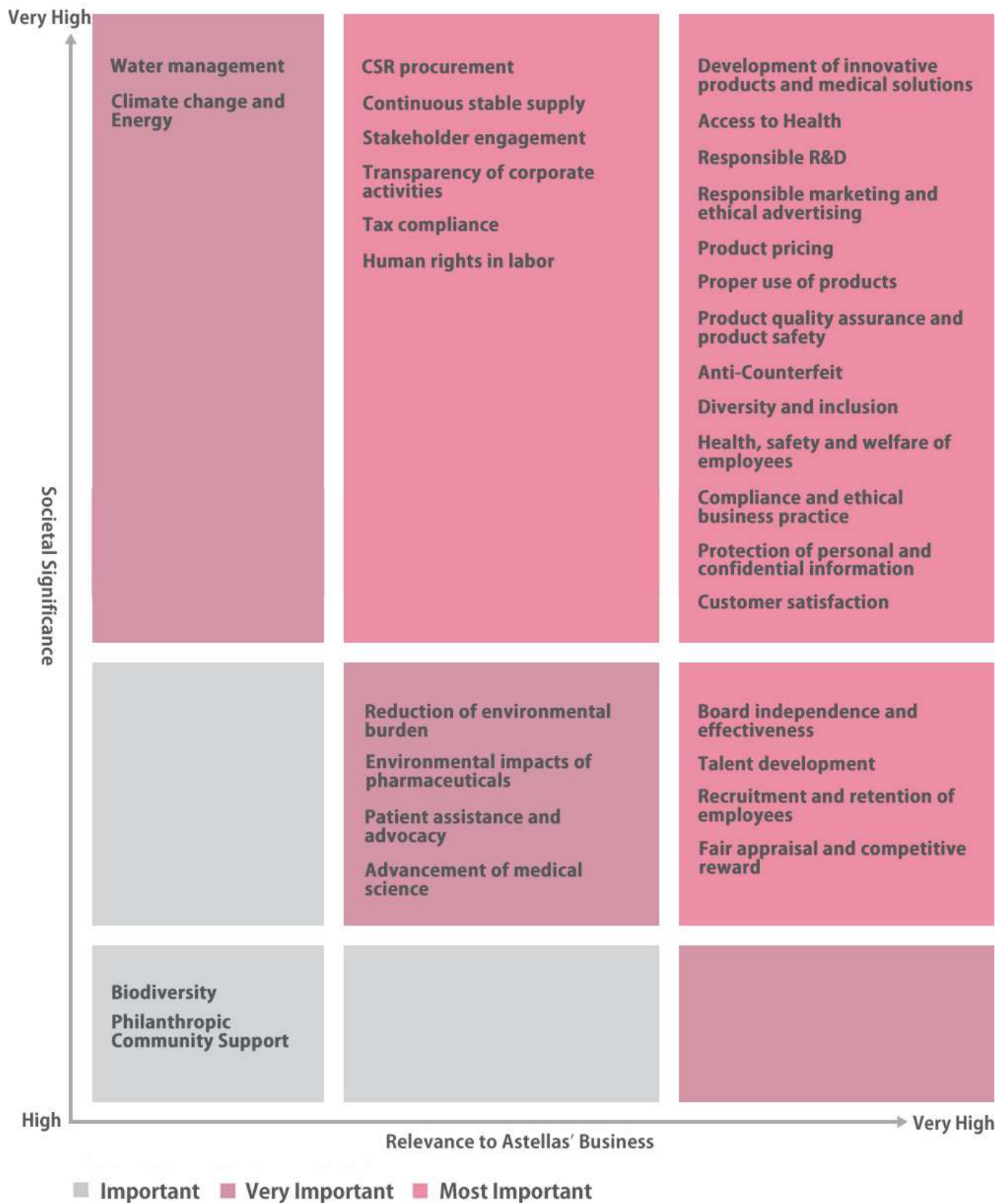
Step 3

Review

- Dialogue with Stakeholders (investors, patient groups, doctors, employees, consultants, and academics)
- Deliberating on and approving matters at the CSR Committee, EC and Board of Directors

Astellas' material issues will be reviewed and verified at the CSR Committee once a year. When necessary, they will be modified depending on the attainment level of initiatives implemented and/or any changes in the needs of society.

CSR Materiality Matrix



Definitions of material issues

Material issue	Definitions / explanation of material issues
Development of innovative products and medical solutions	Creating innovative medicines and medical solutions sustainably in therapeutic areas with a high level of unmet medical needs.

Access to Health	Developing and delivering necessary healthcare to people around the world by accelerating social benefit-driven research and development, enhancing availability, strengthening healthcare system, and improving health literacy.
Responsible R&D	Ensuring the ethical consideration throughout the entire R&D process, and conducting R&D in compliance with global and/or local guidelines, including ethical considerations in animal testing and clinical trials.
Responsible marketing and ethical advertising	In compliance with laws and guidelines in each country, ensuring equitable & appropriate marketing and advertising activities, raising awareness about diseases and treatments to contribute toward improving health of people.
Product pricing	Striking a sustainable balance between fostering innovation and ensuring access to such innovation by setting prices reflecting the benefits of our products.
Proper use of products	Enhancing the proper use of our products by Healthcare professionals and patients to ensure patient safety and the efficacy and safety of our products. It includes the adoption of user-friendly package design in consideration of convenient universal design.
Product quality assurance and product safety	Ensuring our products are manufactured with appropriate quality assurance standards, and maintaining a functional and robust pharmacovigilance system.
Anti-counterfeit	Preventing counterfeit drug problems and its improper distribution.
Diversity and Inclusion	Ensuring equal opportunity and fair employment regardless of characteristics, including race, nationality, gender, sexual orientation, age or disability.
Health, safety and welfare of employees	Ensuring the mental and physical health of employees, and ensuring a safe workplace. Enriching the welfare of employees and their family.
Compliance and ethical business practices	Acting with integrity and making ethical decisions in all aspects, and going beyond compliance with applicable laws, regulations and industry codes. Promoting such behavior through our global compliance structure, the development, implementation, and continuous enhancement of necessary policies and processes, and focusing our activities on Anti-bribery / Anti-corruption compliance, avoiding conflicts of interest, encouraging a "speak-up" culture, and demonstrating our commitment to integrity, ethics and compliance.
Protection of personal and confidential information	Appropriately handling confidential information or our stakeholders' personal information, including data obtained in clinical trials (including postmarketing clinical trials), by complying with applicable laws, regulations, and Company policies and procedures.
Customer satisfaction	Meeting the needs and expectations of customers, such as patients and healthcare professionals, which includes ensuring effective infrastructure and practice to appropriately respond to customers' complaints, inquiries and consultations.

Board independence and effectiveness	The Board of Directors consists of a majority of outside Directors who satisfy the Company's independence standards for outside Directors and the required conditions for independent Director stipulated by Tokyo Stock Exchange, Inc. The independence and effectiveness of the Board of Directors is ensured by analyzing and evaluating its effectiveness.
Talent development	Providing career development opportunities that respect the ownership, talent and aptitude of employees.
Recruitment and retention of employees	Recruiting and retaining talented people.
Fair appraisal and competitive reward	Recognizing the contributions of, and appraising and treating employees in a fair manner according to their role and achievement.
CSR procurement	Selecting suppliers in compliance with selection criteria, including CSR* perspectives, such as compliance with laws and respecting human rights. Coaching less-compliant suppliers and supporting their capacity building for improvement through procurement activity. *CSR: Corporate Social Responsibility
Continuous stable supply	Ensuring a continuous stable supply of products.
Stakeholder engagement	Having mutual dialogues with multiple stakeholders, including patients and shareholders, to understand their expectations and demands from society, to reflect their opinion of Astellas' business activities and decision-making process.
Transparency of corporate activities	Enhancing the transparency of our corporate activities by disclosing information to all stakeholders in a timely, proper, and fair manner regardless of laws and regulations. Examples: <ul style="list-style-type: none"> • Data and information acquired in research and development activities • Board structure • Executive compensation • Risk management system and material risks with mitigation plans
Tax compliance	Complying with the local tax laws and regulations in each country where we operate, and seek to pay the right amount of tax in the right place at the right time.
Human rights in labor	Respecting the human rights of employees and business partners, including the elimination of discrimination, the freedom of association and the protection of the rights to organize, and the exclusion of child labor and forced labor.
Reduction of environmental burden	Mitigating the environmental burdens caused by business operations to the minimum level, including measures for preventing atmospheric pollution, recycling resources, and management of chemical substances.
Environmental impacts of pharmaceuticals	Identifying and managing the environmental impact of our pharmaceutical products throughout their life-cycle from their manufacture, use by humans, to disposal.

Patient assistance and advocacy	Supporting patient organizations for charitable purposes and conducting advocacy activities*, including funding for patient organization activities, sharing knowledge and information such as holding peer support training sessions, promoting disease awareness through disease awareness events, defending patients' rights, and representing the patient's voice. *Advocacy activities: Encouraging the advancement of public policy and society through policy recommendation.
Advancement of medical science	Supporting medical and scientific research which contributes to the advancement of medical sciences.
Water management	Using water resources efficiently by reducing volume of withdrawal, reusing, and recycling.
Climate change and energy	Reducing greenhouse gas emissions associated with business operations by efficient use of energy.
Biodiversity	Mitigating negative impacts on biodiversity and promoting the sustainable use of benefits from biodiversity.
Philanthropic community support	Supporting the communities in which we operate. For example, social contribution, such as Disaster Relief, support for employees' volunteering, and nurturing the next generation.



Close

Annual Report 2020

Contributions to the Sustainable Development Goals

The Sustainable Development Goals (SDGs) were formally adopted at the United Nations General Assembly in 2015 as universal targets that should be achieved by 2030. Astellas assessed the impact on the SDGs across its entire value chain and identified items for priority action, using the SDG Compass as a reference. We contribute to the attainment of the SDGs through a variety of business activities, mainly those related to health and welfare aligned with “Goal 3: Good Health and Well-Being.”



Goal 3: Good Health and Well-Being



Astellas is tackling the SDGs with a focus on Goal 3, which has the strongest affinity to its business philosophy to “contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.” Health is not just a healthcare issue, because losing health could lead to restricting opportunities for education or employment and be the cause of poverty in cases. In light of this, attaining Goal 3 will also contribute to achieving the other SDGs.

Improving Access to Health in Four Areas

Astellas is addressing Goal 3 of the SDGs by improving Access to Health. There are many people with insufficient access to the healthcare they need due to the lack of available treatments, poverty, challenges in healthcare systems and limited healthcare information. We recognize this problem as an [Access to Health](#) issue, and have identified four areas where we are working to address such issues by making full use of the strengths and technology that we have. The four areas are (1) Creating innovation, (2) Enhancing availability, (3) Strengthening healthcare systems, and (4) Improving health literacy. In doing so, we will make maximum use of our partnerships in the manner of Goal 17 of the SDGs.

In creating innovation, Astellas is working to create innovative medicines and medical solutions in disease areas with low treatment satisfaction and delivering them to patients around the world. Moreover, Astellas has been conducting collaborative research with partners for the purpose of creating lead compounds for tuberculosis, malaria, and neglected tropical diseases (Leishmaniasis and Chagas disease). Also Astellas has been working to develop a pediatric formulation of praziquantel tablets for the treatment of schistosomiasis with the consortium members.

To help enhance availability, we have established programs to assist patients facing severe financial constraints with the cost of pharmaceutical products. We also support patients by not filing or enforcing patents in countries facing significant economic challenges.

As part of strengthening healthcare systems and improving health literacy, Astellas has participated in the Access Accelerated global partnership. This initiative aims to contribute to achieving the SDG of reducing premature mortality from non-communicable diseases by one-third by 2030.

In other SDG-related initiatives, Astellas has supported Kenya’s ACTION ON FISTULA program, contributing to improving the environment encompassing Kenya’s fistula patients. Furthermore, we have also donated ambulances and wheelchair transport vehicles and moved forward in activities supporting patient associations.

Moreover, Astellas is working on resolving issues related to Access to Health in countries where Astellas does not have a commercial presence through [the Astellas Global Health Foundation \(AGHF\)](#).

Other Initiatives for SDGs

SDGs	Examples of Astellas' initiatives
	<ul style="list-style-type: none"> • Human resource development for employees • Provision of training for surgeons through support for the ACTION ON FISTULA™ program, and occupational training for obstetric fistula patients
 	<ul style="list-style-type: none"> • Diversity and inclusion initiatives • Human rights initiatives
     	<ul style="list-style-type: none"> • Maintenance/preservation of biodiversity • Reduction of greenhouse gas emissions • Use of renewable energies • Resource recycling initiatives • Prevention of air and water pollution • Disaster relief
	<ul style="list-style-type: none"> • Promotion of a work-life balance • Occupational health and safety initiatives
	<ul style="list-style-type: none"> • R&D to create innovative medicines and medical solutions • Promotion of R&D for global health through collaboration between the public and private sectors (GHIT fund)
	<ul style="list-style-type: none"> • Sustainable procurement • Ensure product quality assurance and safety • Reduce the environmental burden of products



- [Compliance and ethical business practices](#)
- [Established an internal reporting system with a third-party helpline](#)
- [Anti-bribery and anti-corruption](#)



- Collaborated with biotechnology startups and academia to create innovative medical solutions
- [Participated in Access Accelerated](#)
- Participated in the GHIT Fund
- Signatory to the United Nations Global Compact

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Annual Report 2020

Corporate Governance



Corporate Governance

Astellas' basic view on corporate governance and summary of the corporate governance systems

[Read More](#)

Board of Directors

Biography of Astellas' directors

[Read More](#)

Risk Management

Identifying and mitigating risks relating to the performance of business activities.

[Read More](#)

Annual Report 2020

Corporate Governance

Basic view

The Company's raison d'être is to contribute to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The Company aims to sustainably enhance enterprise value by being chosen and trusted by all stakeholders. With this business philosophy, we work to ensure and strengthen the effectiveness of corporate governance from the following perspectives:

1. Ensuring transparency, appropriateness and agility of management; and
2. Fulfillment of our fiduciary duties and accountability to shareholders and appropriate collaboration with all stakeholders.

The Company has established the Corporate Governance Guidelines which clarifies the basic views and guidelines of the Company's corporate governance.

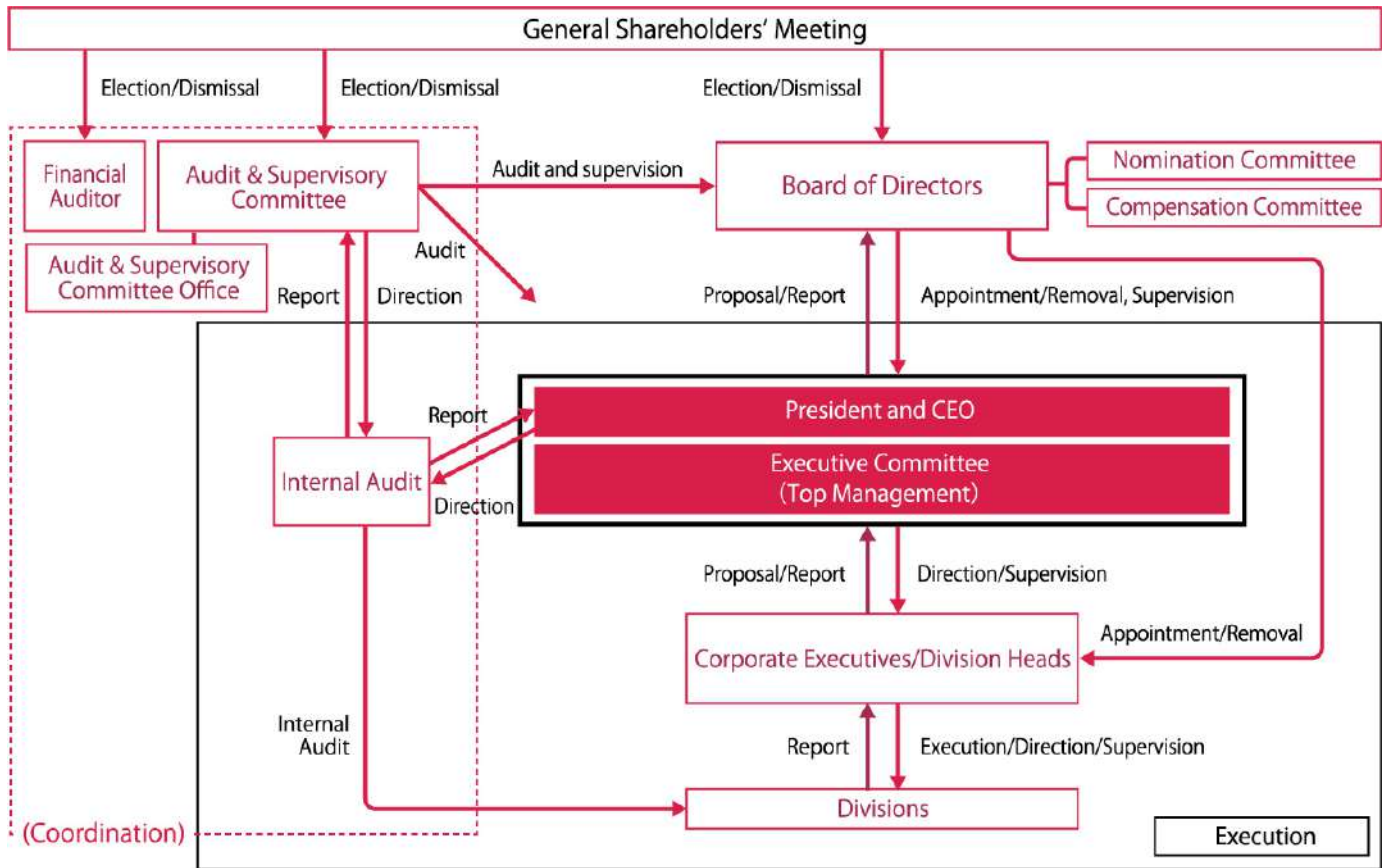
[Corporate Governance Guidelines](#)

Summary of the corporate governance systems

The summary of the corporate governance systems is as follows:

- The Company adopts the organizational structure of "Company with Audit & Supervisory Committee." Outside Directors constitute the majority of the Board of Directors and the Audit & Supervisory Committee, respectively.
- The Board of Directors determines basic policies of management, business strategies and other matters, and serves the oversight function of business execution.
- As an organ for handling execution of business, the Company establishes the Executive Committee for discussing important matters, and also appoints Executive Officers who are responsible for their respective assigned divisions. The responsibility and authority for the execution of business of the organ described above, the President and CEO and the Executive Officers are clearly stipulated in the Corporate Decision Authority Policy.
- As advisory bodies to the Board of Directors, the Company establishes the Nomination Committee and the Compensation Committee, each of which are composed of a majority of Outside Directors.

Chart of corporate governance systems



Please refer to the “Corporate Governance Report” for detail of corporate governance.

[Corporate Governance Report](#)

Related Documents

[Independence Standards for Outside Directors](#)

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Board of Directors



Yoshihiko Hatanaka
Representative Director, Chairman of the Board

Resume, position and responsibilities at the Company

April 1980: Joined Fujisawa Pharmaceutical Co., Ltd.

April 2003: Director, Corporate Planning, Fujisawa Pharmaceutical Co., Ltd.

April 2005: Vice President, Corporate Planning, Corporate Strategy Division, the Company

June 2005: Corporate Executive, Vice President, Corporate Planning, Corporate Strategy Division, the Company

April 2006: Corporate Executive of the Company and President & CEO, Astellas US LLC and President & CEO, Astellas Pharma US, Inc.

June 2008: Senior Corporate Executive of the Company and President & CEO, Astellas US LLC and President & CEO, Astellas Pharma US, Inc.

April 2009: Senior Corporate Executive, Chief Strategy Officer and Chief Financial Officer (CSTO & CFO), the Company

June 2011: Representative Director, President and CEO, the Company

April 2018: Representative Director, Chairman of the Board, the Company (present post)

June 2019: Outside Director, Sony Corporation (present post)



Close



Kenji Yasukawa
Representative Director, President and CEO

Resume, position and responsibilities at the Company

- April 1986: Joined the Company
- April 2005: Vice President, Project Management, Urology, the Company
- June 2010: Corporate Executive of the Company and Therapeutic Area Head, Urology, Astellas Pharma Europe B.V.
- October 2010: Corporate Executive of the Company and Therapeutic Area Head, Urology, Astellas Pharma Global Development, Inc.
- April 2011: Corporate Executive, Vice President, Product & Portfolio Strategy, the Company
- April 2012: Corporate Executive, Chief Strategy Officer (CSTO), the Company
- June 2012: Senior Corporate Executive, Chief Strategy Officer (CSTO), the Company
- April 2017: Senior Corporate Executive, Chief Strategy Officer and Chief Commercial Officer (CSTO & CCO), the Company
- June 2017: Representative Director, Executive Vice President, the Company
- April 2018: Representative Director, President and CEO, the Company (present post)

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Naoki Okamura
Representative Director, Executive Vice President

Resume, position and responsibilities at the Company

April 1986: Joined the Company

October 2010: President & CEO, OSI Pharmaceuticals, Inc.

April 2012: Senior Vice President, Chief Strategy Officer, Astellas Pharma Europe Ltd.

July 2014: Vice President, Licensing & Alliances, the Company

April 2016: Vice President, Corporate Planning, the Company

June 2016: Corporate Executive, Vice President, Corporate Planning, the Company

April 2018: Corporate Executive, Chief Strategy Officer (CStO), the Company

April 2019: Corporate Executive Vice President, Chief Strategy Officer (CStO), the Company

June 2019: Representative Director, Executive Vice President, Chief Strategy Officer (CStO), the Company

October 2019: Representative Director, Executive Vice President, Chief Strategy Officer and Chief Financial Officer (CStO & CFO), the Company (present post)



Close



Mamoru Sekiyama
Outside Director

Resume, position and responsibilities at the Company

April 1974: Joined Marubeni Corporation

April 1997: General Manager, Power Project Dept.-I, Marubeni Corporation

April 1998: General Manager, Power Project Dept.-III, Marubeni Corporation

April 1999: Deputy General Manager, Power Project Div.; General Manager, Power Project Dept. I, Marubeni Corporation

April 2001: Senior Operating Officer, Utility Infrastructure Div.; General Manager, Overseas Power Project Dept., Marubeni Corporation

April 2002: Corporate Vice President, Chief Operating Officer, Plant, Power & Infrastructure Div., Marubeni Corporation

April 2005: Corporate Senior Vice President, Chief Operating Officer, Plant, Power & Infrastructure Projects Div., Marubeni Corporation

June 2006: Corporate Senior Vice President, Member of the Board, Marubeni Corporation

April 2007: Corporate Executive Vice President, Member of the Board, Marubeni Corporation

April 2009: Senior Executive Vice President, Member of the Board, Marubeni Corporation
April 2013: Vice Chairman, Marubeni Corporation
April 2015: Corporate Adviser, Marubeni Corporation; Chairman, Marubeni Power Systems Corporation
June 2017: Director, the Company (present post)
April 2020: Outside Director and Audit & Supervisory Committee Member, A.D.Works Group Co., Ltd. (present post)



Close



Keiko Yamagami
Outside Director

Resume, position and responsibilities at the Company

April 1987: Public Prosecutor, Yokohama District Public Prosecutors Office
April 2002: Coordinator, the Legislative Division, Criminal Affairs Bureau, Ministry of Justice
January 2005: Counselor, the Legislative Division, Criminal Affairs Bureau, Ministry of Justice
August 2005: Public Prosecutor, Supreme Public Prosecutors Office
August 2007: Deputy Director of Public Peace Department, Tokyo District Public Prosecutors Office
July 2008: Deputy Director of Trial Department, Tokyo District Public Prosecutors Office
April 2009: Trial Director, Yokohama District Public Prosecutors Office
April 2010: Registered as an attorney-at-law (Dai-ichi Tokyo Bar Association); Lawyer honorary member, Tokyo Seiwa Law Office (present post)
June 2017: Director, the Company (present post)
June 2019: External Audit & Supervisory Board Member, Denyo Co., Ltd. (present post)



Close



Hiroshi Kawabe
Outside Director

Resume, position and responsibilities at the Company

May 1979: Assistant, Department of Internal Medicine, Keio University School of Medicine

April 1990: Assistant Professor, Health Center, Keio University

April 1991: Assistant Professor, Department of Internal Medicine, Keio University School of Medicine

April 1996: Associate Professor, Health Center, Keio University; Associate Professor, Department of Internal Medicine, Keio University School of Medicine

April 2002: Professor, Health Center, Keio University; Professor, Department of Internal Medicine, Keio University School of Medicine

October 2003: Vice President, Health Center, Keio University

October 2011: President, Health Center, Keio University

June 2013: Trustee, Japan University Health Association

March 2017: Trustee, Daiwa Securities Health Foundation (present post)

March 2018: President, Foundation for Promotion of Medical Training (present post)

April 2018: Professor Emeritus, Keio University (present post)

June 2019: Director, the Company (present post)



Close



Tatsuro Ishizuka
Outside Director

Resume, position and responsibilities at the Company

April 1978: Joined Hitachi, Ltd.

April 2009: Corporate Officer and General Manager, Hitachi Works, Hitachi, Ltd.

April 2011: Vice President and Executive Officer, and President & CEO, Power Systems Company, Hitachi, Ltd.

April 2013: Senior Vice President and Executive Officer, Hitachi, Ltd.

April 2014: Representative Executive Officer, Executive Vice President and Executive Officer, Hitachi, Ltd.

April 2015: Deputy Chairman, Hitachi Europe Ltd.

July 2016: Chairman of the Board, Hitachi Research Institute

April 2017: Representative Executive Officer, Chairman, Hitachi Construction Machinery Co., Ltd.

June 2017: Representative Executive Officer, Chairman, Executive Officer and Director, Hitachi Construction Machinery Co., Ltd.

April 2019: Director, Hitachi Construction Machinery Co., Ltd.; Advisor, Hitachi, Ltd. (present post)

June 2019: Director, the Company (present post)

March 2020: Outside Director, K&O Energy Group Inc. (present post)



Close



Toru Yoshimitsu
Director, Audit & Supervisory Committee Member

Resume, position and responsibilities at the Company

- April 1987: Joined the Company
- April 2013: Senior Vice President, Product & Portfolio Strategy, the Company
- June 2015: Corporate Executive, Senior Vice President, Product & Portfolio Strategy, the Company
- April 2017: Corporate Executive, Senior Vice President, Corporate Finance & Control, the Company
- April 2019: Corporate Executive, Senior Vice President, Corporate Financial Planning & Analysis, the Company
- October 2019: Corporate Executive, Senior Vice President, Finance and Corporate Financial Planning & Analysis, the Company
- April 2020: Report to CEO, the Company
- June 2020: Director (Audit & Supervisory Committee Member), the Company (present post)

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Close



Hiroo Sasaki
Outside Director, Audit & Supervisory Committee Member

Resume, position and responsibilities at the Company

April 1987: Assistant Professor, Faculty of Economics, Nagoya City University
April 1990: Associate Professor, Faculty of Economics, Nagoya City University
April 1993: Associate Professor, School of Commerce, Waseda University
April 1996: Professor, School of Commerce, Waseda University
July 1997: Senior Research Officer, Ministry of Finance, Institute of Fiscal and Monetary Policy (current Policy Research Institute); Special Officer for Research, Minister's Secretariat
July 1999: Professor, School of Commerce, Waseda University
April 2005: Professor, School of Commerce, Waseda University; Professor, Graduate School of Accountancy, Waseda University
September 2010: Professor, School of Commerce, Waseda University; Dean, Graduate School of Accountancy, Waseda University
April 2013: Dean, Graduate School of Accountancy, Waseda University
September 2016: Professor, Graduate School of Accountancy, Waseda University (present post)
June 2018: Director (Audit & Supervisory Committee Member), the Company (present post)



Close



Haruko Shibumura
Outside Director, Audit & Supervisory Committee Member

Resume, position and responsibilities at the Company

April 1987: Joined Chiyoda Mutual Life Insurance Company
August 1987: Joined Kyushu University Press
April 1994: Registered as an attorney-at-law (Dai-ni Tokyo Bar Association); Joined Law Offices of Honma & Komatsu (current Homma & Partners)
April 1999: Partner Lawyer, Homma & Partners (present post)
October 2006: Committee member, Compliance Committee, TAMURA Corporation
June 2015: Outside Audit & Supervisory Board Member, NICHIREKI CO., LTD.
April 2016: Committee member, Compliance Special Committee, TAMURA Corporation
June 2018: Outside Director, TAMURA Corporation (present post)
June 2019: Director (Audit & Supervisory Committee Member), the Company (present post); Outside Director, NICHIREKI CO., LTD. (present post)



Close



Raita Takahashi
Outside Director, Audit & Supervisory Committee Member

Resume, position and responsibilities at the Company

- October 1986: Joined Sanwa · Tohmatsu Aoki Audit Corporation (current Deloitte Touche Tohmatsu LLC)
- August 1995: Joined Chuo Audit Corporation
- May 1997: Established TAKAHASHI Accounting & Tax office (present post)
- April 1999: Representative Partner, ChuoAoyama PricewaterhouseCoopers
- December 2000: Outside Audit & Supervisory Board Member, Alpha Group Inc. (present post)
- March 2001: Representative Director, Yoshida Management Co. Ltd. (present post)
- June 2011: Trustee, Japan Association of Healthcare Management Consultants (present post)
- January 2018: Section President, Japanese Institute of Certified Public Accountants, Minami-Kyushu Chapter, Kagoshima Subcommittee
- June 2020: Director (Audit & Supervisory Committee Member), the Company (present post)



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Risk Management

Business Risks

(1) Identifying and Mitigating Risks Relating to the Performance of Business Activities

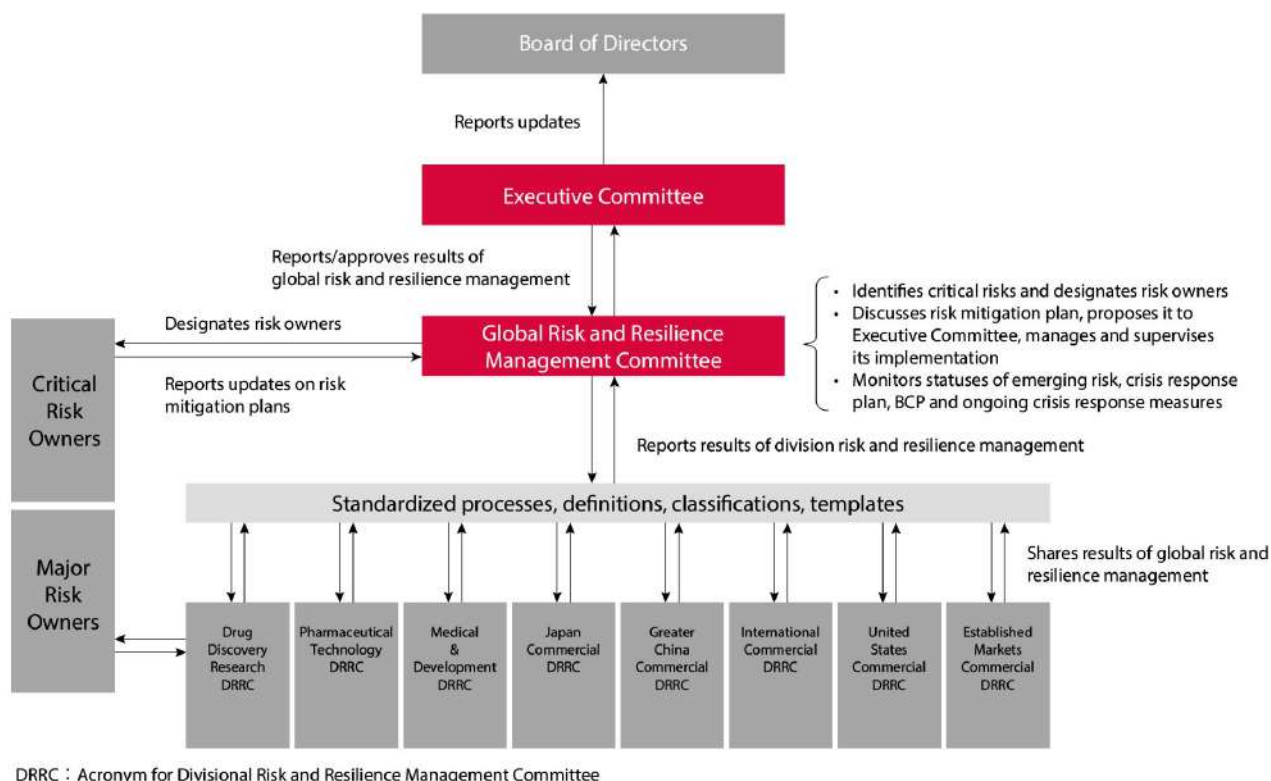
Pharmaceutical companies that expand their business globally are expected to follow various regulations with a high level of compliance; Astellas must also address various risks that could impact its business results and reputation. In FY2019, Astellas pursued its operation of enterprise risk management with the aim of further developing the risk management activities implemented until now. This involved newly establishing the Corporate Risk Management Division to take control over risk management, and the Global Risk and Resilience Management Committee, chaired by the Chief Administrative Officer and Chief Ethics & Compliance Officer.

Under enterprise risk management, risks are identified on the Group-wide level and on the individual division level. Those risks are classified using a uniform evaluation process according to priority and, if deemed necessary, linked to formulation of a universal means for solution. Identified risks are regularly evaluated by the Global Risk and Resilience Management Committee, and solutions and mitigation measures for high priority risks are discussed at the Executive Committee, chaired by the Representative Director, President and CEO.

(2) Risk Management Framework

Astellas' risk management framework is as follows.

Risk Management Framework



DRRC : Acronym for Divisional Risk and Resilience Management Committee

(3) Critical Risks

The risks identified by management as having the potential to have a considerable impact on financial position, business results and cash flow position of the consolidated companies are mainly set forth below.

Any forward-looking statements are based on judgments as of March 31, 2020.

1 Risks related to cybersecurity

In recent years, the technology involved in cyberattacks is advancing at an unprecedented level and the methods of attack are growing more diverse and sophisticated. In light of this environment, Astellas has identified risks related to cybersecurity as one of its critical risks. The Information Systems Division is leading the response to this risk, implementing various countermeasures against cyberattack on a global basis that includes monitoring of networks and facilities, and taking every precaution to manage the risk.

However, despite having such measures in place, in the event that business is substantially interrupted due to a cyberattack or serious system failure, etc. caused by cyberattack, or in the event that important data, including information that could identify individuals, is lost, corrupted or leaked externally, the Astellas Group's business results may be significantly affected.

2 Risks related to supply chain management

In the pharmaceuticals business, the ability to manufacture safe and effective pharmaceuticals reliably and then to provide their stable supply is extremely important. Astellas has identified risks related to supply chain management as one of its critical risks. The Pharmaceutical Technology Division is leading the response to this risk, establishing its own standards compliant with industry standard Good Manufacturing Practice (GMP), including manufacturing and quality controls, and Good Distribution Practice (GDP) and rigorously implementing consistent high-level quality control for not only manufacturing facilities and equipment but inclusive of all operations from ingredient procurement to storage, manufacturing, and delivery. Furthermore, to respond to growing complexities in the supply chain, the Group has introduced on a global basis, management of its Contract Manufacturing Organizations (CMO) and is proceeding with measures including the creation of Business Continuity Plans (BCP) to ensure supply during emergency situations.

However, despite having such measures in place, in the event that interruptions in supply, product shortage, or quality problems arise, or in the event that the reputation of Astellas is damaged as a result of the aforementioned, the Astellas Group's business results may be significantly affected.

3 Risk of impact from pharmaceutical regulatory

The ethical pharmaceutical business is governed by a wide variety of regulations in each country. Astellas has identified changes in pharmaceutical pricing policy by the United States Government as one of its critical risks and is carefully watching trends.

The Astellas Group's business results may be significantly affected by policy for controlling the cost of medical treatment, or a tightening of various regulations concerning development, manufacturing and distribution, particularly in developed countries.

In addition to the above critical risks identified by the Astellas Group, there are many other risks. Some risks are unique to the pharmaceuticals business which include the uncertain nature of research and development, the risk of being infringed upon or infringing intellectual property rights, risk of drug side effects or safety issues arising thereof, and the risk of an Astellas Group business's partial dependence on licensing and sales of third-party developed drugs. Other risks include the risk of infringement of related laws and regulations concerning competition with rival products, or environment or health and safety, or of commercial litigation regarding business processes, as well as risks of delays or stoppages in manufacturing due to natural disaster, etc. or of exchange rate fluctuation. Such risks may affect the Astellas Group's business results and financial position.

Note that the risks stated above do not cover all of the risks relating to the Astellas Group.

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Business Review



Top Management

Executive committee members and management structure

[Read More](#)

Focus Area Approach

Astellas' basic concept for Research & Development

[Read More](#)

Pipeline Projects

Introduction and current status of Astellas' key post-POC pipeline projects

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Rx+ Business

Astellas' activity to create Rx+ Business

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Major Pipeline

Development status in the target diseases for which we aim to obtain approval in Japan, the United States, Europe and/or China

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Main Products

Introduction of Astellas' key marketed products

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Responsible Business Activities

Astellas' CSR-related initiatives in business activities

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Our People, Our Organization

Astellas' Human Resources Development and Organization management basic concept, data, and activities

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Ethics & Compliance

Astellas' Ethics & Compliance basic concept, organization structure and activities

[Read More](#)

Access to Health

Astellas' Access to Health initiatives. Astellas is committed to address Access to Health issues.

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Social Contribution

Astellas' Social Contribution activities

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EHS ; Environment, Health & Safety

Astellas EHS (Environment, Health & Safety) initiatives and data

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Top Management

Executive Committee (as of October 2020)

The Executive Committee discusses important matters of management across Astellas. It is chaired by the Representative Director, President and CEO. Extended members include the officers responsible for research, development and pharmaceutical technology capabilities together with the officers responsible for each commercial region, and these members participate in any necessary discussions at the request of the chairman.

Standing Members

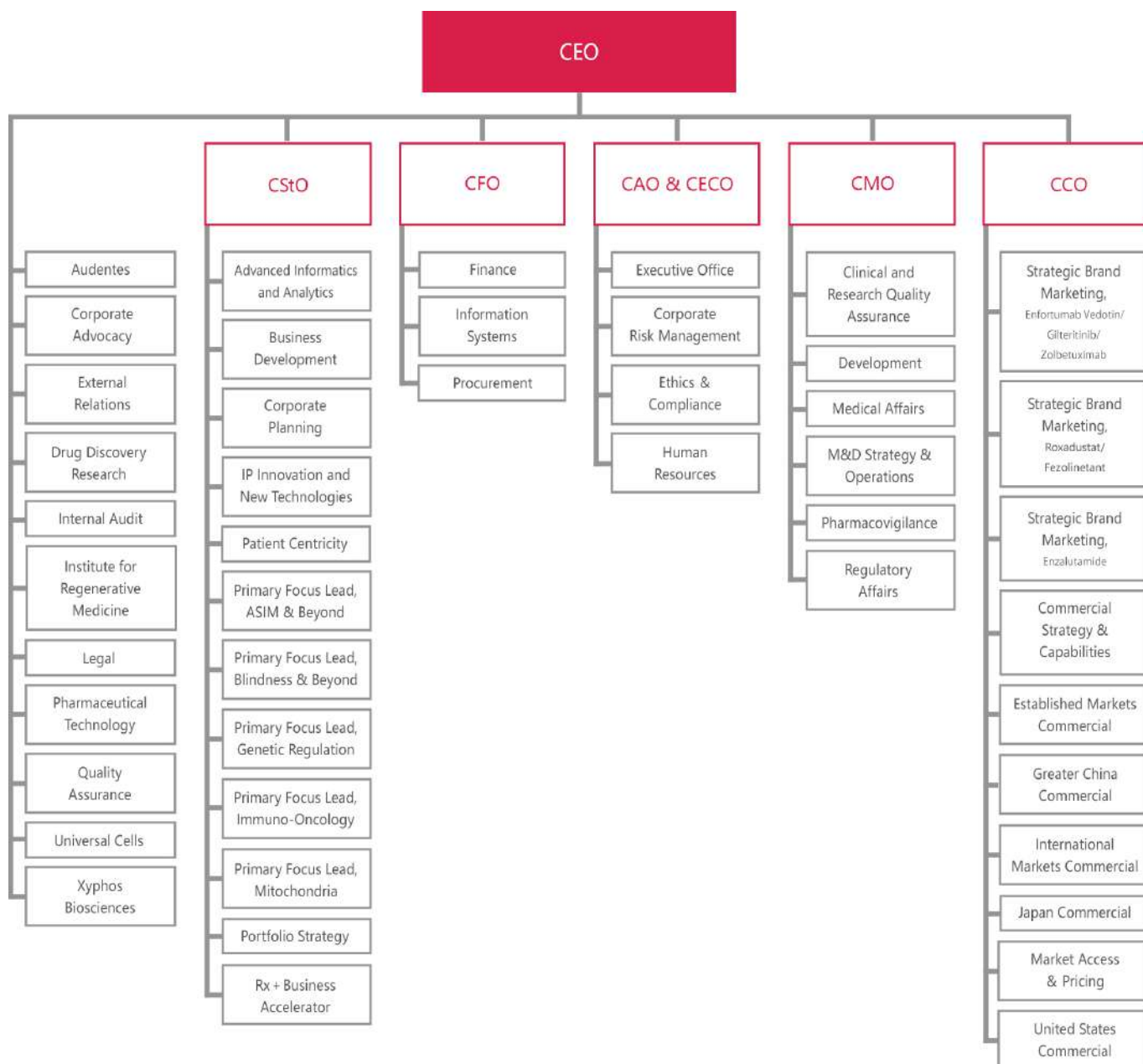
Representative Director, President and Chief Executive Officer (CEO)	Kenji Yasukawa, Ph.D.
Representative Director, Corporate Executive Vice President, Chief Strategy Officer (CStO) and Chief Financial Officer (CFO)	Naoki Okamura
Chief Administrative Officer (CAO) and Chief Ethics & Compliance Officer (CECO)	Fumiaki Sakurai
Chief Medical Officer (CMO)	Bernhardt Zeiher, M.D.
Chief Commercial Officer (CCO)	Yukio Matsui
General Counsel (GC)	Catherine Levitt

Extended Members

President, Drug Discovery Research	Akihiko Iwai
President, Pharmaceutical Technology	Hideki Shima
President, Development	Steven Benner
President, Established Markets Commercial	Dirk Kosche

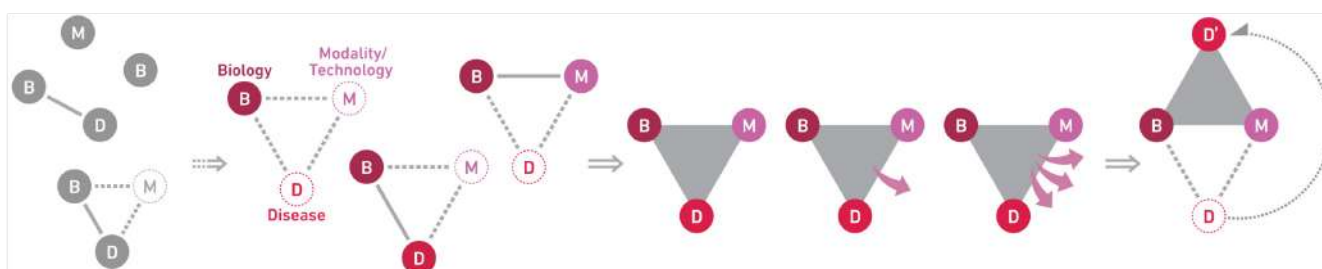
President, Greater China Commercial	Hiroshi Hamaguchi
President, International Markets Commercial	Claus Zieler
President, Japan Commercial	Yasuhiro Tsutsui
President, US Commercial	Percival Barretto-Ko

Group Management Structure (As of October 1, 2020)



Annual Report 2020

Focus Area Approach



Our Focus Area Approach

Astellas has established a Focus Area Approach for its research and development strategy. Specifically, our Focus Area Strategy is defined as combinations of three components: (1) biologies with high disease relevance, (2) versatile modalities/technologies, and (3) diseases with high unmet medical needs that are expected to be tackled by the first two components. We view this strategy as a way to build a sustainable, expandable drug discovery approach to develop new platforms, leverage expertise and create innovative products.

The Focus Areas are constantly adapting in response to advances in science and changes in disease treatment paradigms.

In the past, we have achieved success by identifying business opportunities from a disease domain perspective, based on the concept of the Global Category Leader (GCL) model. However, given major changes in the healthcare industry environment, we realize that identifying drug discovery opportunities more flexibly and efficiently is becoming crucial to continuously create new drugs and bring VALUE for patients. To this end, we developed our Focus Area Approach. It is designed to identify opportunities for the continuous creation of new drugs by focusing on biology, modalities, and technologies regardless of the disease area.

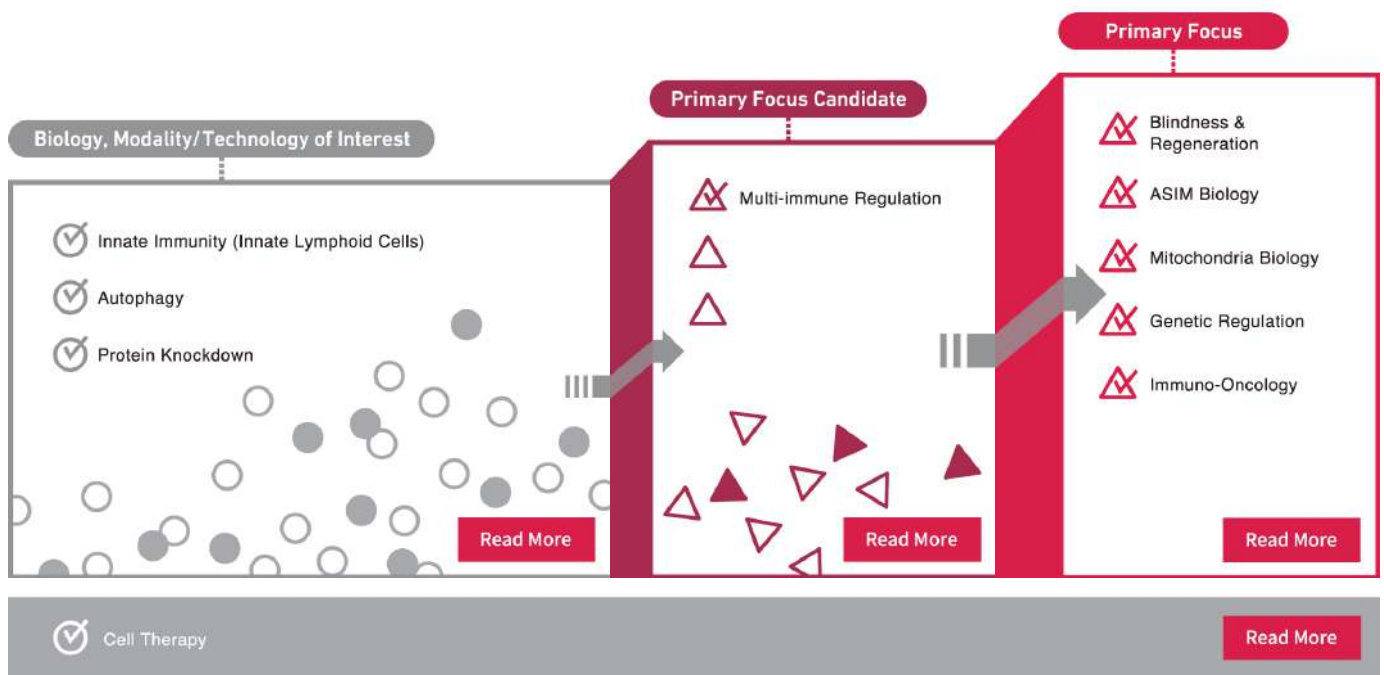
We will continue to develop new drug candidates for diseases with high unmet medical needs based on our expertise in each biology, modality, and technology that make up the Focus Area. What is particularly noteworthy is that the Focus Area Approach is not fixed, but continuously evolving by adapting its components to reflect the progress of research and development and the latest progress in science and technology. This will allow Astellas to develop its strengths while flexibly and efficiently identifying and realizing new drug discovery opportunities.

In particular, Primary Focus is a specific focal point within our Focus Area Approach where a lead and follow-on projects show a clear R&D path with expected commercial feasibility. Based on criteria such as higher scientific validity and

identification of leads and follow-on programs, we are currently working on five Primary Focus.

Primary Focus

Based on a Focus Area approach, we concentrate our R&D investments on Primary Focus, and work to develop innovative treatments. These include Blindness & Regeneration, which offers new treatment options such as cell therapy for restoring and maintaining vision; ASIM Biology, which aims to treat allergies and autoimmune diseases; Mitochondria Biology, which tackles development of mitochondrial replacement therapy; Genetic Regulation, which works on making progress in gene therapy; and Immuno-Oncology, which works on discovering, developing and delivering the best innovative cancer medicines to patients.



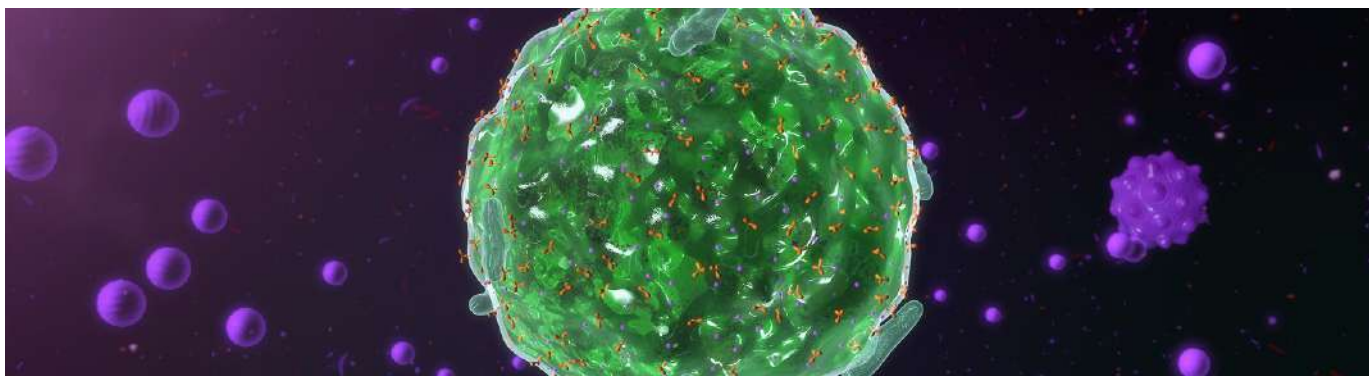
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Biology, Modality/Technology of Interest

We will continue to develop new drug candidates for diseases with high unmet medical needs based on our expertise in each biology, modality, and technology that make up the Focus Area. What is particularly noteworthy is that the Focus Area Approach is not fixed, but continuously evolving by adapting its components to reflect the progress of research and development and the latest progress in science and technology. This will allow Astellas to develop its strengths while flexibly and efficiently identifying and realizing new drug discovery opportunities.

Innate Immunity (Innate Lymphoid Cells)



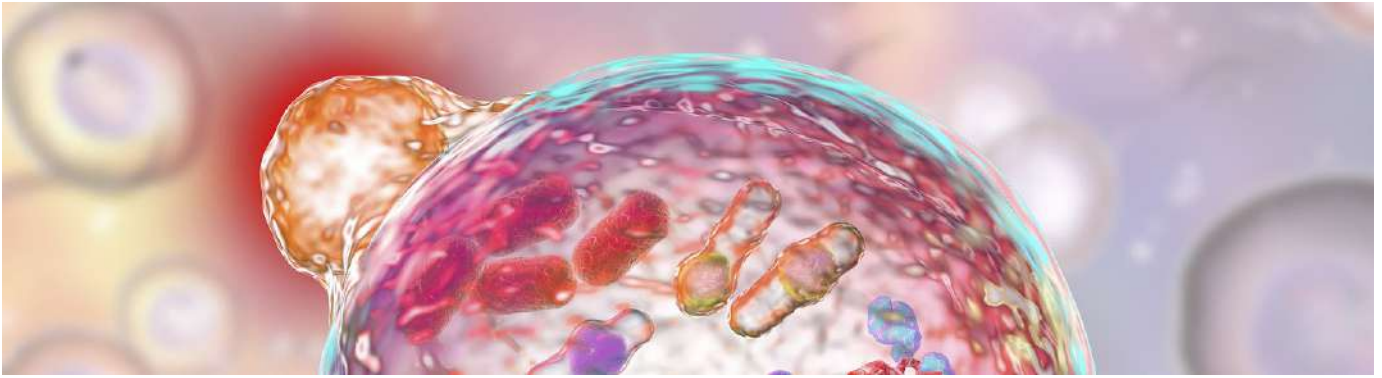
Innate Lymphoid Cells (ILCs) are newly discovered cells of the immune system. Compared to other immune cells, ILCs have superior effector functions, with production of large amounts of cytokines to induce inflammation. On the other hand, they are also known to induce immune tolerance.

If agents that regulate the function of ILCs are found, it is expected to lead to the avoidance of side effects associated with the use of immunosuppressants in addition to the effects that could not be achieved by conventional immunoregulation targeting known immune cells.

Astellas aims to create products that can expect high efficacy against autoimmune and allergic diseases, cancer, etc., which have high unmet medical needs, by utilizing our extensive experience in the field of immunity and the new biology of ILCs with an aim to provide new treatment options.

Close

Autophagy



Many diseases are marked by the accumulation of defective, damaged or no longer required proteins which compromise cellular function.

Autophagy is a key quality control process by which cells eliminate such aberrant proteins.

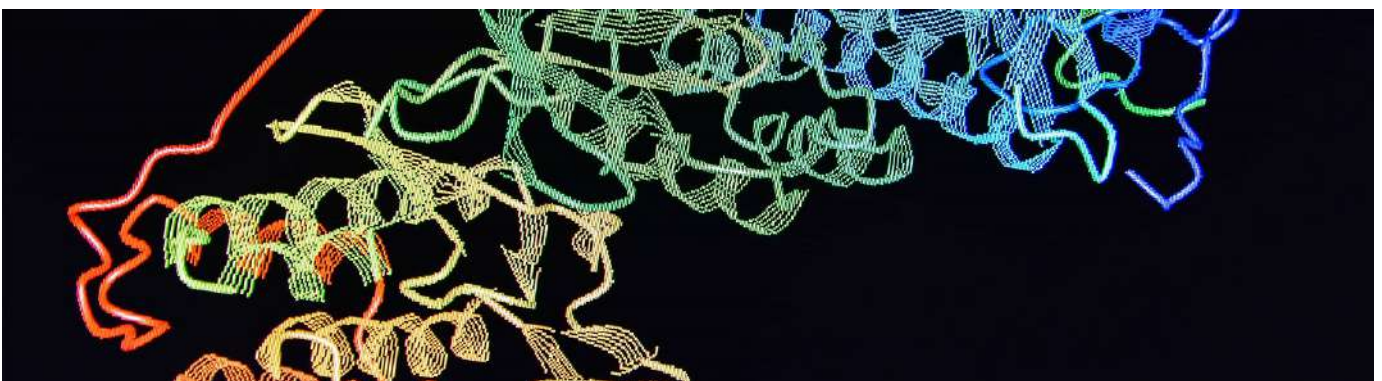
Potentiating autophagy is a direct way to address the wide range of diseases characterized by defective protein accumulation and is expected as an approach applicable to neurodegeneration, lysosomal storage disorders, renal disease, infectious disease, HIV, cancers, and even some psychiatric disorders.

Astellas utilizes its biochemistry and cell biology expertise in autophagy and aims to provide new safe and effective treatment options to patients who are suffering from various diseases without effective treatments.



Close

Protein Knockdown



Technologies that specifically degrade target proteins, such as utilizing the proteolytic mechanism originally existing in human cells or targeting RNA in the process of target protein production, have received considerable attention in recent years.

Utilizing these technologies is expected to greatly expand the potential of drug discovery for target molecules that were previously identified as the cause of disease but could not be accessed using existing technologies.

Astellas aims to provide new treatment options for patients in diseases with unmet medical needs such as cancer caused by, for example, undruggable oncogenes by combining these protein knockdown technologies with the small molecule

drug discovery technology of Astellas.


Close

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Primary Focus and Its Candidate

Based on a Focus Area approach, we concentrate our R&D investments on Primary Focus, and work to develop innovative treatments.

Blindness & Regeneration



Our mission of the Primary Focus Blindness & Regeneration is to free patients from the fear of vision loss, and offer the hope of recovery of lost sight. By taking advantage of next-generation modalities such as cell therapy and gene therapy for patients with back of the eye diseases at high risk of blindness, we will provide new treatment options to restore and maintain vision. Cell therapy and gene therapy will enable us to meet unmet medical needs that were difficult to meet with existing therapeutic approaches. It has the promise of delivering safe, effective, and sustainable options for patients who previously have not had any treatment options.

Our capabilities range from research, CMC and development of pluripotent stem cell (PSC)-based cell therapy, Universal donor cell technology, research and CMC of adeno-associated virus (AAV)-based gene therapy, in ophthalmic clinic and clinical. Astellas can be uniquely positioned as an innovative company, armed with both cell-based medicine and virus-based medicine as core strengths.

Our Primary Focus Blindness & Regeneration has been working on below leading programs.

[Human pluripotent stem cell (PSC) -derived cell therapy programs]

- Retinal pigmental epithelial cell (ASP7317, Phase 2)
- Photoreceptor, retinal ganglion cell, corneal endothelial cell (preclinical)
- Universal donor cell-based retinal pigmental epithelial cell (preclinical)

[Gene therapy programs based on adeno-associated virus (AAV)]

- Optogenetics (ASP1361, preclinical)
- Next generation gene therapy targeting retinal diseases (preclinical)

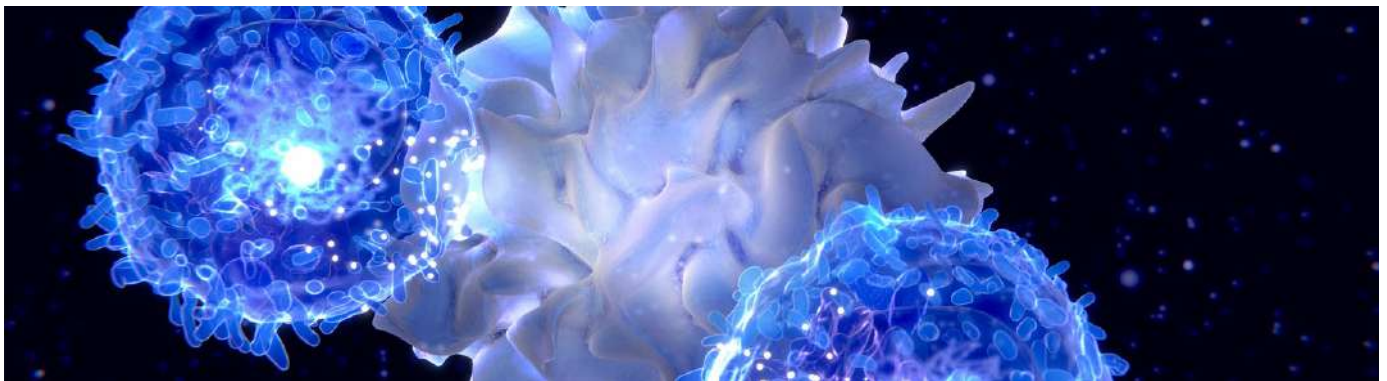
In addition, Astellas has the following capabilities:

- Creation, manufacturing and development of PSC-derived differentiated cells for therapeutic
- Universal donor cell technology
- Creation of next generation cell products using gene-editing technology
- Design and manufacturing of AAV-based gene therapy product
- Preclinical evaluation of cell and gene therapy candidates



Close

ASIM Biology/Multi-immune Regulation



Our vision for Primary Focus ASIM Biology is to deliver curative therapy for patients suffering from allergies and autoimmune diseases. Current treatments, such as corticosteroids, are mainly symptomatic treatments that suppress the entire immune response, and have problems such as side effects and susceptibility to infection. In addition, most autoimmune diseases are chronic and difficult to control and/or cure. It would be a significantly safe and effective treatment if we could specifically suppress the immune response against pathogenic autoantigens.

Astellas has been actively engaged in research and development of various immunoregulatory drugs, including Prograf, with the transplant/immunology field as our focus therapeutic area. Leveraging our immunology R&D experience and capabilities, we are currently exploring innovative technologies in order to realize antigen-specific immune modulation (ASIM).

We are currently utilizing the following platforms to promote our lead programs. We are also exploring a unique Astellas platform that can selectively control B cells that produce autoantibodies.

- Clinical trials on peanut allergy (ASP0892)
- Clinical trials on house dust mite-induced allergic rhinitis (ASP2390)

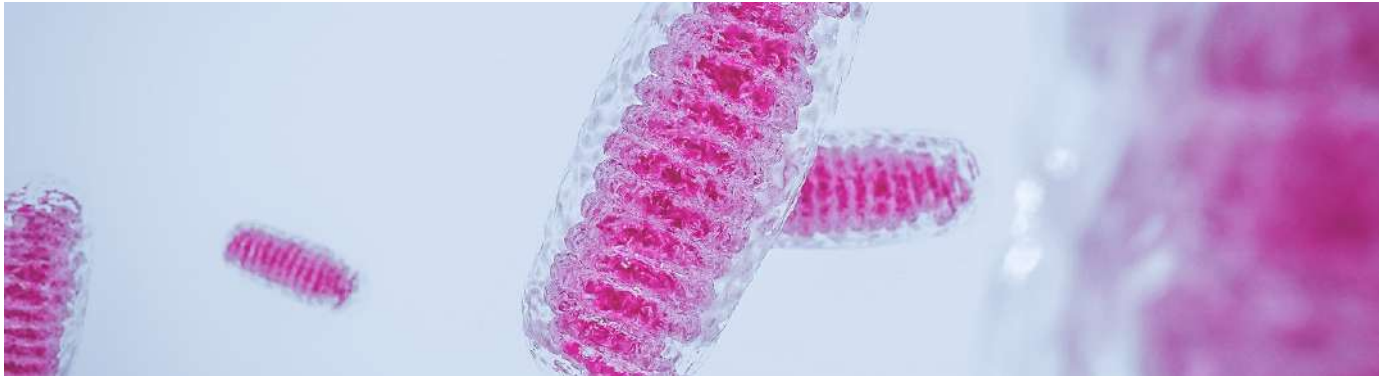
Another challenge we face is the fact that there are many autoimmune diseases where the pathogenic antigens are diverse or are not clearly identified. These diseases require new modalities that can effectively control the immune response to multiple antigens. Astellas is exploring innovative technologies and modalities (Multi-immune Regulation) that can suppress disease-specific immune responses in complex immune-related diseases as a new Primary Focus Candidate following ASIM biology (Multi-immune Regulation). In addition, it is necessary to develop preclinical disease

models and clinical biomarkers that can predict the technologies that can show efficacy. We hope to expand our technologies and capabilities through external collaboration.



Close

Mitochondria Biology



Health is Our Passion and Priority. Astellas' VISION is to turn innovative science into VALUE for patients. We are committed to making a difference for our patients today and providing them with additional therapeutic options for a brighter future tomorrow.

Our target, the mitochondrion, is remarkably complex. While it is primarily thought of as an energy supplying organelle, it also has multifaceted functions and is controlled by multiple biological pathways. In fact, mitochondria play an important role in the aging process with many clinical and preclinical evidence, and mitochondrial dysfunction causes and/or aggravates a wide variety of diseases.

Our goal in Primary Focus Mitochondria Biology is to become the global leader in discovering, developing and commercializing mitochondrial biology-based medicine that provides clear VALUE for patients, clinicians and healthcare systems.

To achieve the goal, Astellas acquired Mitobridge in January 2018 and established it as an Astellas Company based in Cambridge, Massachusetts. Building upon the emerging scientific findings linking mitochondrial function with disease pathophysiology, Mitobridge and Astellas are advancing innovative mitochondrial approaches to the treatment of diseases with high unmet medical needs.

Astellas continues to prioritize investment in the field, including in our two clinical stage compounds:

- ASP0367: This is a highly selective Peroxisome Proliferator-Activated Receptor (PPAR) delta modulator with oral formulation. It stimulates mitochondrial respiration through increased fatty acid oxidation-related genes and mitochondrial biogenesis. Thus, ASP0367 has the potential to improve function for Duchenne Muscular Dystrophy (DMD) and Primary Mitochondrial Myopathy (PMM) patients.
- ASP1128: This is a highly selective PPAR-delta modulator which is administered as an i.v. formulation. ASP1128 is being evaluated for the treatment of acute kidney injury (AKI) after Coronary Artery Bypass Grafting (CABG) and a POC study started in November 2019.

Astellas is also evaluating several other modulators of mitochondrial function in preclinical studies for potential use in additional indications.



Close



Genetic medicines have the potential to be transformative. Genetic deficiencies cause over 6,000 rare diseases* and contribute to the pathophysiology of many common diseases. New technologies to replace or regulate genes safely have advanced rapidly and are now a reality. One single treatment intervention has the potential to deliver transformative benefits to patients with few or no alternative treatment options.

Our vision and strategy aim to build capabilities for global leadership in Adeno-Associated Virus (AAV) -based genetic medicines. In January 2020 we completed the acquisition of Audentes Therapeutics, a leader in developing AAV-based genetic medicines with a focus on rare neuromuscular diseases. Audentes will become our Center of Excellence for Genetic Regulation as we aspire to address unmet medical need in patients with rare as well as more common diseases. In February 2020 Audentes announced plans to further strengthen its manufacturing capacity with a new cutting-edge gene therapy manufacturing facility in North Carolina which will become operational in 2021.

*: Online Mendelian Inheritance in Man® (OMIM®) Gene Map Statistics available at <https://www.omim.org/statistics/geneMap> (Accessed May 12, 2020)

Our Primary Focus Genetic Regulation has been working on below leading programs

- AT132: A gene replacement therapy being investigated for X-linked Myotubular Myopathy (XLMTM), a rare and fatal disease caused by lack of myotubularin protein in skeletal muscle cells.
- AT845: A gene replacement therapy being investigated for Pompe Disease, a severe progressive neuromuscular condition caused by lack of acid alpha-glucosidase (GAA) enzyme activity leading to accumulation of glycogen in skeletal and cardiac muscle.
- AT702/751/753: A vectorized exon skipping gene regulation therapy being investigated for the treatment of Duchenne Muscular Dystrophy (DMD), a severe progressive neuromuscular disease caused by mutations in the gene coding for dystrophin.

With Audentes as our Center of Excellence we have access to a pipeline of transformative therapies, including AT132 in late stage clinical development, and industry-leading manufacturing capabilities.



Close



Our mission is to discover, develop and deliver the best innovative cancer medicines to patients and ultimately, cure cancer. We are activating our best innovative capabilities and building a strong network of collaborations with external partners, in order to complete our mission.




















Despite the approval of multiple novel cancer treatments, such as immune checkpoint inhibitors, over the past few years, significant unmet needs still exist. Many cancer patients do not respond to a given treatment (“refractory”) or fail to maintain a response (“relapse”) during the treatment, with as many as 80 percent of patients estimated to be refractory to immune checkpoint inhibitors or to relapse during the treatment.

Our strategy is to target multiple aspects of the immune response to the cancer simultaneously.

Our Primary Focus Immuno-Oncology has been working on below leading programs

We have established a robust and competitive development-stage Immuno-Oncology portfolio through strategic external collaborations. We have built internal discovery, protein engineering, pre-clinical and clinical development, translational sciences and manufacturing capabilities in the US (greater Boston area, Seattle, WA, South-San Francisco, CA, and Northbrook, IL) and in Tsukuba, Japan. We have also formed collaborations with leading academic institutions and biotech companies worldwide to develop unique therapeutic approaches in Immuno-Oncology.

- ASP8374: Anti-TIGIT antibody
- ASP1948: Anti-NRP1 antibody
- ASP1951: GITR agonistic antibody
- ASP9801: Oncolytic virus (Collaboration with Tottori University)
- ASP7517: WT1 loaded artificial adjuvant vector cell (aAVC) (Collaboration with Riken)

Compound	Modality/Mechanism	Origin/Partner	Target tumor	Current stage ***			
				P	1	2	3
ASP8374	Anti-TIGIT antibody	 *	(To be determined)				
ASP1948	Anti-NRP1 antibody	 *	(To be determined)				
ASP1951	GITR agonistic antibody	 *	(To be determined)				
ASP9801	Oncolytic virus	 **	(To be determined)				
ASP7517	WT1 loaded artificial adjuvant vector cell (aAVC)	 **	Acute myeloid leukemia, myelodysplastic syndrome (as the first targets)				
(Not disclosed)	Other tumor antigens loaded aAVCs	 **	(Not disclosed yet)				
(Not disclosed)	Bispecific antibodies	 **	(Not disclosed yet)				

* Acquired in 2018 (currently their programs classified into in-house ones)

** Programs developed under joint research

*** The details of numbers and alphabets are as follows. P: Preclinical/Research, 1: P- I , 2: P- II , 3: P-III

We are Building a Pipeline of Multi-Functional Modality Platforms



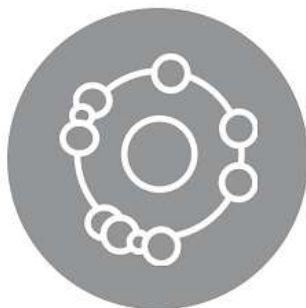
Novel immune checkpoint



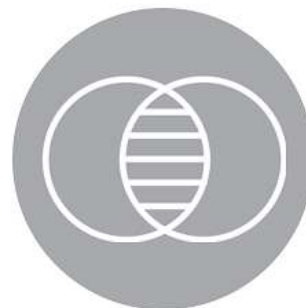
Oncolytic virus



Vaccination



Cell therapy



Combinations across our pipeline



Close

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Cell Therapy



Cell-based therapeutics have tremendous potential to satisfy unmet patient needs across a broad range of disease areas. They are also in their earliest stages of use within healthcare systems around the world, in only a handful of diseases. Those two facts put cell therapy at Astellas' sweet spot, turning innovative science into VALUE for patients. There is still so much to explore in terms of both where the science can go and how it can help patients, particularly those for whom no other treatment exists.

Over the last few years, we have acquired and developed the means to create a broad portfolio of different cell types. We collaborate with leading minds in a variety of therapeutic areas to fully explore the potential of cell therapy for treating diseases with high unmet medical need and unlock the VALUE that it can provide to patients. We also work hard to apply the latest technologies to the development of these therapies which allows us to stay at the forefront of breakthroughs in this fast-paced and emerging new field. Our goal is to develop "off-the-shelf" cell-based therapies that can be used in any patient and so we are working at the intersection of cell science and genetic science to develop the cell-based therapies of the future. The field of cell-based therapies truly excites us because we believe through our scientific expertise, we can make a difference for patients.

Our leading programs in Cell Therapy

Our most clinically-advanced program is looking at the use of retinal pigmented epithelium cells for improving vision in patients with dry age-related macular degeneration. We also have several other ocular cell types in our portfolio, such as Photoreceptor Cells, Corneal Endothelial Cells and Retinal Ganglion Cells. Our lead asset in the non-ocular space is our human hemangioblast-derived mesenchymal stem cell program, which has the potential to be of use in a wide range of conditions and diseases that involve immune response. This is closely followed by our Vascular Progenitor Cell asset with potential to add value in areas such as chronic limb ischemia and pulmonary hypertension.

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Pipeline Projects

Astellas aims to create a continuous stream of innovative medicines. We focus on steady progress of six key late stage projects so that we can deliver the value to patients as soon as possible.

Please see [here](#) for the details of target diseases and status for each project.

enzalutamide (brand name: XTANDI)

Enzalutamide is marketed worldwide for the treatment of castration-resistant prostate cancer (CRPC). As an additional indication, it was approved also for the treatment of metastatic castration-sensitive prostate cancer (M1 CSPC) in the US and for the treatment of prostate cancer patients with distant metastasis in Japan. Astellas is developing to expand the indications to earlier stages of prostate cancer in collaboration with Pfizer, Inc.

Enzalutamide is an androgen receptor (AR) inhibitor. It targets the AR and exerts its effects on three steps of the AR signaling pathway: inhibiting androgen binding to the receptor; preventing nuclear translocation; impairing DNA binding of the AR to the DNA.

Prostate cancer is the second most common in the cancers in men, and annually 1.3 billion men is newly diagnosed worldwide.*¹ Astellas focuses on the further development so that enzalutamide can contribute to more patients.

*¹ World Health Organization Cancer Fact Sheet 2018



Close

gilteritinib (brand name: XOSPATA)

Gilteritinib is marketed for the treatment of patients with relapsed or refractory FLT3 mutation-positive acute myeloid leukemia (AML) in Japan, the US, and the EU. Astellas is developing gilteritinib to expand the indications to earlier stages of AML.

Gilteritinib inhibits mutated FLT3, a receptor type tyrosine kinase known to be involved in cancer cell proliferation. FLT3 mutations are seen in approximately one-third of patients with AML.*¹ Gilteritinib has demonstrated inhibitory activity against major type of mutations that are internal tandem duplication and tyrosine kinase domain.

AML is a cancer that is most commonly experienced in elderly people with the incidence rate increasing with age. The number of newly diagnosed AML patients are approximately 5,500 in Japan,^{*2} 19,000 in the US^{*3} and 18,400 in the European Union^{*4} each year. AML is a life-threatening disease and requires early intervention. Induction and consolidation chemotherapy are the current standard care. However, resistance to current AML treatments and ineligibility of high-intensity induction chemotherapy for elderly patients due to an excessive physical burden make challenges in AML treatment. Promising new treatment options targeting specific genetic mutations have been awaited in AML treatment landscape.

*1 Patel JP, et al., 2012

*2 KantarHealth. TREATMENT ARCHITECTURE: JAPAN LEUKEMIA, ACUTE MYELOID. CancerMPact[®] Japan, February 2017

*3 American Cancer Society. Key Statistics for Acute Myeloid Leukemia (01-04-2018),

*4 Visser O, et al., 2012



Close

enfortumab vedotin (brand name: PADCEV)

Astellas is developing enfortumab vedotin as a treatment for urothelial cancer under collaboration with Seattle Genetics, Inc. In the US, enfortumab vedotin is marketed by Seattle Genetics, Inc. for the treatment of locally advanced or metastatic urothelial cancer, previously treated with platinum and anti-PD-1/PD-L1 antibody. Further development is ongoing to expand the regions and the indications to earlier stages of urothelial cancer.

Enfortumab vedotin is an investigational antibody drug conjugate (ADC)^{*1} composed of an anti-Nectin-4 monoclonal antibody attached to a microtubule-disrupting agent, MMAE, using Seattle Genetics' proprietary linker technology. Enfortumab vedotin targets Nectin-4, a cell adhesion molecule that is expressed on many solid tumors.

Urothelial cancer is the most common type of bladder cancer (90 percent of cases). Globally, approximately 549,000 people were diagnosed with bladder cancer annually, and there are approximately 200,000 deaths worldwide.^{*2} It is known that Nectin-4 is highly expressed in urothelial cancer.^{*3}

Enfortumab vedotin is currently under development also in other solid tumors.

*1 Antibody drug conjugate (ADC): ADCs are monoclonal antibodies that are designed to selectively deliver cytotoxic agents to cancer cells.

*2 World Health Organization Cancer Fact Sheet 2018

*3 Challita-Eid PM, et al., 2016



Close

zolbetuximab

Astellas is developing zolbetuximab as a treatment for gastric and gastroesophageal junction (GEJ) cancer.

Zolbetuximab is an antibody that targets Claudin 18.2, a transmembrane protein that forms a tight junction connecting and binding two adjoining cell membranes. In normal cells, Claudin 18.2 is expressed locally in stomach cells, while it is expressed in various cancer types including gastrointestinal adenocarcinomas as well as pancreatic, biliary duct, ovarian and lung cancers.

Gastric and GEJ cancer is one of the malignancies with the highest unmet medical needs. Gastric cancer is the third leading cause of cancer death worldwide.^{*1} Moreover, the overall five-year survival rate for metastatic gastric and GEJ cancer is under 20%.^{*2} Chemotherapy and anti-HER2 antibodies are widely used for the treatment of metastatic or

recurrent gastric and GEJ cancer. However, other therapeutic options are awaited especially in HER2-negative patients with a lack of effective targeted therapies.

Zolbetuximab is currently under development also in pancreatic adenocarcinoma. Pancreatic cancer is the seventh leading cause of cancer death worldwide,^{*1} and shows low overall five-year survival rate as 4%.^{*3}

*1 World Health Organization Cancer Fact Sheet 2018.

*2 Pennathur A, et al., 2013; Sahin et al., 2008

*3 Ilic M, et al., 2016



Close

roxadustat (brand name: EVRENZO)

Astellas is developing roxadustat as a treatment for anemia associated with chronic kidney disease (CKD) on dialysis and not on dialysis, in collaboration with FibroGen Inc. Astellas has the development and commercialization rights in Japan, Europe, the Commonwealth of Independent States, the Middle East and South Africa. Roxadustat is marketed in Japan for the treatment of renal anemia on dialysis.

Roxadustat has a new mechanism of action, inhibiting hypoxia-inducible factor (HIF) prolyl hydroxylase (PH). By inhibiting HIF-PH, roxadustat increases HIF involved in the production of red blood cells, thereby enhancing the production of red blood cells and improving anemia.

Anemia is one of the common complications of CKD. It is reported that the progression of anemia in CKD leads to end-stage renal disease and increases the mortality rate.^{*1}

Roxadustat can be administered orally and demonstrates equivalent efficacy and safety to the conventional treatments with erythropoietin-stimulating agent injections, as well as reducing the need for iron injections.^{*2,3} This is expected to be a new treatment option, which provides both effectiveness and convenience for patients.

Roxadustat is currently under development also in chemotherapy-induced anemia.

*1 Stauffer ME, et al., 2014

*2 American Society of Nephrology Kidney Week 2019

*3 European Renal Association-European Dialysis and Transplant Association 2020



Close

fezolinetant

Astellas is developing fezolinetant as a non-hormonal treatment for menopause-related vasomotor symptoms (MR-VMS: hot flashes and night sweats).

Fezolinetant is an antagonist of the NK3 receptor. Fezolinetant works by blocking neurokinin B (NKB) signaling and normalizing KNDy (kisspeptin/NKB/dynorphin) neuron activity, which modulates the temperature control center and reduces the frequency and severity of MR-VMS.

Hot flashes are the most common symptom for women transitioning through menopause.^{*1} Globally, approximately 57 percent of women aged 40 to 64 years have reported the occurrence of hot flashes and sweating.^{*2}

VMS have a significant impact on women's quality of life (QoL), including sleep. Currently, there are limited non-hormonal options for managing it, and new safe and effective non-hormonal therapeutics are needed.

*1 Freedman RR, 2014

*2 Utian WH, 2005



Close

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Rx+ Business



Rx+[®]

In order to realize Astellas' VISION of "on the forefront of healthcare change to turn innovative science into VALUE for patients," we recognize that we can take different approaches from treatment with prescription drugs (Rx) by leveraging the strengths we've acquired through Rx development. Based on this concept, Astellas launched a new initiative called Rx+[®] business.

Rx+[®] business is defined as a business that leverages the expertise and knowledge of Astellas, which have been cultivated through its Rx business, integrates innovative medical technology with cutting-edge technology in different fields, contributes to patients through Patient Journey (overall medical care, including diagnostic, preventive, therapeutic and prognostic care) and create new revenue streams separate from our core Rx products. This is the innovative value we are aiming to provide through the Rx+[®] initiative.

"A world where people can live mentally and physically healthy lives and be true to themselves through healthcare solutions based on scientific evidence"— This is the world for which we aim in "Rx+ Story™," a strategic direction for the creation of Rx+[®] businesses that will allow us to realize the following three value propositions:

- Prevent disease onset and slow progression by using personal data
- Expand options for people with limited access to current therapeutics
- Support active living by enhancing physical and sensory function

Rx+ Story™
 A world where people can live mentally and physically healthy lives and be true to themselves through healthcare solutions based on scientific evidence

Preventing onset and progression of disease by using personal data
 Expanding options for people with limited access to current therapeutics
 Supporting active living by enhancing physical and sensory function

We're working on six Spheres.

To make Rx+ Story™ a reality, we have established the following six areas, which we call "Spheres." We are actively developing new businesses in these Spheres:

(1) Chronic Disease Progression Prevention; (2) Motor Function Support/Replacement; (3) Digital × Neuroscience; (4) Patient w/o Effective Medicines; (5) Patient Outcome Maximization via Precise Surgery/Diagnosis; and (6) Sensory Function Support/Replacement.

- [Chronic Disease Progression Prevention](#)
- [Motor Function Support/Replacement](#)
- [Digital × Neuroscience](#)
- [Patient w/o Effective Medicines](#)
- [Patient Outcome Maximization via Precise Surgery/Diagnosis](#)
- [Sensory Function Support/Replacement](#)

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Six Spheres

To make Rx+ Story™ a reality, we have established the following six areas, which we call "Spheres." We are actively developing new businesses in these Spheres:

Chronic Disease Progression Prevention



In the aging populations, the gap between average life expectancy and healthy life expectancy is not closing, and controlling ever-increasing health care costs is becoming important social challenges. Pharmaceuticals have made a significant contribution to the treatment of lifestyle-related diseases and other chronic diseases such as diabetes and cardiovascular diseases. For now, the role of pharmaceuticals is not only providing such treatment but also “preventing disease” and “limiting the severity of disease” is becoming much more important.

Solutions for disease management and prevention from disease progression based on scientific evidence utilizing digital technology and medical big data, which have been rapidly developed and widely accepted in recent years, is expected to contribute to further progress in medical care and potential solutions for social problems.

With Sphere "Chronic Disease Progression Prevention," we aim to prevent the onset and severity of chronic diseases such as lifestyle-related diseases by providing solutions for disease management and prevention of severity based on scientific evidence.

In the short and medium term, we aim to develop and provide exercise programs and services that incorporate gamification (applying game elements to services and systems to improve user motivation and satisfaction) for diabetes and cardiovascular diseases. Based on the data accumulated through digital devices, we also are working to develop and provide risk prediction and individualized intervention measures through deep learning, which will help lead to disease management and prevention of disease progression according to individual constitution and lifestyle.

In the long term, we aim to prevent the onset of symptoms of the diseases and the progression of severity by highly individualized optimization by developing personalized scientific intervention measures from PHR (Personal Health Record)/EMR (Electronic Medical Record).



Close

Motor Function Support/Replacement



At Sphere "Motor Function Support/Replacement," we are currently working on providing new, drug-free medical care to patients with difficult-to-treat diseases, particularly those who suffer from impaired motor function related to muscles and nerves, and to caregivers who support such patients.

The main diseases we include in this area are excretion disorder, physical frailty, limb disorder due to cerebrovascular disease such as stroke, spinal cord injury, limb amputation, and communication disorder such as Amyotrophic Lateral Sclerosis (ALS), etc. In order to develop new medical methods to assist patients with motor function related disease, we intend to utilize multimodal device technologies, especially bioelectronics (the technologies that complement and replace the above obstacles with cutting-edge bioelectronics are called Neuroprosthesis and Brain-Machine Interfaces (BMI)), based on the following three technologies:

1. Sensing technology that clarifies biological activity information of cells, nerves, organs, muscles, etc.
2. Modulation technology that activates or bypasses muscles or nerves that are disordered by electrical, magnetic, or ultrasonic stimulation
3. Digital technologies such as sensing and modulation technologies for accurate diagnosis, data utilization for effective and efficient treatment, user interfaces, and applications

In the medium to long term, we aim to provide solutions that utilize individual or multiple technologies among these three technologies for various diseases. Finally, we will work to integrate these three technologies to provide closed-loop medical care that enables autonomous and active diagnosis and treatment throughout the body, thereby creating a society that complements and replaces physical exercise functions.



Close

Digital × Neuroscience



Drug Discovery Research aimed at treating central nervous system (CNS) diseases has led to the discovery of a number of medicines that are now being used in practice. On the other hand, not all medications can relieve patients from problems associated with their diseases, and CNS disorder is still an area with a high number of unmet medical needs.

Sphere "Digital × Neuroscience" aims to provide medical solutions that utilize digital technology to help address daily problems caused by CNS disorders. In addition, by combining multiple medical solutions, we aim to provide personalized solutions tailored to each individual's symptoms. In the long term, we aim to prevent the onset of disease and prevent the worsening of symptoms by early detection and improvement of various symptoms recognized in CNS disorders through the acquisition of various biometric information.



Close

Patient w/o Effective Medicines



Sphere "Patient w/o Effective Medicines" aims to provide patients access to new drugs where alternate solutions exist but where drug access is limited. The situation which is difficult to obtain the medicine depends on each patient's situation. Patients may face a variety of realities, for example based on their individual circumstances, such as not seeing a doctor because it is difficult to judge for themselves whether their physical condition is good or bad, or they may know it is good to take medicine but they do not want to do so.

To improve the situation for these patients, Astellas started with changing the medical-care environment for pregnant women, newborns and infants. The general idea is that some degree of discomforts and anxiety cannot be avoided in case of pregnancy, and issues regarding pregnant women had not been taken seriously in the past. For newborns and infants, who cannot communicate their own condition to adults around them, important signs may be overlooked. This is an issue that we hope to address through Rx+®.

For pregnant women, we are considering providing perinatal management solutions based on prenatal checkup information and various monitoring methods. Monitoring the situation when a pregnant woman is both in or out of the home, not just in the hospital, may reduce her anxiety and make it easier to find situations that require intervention. In the event that such a situation is discovered, we aim to establish a system that can lead to prompt treatment. By monitoring newborns and infants while they are both in or out of the home, we hope to quickly detect situations that require intervention. We will also aim to make it easier for newborns and infants under treatment to be observed.



Close

Patient Outcome Maximization via Precise Surgery/Diagnosis



In the evolving medical care environment, hospitals increasingly need to change how they respond to patient needs. In addition to treating patients, hospitals are expected to provide a high quality patient experience (patient experience value) in the future.

Personalizing medical care and enhancing care quality in order to meet changing patient needs are inevitable. As one of the solutions for such trends, Sphere "Patient Outcome Maximization via Precise Surgery/Diagnosis" aims to optimize patient value with smart hospital services.

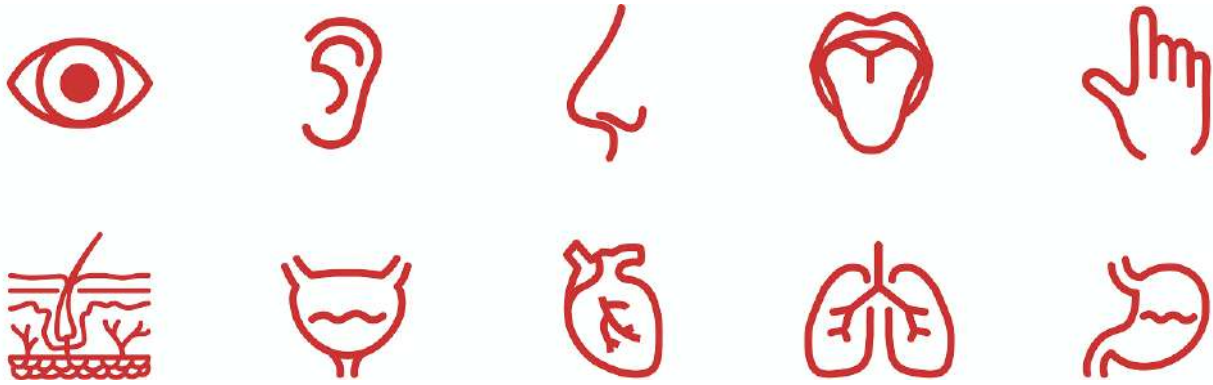
Astellas aims to provide various solutions to support realization of personalized smart hospitals. In particular, we are considering the following:

- Surgical navigation utilizing technique-upgrading technology and individual image data
- Minimally invasive medical care as an alternative to surgery
- Enhancing individual patient management, considering suitable treatment and preventing recurrence by adapting to individual circumstances



Close

Sensory Function Support/Replacement



In our daily lives, we receive, transmit, and process information from the outside world even unconsciously. Much of the information about the outside world is received by the sensory organs (eye, ear, nose, tongue, and skin), and internal organs (i.e. bladder and intestine). And that is transmitted to and processed by the brain, where it is interpreted as light (vision), sound (auditory sense), smell (sense of smell), taste (taste), feel (sense of touch) and sensation that develops in various internal organs.

What happens if these functions are compromised? Needless to say, quality of life (QOL) is greatly affected.

With Sphere "Sensory Function Support/Replacement," we aim to improve QOL of people with impaired sensory functions by incorporating new science and technology, such as engineering, in order to develop a multidisciplinary and superior solution, including a system that supports the patient, surrounding family members, as well as doctors and caregivers. With the elemental technologies to control a sensory function established through these initiatives, we plan to develop new sensory argumentation technologies in the future as well as support/replacement solutions for sensory dysfunction. We are looking at solutions and services that promote, complement, and replace sensory functions, specifically implantable devices, wearable devices, and digital applications. In order to achieve these goals, we are considering the following technologies:

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Major Pipeline



The list shows the development status in the target diseases for which we aim to obtain approval in Japan, the United States, Europe and/or China (as of August 2020).

Key Post-POC Projects and Projects to Maximize Their VALUE

Therapeutic Area	Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase *					Licensor **	
				1	2	3	F	A		
Oncology	enzalutamide MDV3100 (XTANDI®)	Androgen receptor inhibitor	Non-metastatic castration-resistant prostate cancer	■	■	■	■		China Oct 2019	Pfizer
			Metastatic castration-sensitive prostate cancer	■	■	■	■	■	Japan May 2020	
				■	■	■	■		Europe Jul 2019	
				■	■	■			China	
			Non-metastatic castration-sensitive prostate cancer	■	■	■				
	gilteritinib ASP2215 (XOSPATA®)	FLT3 inhibitor	Relapsed or refractory acute myeloid leukemia	■	■	■	■		China Mar 2020	In-house
			Post-chemotherapy maintenance acute myeloid leukemia	■	■	■				
			Post-hematopoietic stem cell transplant maintenance acute myeloid leukemia	■	■	■				
			Newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy	■	■	■				
			Newly diagnosed acute myeloid leukemia with high intensity induction of chemotherapy	■	■	■				
			Acute myeloid leukemia in pediatric patients	■	■	■				
	enfortumab vedotin ASG-22ME (PADCEV®)	Nectin-4 targeted ADC	Metastatic urothelial cancer, PD-1/PD-L1 inhibitor and platinum-containing chemotherapy pretreated	■	■	■			In-house [Co-development with Seattle Genetics]	
Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)			■	■	■					
Metastatic urothelial cancer, PD-1/PD-L1 inhibitor pretreated			■	■						
Other solid tumors			■	■						
zolbetuximab IMAB362	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	■	■	■			In-house (Ganymed)		
		Pancreatic adenocarcinoma	■	■						
Urology and Nephrology	roxadustat ASP1517/FG-4592	HIF-PH inhibitor	Anemia associated with chronic kidney disease in patients on dialysis	■	■	■	■		Europe Apr 2020	FibroGen
			Anemia associated with chronic kidney disease in patients not on dialysis	■	■	■	■		Japan Jan 2020	
				■	■	■	■		Europe Apr 2020	
			Chemotherapy-induced anemia	■	■					
Others	fezolinetant ESN364	NK3 receptor antagonist	Menopause-related vasomotor symptoms	■	■	■			In-house (Ogeda)	

* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region. The list specifies the area if the compound is developed in limited areas. The details of numbers and alphabets are as follows. 1: P-I, 2: P-II, 3: P-III, F: Filed, A: Approved

** Compounds with "In-house" in this column include ones discovered by collaborative research.

Projects with Focus Area Approach

Target (Biology)	Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase *					Licensor **
				1	2	3	F	A	
Immuno-Oncology	ASP8374/PTZ-201	Anti-TIGIT antibody	Cancer						In-house (Potenza Therapeutics)
	ASP1948/PTZ-329	Anti-NRP1 antibody	Cancer						In-house (Potenza Therapeutics)
	ASP1951/PTZ-522	GITR agonistic antibody	Cancer						In-house (Potenza Therapeutics)
	ASP9801	Oncolytic virus carrying IL-7 and IL-12	Cancer						Tottori University [Discovered through collaborative research]
	ASP7517	WT1 loaded artificial adjuvant vector cell	Cancer						RIKEN [Discovered through collaborative research]
Regeneration	ASP7317	Retinal pigment epithelium cells	Dry age-related macular degeneration, Stargardt's disease						In-house (Astellas Institute for Regenerative Medicine)
	FX-322	Inner ear progenitor cell activator (combination of GSK-3 inhibitor and HDAC inhibitor)	Sensorineural hearing loss						Frequency Therapeutics
	ASP0598	Recombinant human heparin-binding epidermal growth factor-like growth factor	Chronic tympanic membrane perforation						Auration Biotech
Antigen-specific immunomodulation (ASIM)	ASP0892		Peanut allergy						Immunomic Therapeutics
	ASP2390		House dust mite-induced allergic rhinitis						Immunomic Therapeutics [Discovered through collaborative research]
Mitochondria	ASP1128/MA-0217	PPAR δ modulator	Acute kidney injury						In-house (Mitobridge)
	ASP0367/MA-0211		Duchenne muscular dystrophy						In-house (Mitobridge)
Genetic Regulation	resamirigene bilparvovec AT132	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy						In-house (Audentes)
	AT845	GAA gene replacement to express GAA enzyme	Pompe disease						In-house (Audentes)
Others	ASP3772	Pneumococcal vaccine based on a multiple antigen- presenting system (MAPS) platform	Prevention of pneumococcal disease						Affinivax

* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region. The list specifies the area if the compound is developed in limited areas. The details of numbers and alphabets are as follows. 1: P- I , 2: P- II , 3: P-III, F: Filed, A: Approved

** Compounds with "In-house" in this column include ones discovered by collaborative research.



Others

Therapeutic Area	Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase *						Licensor **
				1	2	3	F	A		
Oncology	ASP1650	Anti-Claudin 6 monoclonal antibody	Testicular cancer							In-house (Ganymed)
	ASP1235/AGS62P1		Acute myeloid leukemia							In-house [ADC technology, EuCODE license from Ambrx]
Urology and Nephrology	solifenacin YM905 (VESIcare LS)	Muscarine M ₃ receptor antagonist	Neurogenic detrusor overactivity in pediatric patients						US May 2020	In-house
	mirabegron YM178	β ₃ receptor agonist	Overactive bladder and neurogenic detrusor overactivity in pediatric patients							In-house
	ASP8302	Muscarine M ₃ receptor positive allosteric modulator	Underactive bladder							In-house
Immunology	peficitinib ASP015K	JAK inhibitor	Rheumatoid arthritis						China	In-house
	bleselumab ASKP1240	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients							Kyowa Kirin
	ASP1617		Systemic lupus erythematosus							In-house
Others	isavuconazole	Azole antifungal	Invasive aspergillosis and mucormycosis in pediatric patients						US	Basilea
	ASP8062	GABA _B receptor positive allosteric modulator	Substance use disorders							In-house

* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region. The list specifies the area if the compound is developed in limited areas. The details of numbers and alphabets are as follows. 1: P-I, 2: P-II, 3: P-III, F: Filed, A: Approved

** Compounds with "In-house" in this column include ones discovered by collaborative research.

Rx+® Program

Sphere (Business area)	Project	Concept	Status	Partner
Chronic Disease Progression Prevention 	Smartphone application	Offer smartphone application to support exercise using wearable device to people who needs regular exercise	Implementing medical and health research	BANDAI NAMCO Entertainment
	Fitness service (Fit-eNce)	Scientifically evidenced exercise programs and systems which support regular exercise	Preparing to begin sales through fitness clubs in limited regions	
	BlueStar	Digital therapeutics for adults with diabetes	Under development	Welldoc
Patient Outcome Maximization via Precise Surgery /Diagnosis 	ASP5354	Precision surgery-guide enabling identification of ureter in hysterectomy and colorectal surgery, etc.	P-II	

Reference Materials

Please click [IR Library: Overview of R&D Pipeline](#) for more detailed information.

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Main Products

Main Products

Astellas is focused on maximizing the VALUE of its main products, XTANDI and Betanis/Myrbetriq/BETMIGA, and new products, XOSPATA, Evrenzo and PADCEV.

Prostate Cancer Treatment

XTANDI

XTANDI is an androgen receptor signaling inhibitor indicated for the treatment of forms of advanced prostate cancer in different countries.

Since being launched in the United States in 2012, XTANDI is now available around the world, including in Europe, Japan and Asia.

Since its launch, it has obtained additional indications for the earlier stages of prostate cancer and has contributed to the treatment of many patients.

With a strong presence in the urological field and by leveraging abundant data based on accumulated clinical experience since its launch, Astellas aims for a further penetration of approved indications.

Acute Myeloid Leukemia (AML) Treatment

XOSPATA

XOSPATA is a FLT3 inhibitor for adult patients with relapsed or refractory Acute Myeloid Leukemia (AML) with a FLT3 mutation-positive. It was launched in Japan and the United States in December 2018 and in Europe in November 2019.

AML is a cancer that affects the blood and bone marrow, and about 30% of the patients are reported to have mutations in the protein FLT3, a receptor tyrosine kinase involved in the growth of cancer cells. XOSPATA is believed to inhibit the growth of tumor cells bearing FLT3 mutations by showing inhibitory activity against mutations in both internal tandem duplication mutations (Internal Tandem Duplication: ITDs) and tyrosine kinase domain mutations (Tyrosine Kinase Domain: TKDs), which are activating mutations in FLT3.

Astellas contributes to the treatment of AML by providing XOSPATA as a new treatment option for FLT3m+ relapsed or refractory AML patients and healthcare professionals.

Metastatic Urothelial Cancer Treatment

PADCEV

PADCEV (enfortumab vedotin-ejfv), a treatment for adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1/L1, and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally

advanced or metastatic setting, was launched in the United States in December 2019.

PADCEV is a first-in-class antibody-drug conjugate (ADC) that is directed against Nectin-4, a protein located on the surface of cells. Nonclinical data suggest that the anticancer activity of PADCEV is due to the binding of the ADC to Nectin-4-expressing cells, followed by internalization of the ADC-Nectin 4-complex and release of MMAE via proteolytic cleavage. Release of MMAE disrupts the microtubule network within the cell subsequently inducing cell-cycle arrest and apoptotic cell death.

Metastatic urothelial cancer is a serious disease with limited treatment options. Astellas will contribute to the treatment of metastatic urothelial cancer by providing PADCEV as a treatment option in the United States for adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1/L1, and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting. In addition to the United States, we and Seattle Genetics are advancing the development of PADCEV in Japan, Europe, and other countries worldwide.

Overactive Bladder (OAB) Treatment

Betanis/Myrbetriq /BETMIGA

Betanis/Myrbetriq/BETMIGA for the treatment of OAB is a beta-3 adrenergic receptor agonist. Since the first launch in Japan in 2011 under the brand name of Betanis, the product has since been launched as Myrbetriq in the Americas, and BETMIGA in Europe and Asia & Oceania.

The drug improves various symptoms associated with OAB, such as urgency, urinary frequency, and urge urinary incontinence, through a new mode of action.

Astellas aims to maximize its product VALUE by ensuring that more physicians understand the balance between efficacy and tolerability, the feature of this product.

Renal Anemia Treatment

Evrenzo

Evrenzo is an oral, first-in-class treatment for anemia associated with chronic kidney disease (CKD). In November 2019, it was launched in Japan for the treatment of anemia in adult CKD patients that are dialysis dependent (DD). Additionally, in January 2020, we submitted a supplemental application to the Pharmaceuticals and Medical Devices Agency (PMDA) for approval of an additional indication of anemia associated with CKD in adults who are non-dialysis dependent (NDD).

Evrenzo is an inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase (PH), which is different from that of erythropoiesis-stimulating agents (ESAs). As a HIF-PH inhibitor, Evrenzo activates a response that occurs naturally when the body responds to reduced oxygen levels in the blood. This response involves the regulation of multiple, complementary processes to promote erythropoiesis and to increase the blood's oxygen-carrying capacity.

As a new treatment option for adults with CKD anemia in the dialysis phase, where unmet medical needs still exist, the drug will further contribute to patients with CKD anemia and healthcare professionals involved in its treatment. In addition to Japan, it is under development in Europe and elsewhere.

Immunosuppressants

Prograf and Advagraf/Graceptor/ASTAGRAF

Prograf and Advagraf/Graceptor/ASTAGRAF are immunosuppressants used to suppress organ rejection following a transplant. Although the patent for this drug has already expired in major countries, it continues to be used in transplants globally, and contributes to the treatment of autoimmune diseases such as rheumatoid arthritis and ulcerative colitis in Japan.

Other Main Products

OAB treatment:	Vesicare
Prostate cancer treatment:	Eligard
Benign prostatic hyperplasia treatment:	Harnal/Omnice
Antifungal agent:	Funguard/MYCAMINE

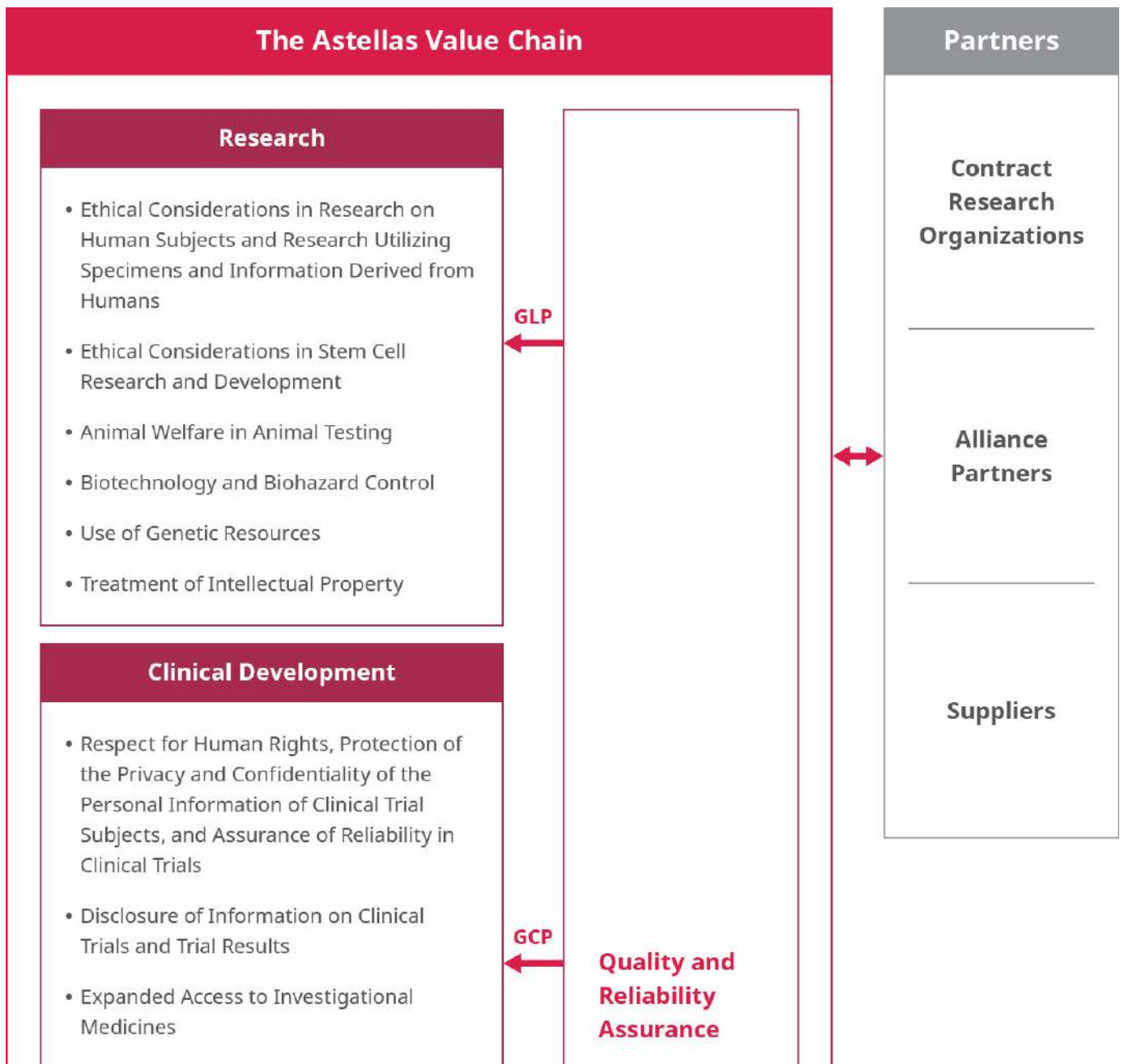
Please refer to the Supplementary Documents (pdf) of the [Business Results](#) in regard to the sales of major products in each region, including the products above.

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Responsible Business Activities

Astellas is committed to fulfilling its social responsibilities in the course of conducting business activities as a pharmaceutical company, based on the Raison D'être of "Contribute to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products." We respect human rights in every stage of our entire value chain, from research and development to the provision of product information. We also endeavor to ensure compliance with the Pharmaceutical and Medical Device Act and other relevant laws and regulations.





GLP: Good Laboratory Practice / **GCP:** Good Clinical Practice / **GMP:** Good Manufacturing Practice / **GQP:** Good Quality Practice / **GDP:** Good Distribution Practice / **GVP:** Good Vigilance Practice / **GPSP:** Good Post-marketing Study Practice

Ethical Considerations in Research on Human Subjects and Research Utilizing Specimens and Information Derived from Humans

Astellas conducts research on human subjects and research utilizing specimens and information derived from humans after appropriately obtaining the consent of the subjects in accordance with the Declaration of Helsinki*¹ as well as the laws, regulations and guidelines of relevant countries.

In Japan, Astellas provides training for employees that conduct research, in areas such as bioethics, genome research and related clinical research based on a strong commitment to respecting the human rights of research subjects and protecting the privacy and confidentiality of their personal information.

The Astellas Research Ethics Committee has been established with external experts participating in the committee to determine the ethical acceptability and scientific propriety of research plans in a fair and impartial manner. The details of the Astellas Research Ethics Committee have been released on the Ministry of Health, Labour and Welfare's ethics committee reporting system website*².

*1 Declaration of Helsinki: A statement of ethical principles for medical research involving human subjects, addressed to physicians and others who are involved in medical research on human subjects.

*2 For details, please visit the following website:

<https://rinri.niph.go.jp/>

Ethical Considerations in Stem Cell Research and Development

Astellas is advancing research and development activities using stem cells in order to supply new treatment methods to address diseases that previously had no known treatment methods.

On the other hand, Astellas also recognizes that concerns which need careful consideration could arise when promoting research using human stem cells. In particular, it is necessary to pay full attention to the social and bioethical issues associated with research using human embryonic stem cells (ES cells).

Based on these principles and awareness, Astellas has established its "Policy on Human Stem Cell Research and Development*," which sets forth the basic matters it must comply with in the course of conducting human stem cell research and development. Specifically, in all of its research and development activities involving human stem cells, Astellas will comply with the relevant laws, ordinances and regulations of the countries and regions where it undertakes these research and development activities. Moreover, Astellas will set up a committee comprising internal and external experts, from which it will obtain oversight and advice on the ethical aspects and the scientific validity and legitimacy of these research and development activities. All research and development programs will be implemented upon investigation by the committee from an ethical and scientific standpoint. Furthermore, when establishing and using human ES cells, Astellas will take steps to satisfy the ethical standards established by the world's major scientific authorities, including the guidelines laid out by the National Academy of Sciences of the United States of America.

* For details, please visit the following website:

https://www.astellas.com/system/files/policy_en.pdf

Animal Welfare in Animal Testing

Astellas conducts animal testing based on its Policy on Animal Care and Use*¹, which was created based on various relevant laws, regulations and guidelines related to animals such as the Act on Welfare and Management of Animals. We have established the Corporate Institutional Animal Care and Use Committee with external experts that verify the 4R Principles*² and determine whether to conduct animal testing. All of Astellas' animal testing facilities have acquired accreditation from AAALAC international*³.

*1 For details, please visit the following website:

https://www.astellas.com/jp/system/files/policy_on_animal_care_and_use_en.pdf

*2 4R Principles: Developing non-animal testing alternatives and replacing animals of phylogenetically lower species (Replacement); reducing the number of animals involved to the minimum necessary to achieve the scientific purpose (Reduction); avoiding the infliction of distress on animals wherever possible (Refinement); and scientifically and ethically justifying animal use in light of their significance, necessity, predictability and other criteria (Responsibility).

*3 AAALAC International: The Association for Assessment and Accreditation of Laboratory Animal Care International. An international organization that promotes the humane treatment of animals through voluntary accreditation and assessment programs. Studies are undertaken from both scientific and ethical standpoints to verify the quality of animal control and use programs.

Biotechnology and Biohazard Control

In compliance with the World Health Organization Laboratory Biosafety Manual^{*1}, the U.S. Centers for Disease Control (CDC) Biosafety Manual^{*2} and the U.S. National Institutes of Health Guidelines^{*3}, as well as the laws of individual countries, Astellas handles experimental materials containing genetically modified organisms and pathogens.

*1 Laboratory Biosafety Manual 3rd Edition

*2 Biosafety in Microbiological and Biomedical Laboratories 5th Edition

*3 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

Use of Genetic Resources

Based on its Position on Genetic Resources^{*1}, Astellas is committed to full compliance with the relevant laws and regulations of countries supplying genetic resources upon obtaining such resources, and to the fair distribution of profits derived from the use of such resources according to the conditions mutually agreed upon with each country. This commitment is in accordance with guidelines related to genetic resource utilization and the associated distribution of profits set out in the Nagoya Protocol^{*2} with regard to the Convention on Biological Diversity^{*3}. The impacts of the use of new genetic modification technologies on the environment, biodiversity, and human health are not fully known. Therefore, Astellas will proceed cautiously with regard to these technologies while remaining mindful of the need to preserve biodiversity and consider ethical issues.

*1 For details, please visit the following website:

https://www.astellas.com/system/files/Position%20Statement_Genetic%20Resources_ver.1.1_EN.pdf

*2 Nagoya Protocol: Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization

*3 The Convention on Biological Diversity: International convention on the sustainable use and conservation of biological diversity

Treatment of Intellectual Property

Appropriate protection of intellectual property is critical to addressing unmet medical needs and maintaining a competitive advantage. With this in mind, Astellas has established a Policy on Intellectual Property^{*1}.

In view of the importance of improving people's access to health, Astellas participates in the Patent Information Initiative for Medicines (Pat-INFORMED) implemented by the World International Patent Organization (WIPO) to ensure easy access to Astellas' patent information on medicines by health agencies tasked with the procurement of medicines in various countries. The patent information for XTANDI, Lexiscan, Gonax, Suglat, Tarceva and XOSPATA are listed in the Pat-INFORMED database.

Astellas commits to not filing or enforcing patents in Least Developed Countries (LDCs) defined by the United Nations or Low Income Countries (LICs) defined by the World Bank.

Astellas also commits to considering flexibilities in licensing patents in other developing countries on a case-by-case basis, in order to address pressing health challenges, while recognizing these challenges are the shared responsibility of multiple actors, including the pharmaceutical industry^{*2}.

*1 For details, please visit the following website:

https://www.astellas.com/system/files/property_en.pdf

*2 For details, please visit the following website:



Close

Clinical Development

Respect for Human Rights, Protection of the Privacy and Confidentiality of the Personal Information of Clinical Trial Subjects, and Assurance of Reliability in Clinical Trials

Astellas conducts clinical trials to assess the efficacy and safety of new drug candidates in patients under the Declaration of Helsinki, Good Clinical Practice (GCP) and all relevant laws and regulations with full consideration to protecting human rights and the privacy and confidentiality of clinical trial subjects' personal information. Clinical study protocols developed by Astellas are evaluated and approved for ethical acceptability and scientific validity by internal and external evaluation committees.

In conducting clinical trials, Astellas confirms that clinical trial subjects have provided informed consent, having received a full explanation of the purpose and methods of the trial, its expected benefits and disadvantages, matters related to compensation for health impairment and other details. Moreover, we regularly implement education and training for any employees or staff members involved in clinical trials, and monitor medical institutions that perform clinical trials to ensure full GCP compliance.

In addition, we protect the privacy and confidentiality of the personal information of clinical trial subjects by managing trial data appropriately. Periodic assessments are also made to check that any outsourced clinical trials are conducted in accordance with the same standards.

Disclosure of Information on Clinical Trials and Trial Results

Astellas is committed to increasing transparency and providing disclosure of clinical trial data. Maximizing the value of clinical trial data, and putting it to good use in driving scientific advancement and increasing innovation, requires that the clinical trial data be appropriately accessible to the research community and others who might utilize it. The Policy on Disclosure of Clinical Trial Data^{*1} has been published on the Company website to present Astellas' position on this matter.

Astellas registers clinical trials, posts clinical trial information, and discloses clinical trial results. Astellas provides patient-level data that have been anonymized in accordance with applicable laws and regulations through an external website^{*2} to those scientists and healthcare professionals requesting it in the case that review panel consisting of third party experts evaluates and approves the request based on scientific usefulness and scientist eligibility. In addition to disclosing summaries of clinical trial findings from phase 1-4 interventional studies after the approval or discontinuation of the study so that healthcare professionals and the public can confirm them via the website, this website also gives patients access to plain language summaries of study results prepared for non-experts^{*3}.

*1 For details, please visit the following website:

https://www.astellas.com/system/files/Clinical_Trial_Data_Disclosure_Policy_En_2018_1.pdf

*2 Patient-level data are provided through the following website:

<http://www.clinicalstudydatarequest.com>

*3 Results of the clinical trials are provided through the following website:

<https://www.astellasclinicalstudyresults.com/Welcome.aspx>

Expanded Access to Investigational Medicines

Astellas has set forth its approach to supplying investigational medicines to patients for purposes other than clinical studies in its Position on Expanded Access to Investigational Medicines*.

Astellas recognizes that patients with serious or life-threatening diseases may have exhausted all of their available treatment options, may not qualify for a clinical trial and may seek access to investigational medicines. In these cases, in response to a request for investigational medicines from a primary physician, Astellas fairly, impartially and rapidly evaluates whether or not the patient meets the required conditions and commits to establishing an expanded access plan as appropriate. The expanded access program will target countries where the clinical development of an investigational medicine is progressing and the drug is scheduled to obtain approval. This procedure will be implemented in accordance with the regulations of the country where expanded access is requested.

* For details, please visit the following website:

https://www.astellas.com/jp/system/files/position_on_expanded_access_e_annual_review_2018_1.pdf

Patient Centricity in Clinical Drug Development

The pharmaceutical industry is actively working on patient centricity in clinical drug development, and is discussing it at all points in pharmaceutical development.

We are listening to the opinions of patients and their families by working with patient organizations, and discussing the design of clinical trials and setting key outcome measures.

Moreover, with the launch of the website for patients, we are actively introducing information related to clinical trials and diseases to patients and their families. In addition, we have improved the ease with which informed consent and explanatory documents used for clinical trials can be read. Through these efforts, we try to make it easier for patients to participate in clinical trials so that we can obtain trial results with scientific significance for patients.



Close

Quality and Reliability Assurance

Anti-counterfeiting Activities

The infiltration of counterfeit/falsified medicines into the legitimate supply chain not only leads to the loss of opportunities for patients to receive effective medical treatment but could also have severe adverse health consequences. This has become a serious problem worldwide.

Astellas has published a clearly defined [Counterfeit/Falsified Medicines Position Statement](#) on our global website.

As a countermeasure, Astellas commissioned an Anti-Counterfeit Committee comprised of leaders from multiple stakeholder functions (quality assurance, supply chain, etc.), and has also established a product security function to oversee daily activities relevant to product-related security risks. These entities monitor the global market for suspicious activities affecting Astellas products, and implement countermeasures targeting not only counterfeit/falsified medicines, but also diversion, theft and other illicit activities that potentially affect our products and/or present a potential risk to patients. Astellas systematically introduces anti-counterfeit measures, including, but not limited to, product serialization as stipulated by current regulations and pharmaceutical laws. In addition, Astellas regularly engages in various collaborative activities with other members of the pharmaceutical industry to help prevent the spread of counterfeit/falsified medicines. We also proactively endeavour to support and cooperate with national regulatory and judicial authorities to crack down on counterfeit/falsified medicines.

Anti-doping Measures

Doping is an issue closely related to abuse and misuse of medicines in sports. It is a serious priority for the pharmaceutical industry given that it is not only associated with a risk of inducing serious side effects, but it can also become a breeding ground for the unauthorized distribution and counterfeiting of medicines. Astellas is working to identify the compounds under development that have the potential to be used in doping and to prevent the misuse of those compounds.

[In October 2016, Astellas made a global agreement with the World Anti-Doping Agency \(WADA\) to partner on the prevention of misuse and abuse of medicines for doping in sports which aims to contribute to the eradication of doping and improvement of public health.](#)

Doping in sports relies primarily on the misuse and abuse of commercially available medicines, as well as compounds in development that are not as well-known or easily detected. To support WADA in its efforts to address this issue, Astellas identifies compounds solely developed by Astellas or its affiliates with the potential for sport-related doping abuse and cooperates in sharing relevant information to aid WADA in the organization's development of detection methods for these compounds. Additionally, Astellas cooperates with WADA to minimize the risk of misuse of compounds with doping potential during clinical trials to avoid opportunities for abuse.

Product Recalls

Astellas has a recall system in place that is activated when the safety, efficacy or quality of a product is brought into question. The system ensures relevant information is promptly passed on to medical institutions and other affected parties, and that a recall of the product in question is instigated. Astellas voluntarily initiated 2 product recalls in fiscal 2019. As of March 2020, there were no reports of any related health impairments received.

History of product recall

FY	The number of recall	Severe (Class I)	Moderate (Class II)	Minor (Class III)	Non Classified
2014	3	0	1	1	1
2015	3	0	1	1	1
2016	3	0	2	1	0
2017	3	0	2	0	1
2018	7	0	4	2	1*
2019	2	0	1	0	1

* Authority-initiated recall

FDA Inspection

Astellas has established its own quality standards in compliance with current Good Manufacturing Practice (cGMP) and applies these standards to Astellas Group manufacturing sites. In fiscal 2019, Astellas underwent 2 US FDA inspections globally overall, of which Astellas only received a single Form 483.

*Form 483: An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.

US FDA inspection history

FY	The number of FDA Inspection	Warning Letter issued	Form 483 issued	Location of Form 483 issued
2014	5	None	1	Takaoka (Japan)
2015	4	None	2	Norman (US) * Takaoka (Japan)
2016	2	None	1	Toyama (Japan)
2017	2	None	1	Toyama (Japan)
2018	3	None	1	Takaoka (Japan)
2019	2	None	1	Toyama (Japan)

* The Norman plant in the U.S was transferred to the Avara Norman Pharmaceutical Services, Inc. in August 2016.

Quality Manual

Astellas has set forth the quality assurance function and activities in the Quality Manual. The Quality Manual sits on the apex of the document management system hierarchy. Underneath the Quality Manual, policies, standard operating procedures, and guidelines exist defining quality assurance systems and operational management and procedures for a variety of quality assurance-related activities at the global, regional and national levels. Education and training programs are implemented to promote understanding and awareness of these matters.

These documents are revised periodically and as necessary. We respond swiftly to developments in the external environment, such as regulatory changes and amendments.

Strengthening of Quality Assurance Systems at Affiliates

Astellas has developed a robust global quality assurance system so that it can ensure patients worldwide a supply of uniformly high quality of pharmaceuticals. This quality management system was developed to be consistent with our quality policy on a global, company-wide basis. The organisational structure of the global quality assurance system incorporates the quality assurance activities of all Astellas affiliates. Our sales affiliates globally receive ongoing support in strengthening our quality culture whilst educating our personnel to the highest standards.

Improving the Pharmacovigilance (PV) System

Astellas is continuously improving its pharmacovigilance (PV) system by strengthening collaboration between its PV function and other relevant functions, affiliates and licensing partners. This is to respond to expansion of product strategies and advance the provision of trustworthy product information and proper product use, along with compliance with regulatory requirements.

Astellas has been building a system to collect product safety information from a variety of sources. The Company annually provides product safety awareness training not only to staff closely involved with the PV function but also to all employees and contractors including affiliate staff, to maintain and strengthen swift and appropriate collection of product safety information. For external service providers outsourced by functions other than the PV function, Astellas adds requirements for the collection of product safety information in their contracts as necessary.

Astellas has been maintaining safety databases and procedures used globally to respond to environmental change. In fiscal 2018, it completed a major upgrade of its safety database and procedures to meet regulatory requirement changes. In fiscal 2019, it continued to implement electronic submissions of safety reports to local regulatory authorities to meet new requirements.

Astellas is exploring utilizing real-world data such as large healthcare databases for evaluation of its product safety to help minimize risk by enhancing collaboration between PV and other functions. Furthermore, Astellas has started exploring and assessing automation technologies and artificial intelligence technologies that can be used for monitoring, processing and reporting of product safety information, and early identification and analysis of safety signals. We plan to use these technologies to strengthen our PV system.



Close

Technology Development & Manufacturing

Stable Supply and Quality Control

Astellas places highest priority on ensuring robust manufacture and stable supply of safe and effective pharmaceuticals to patients. To ensure this, we have established our own standards aligned with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) as the basis for consistently achieving high levels of quality. We apply these standards to manufacturing facilities and equipment, and to all stages from raw material procurement and storage to production and shipment.

Astellas is continuously investing in various manufacturing facilities with the aim of maintaining and strengthening stable supply. In 2020, construction of the Center for Active Ingredient for Biopharmaceuticals was completed at Astellas Pharma Tech's Toyama Technology Center. Bio-drug substances for clinical trials and commercial use are manufactured at the Center and supplied according to global standards. In addition, construction of the Third Fermentation Building has commenced. When the construction is completed, the active pharmaceutical ingredients of immunosuppressant Prograf® that suppress rejection after organ transplants will be manufactured at the facility. By constructing such in-house state-of-the-art manufacturing facilities, we aim to build a more robust manufacturing system capable of supplying high quality products going forward.

Quality Audits

Astellas has quality systems for auditing both internal sites and external manufacturing and distribution partners. The risk-based auditing approach determines the sites audit frequency and intensity.

Internal audits are conducted on all Astellas organizations that conduct current Good Manufacturing Practice (cGMP) and/or current Good Distribution Practice (cGDP) activities at all points across the product lifecycle and across the supply chain, in accordance with documented policies and procedures.

Quality audits are conducted for new or established external partners of Astellas. Such audits are performed to evaluate compliance with cGMP, cGDP and applicable Astellas requirements.

In fiscal 2019, Astellas performed a total of 332 audits, including 33 internal audits and 299 quality audits of external partners globally.

Supply Chain Management Structure for Stable Supply

Supply chains are becoming more complicated than ever due to the increase in global products and diversification of modality, along with the increase in partnerships and cooperation with suppliers.

Taking these environmental changes into account, Astellas is strengthening its supply chain management globally by building a framework to centrally manage demand forecasts, inventory data and supply plans for regions all over the world, encompassing the manufacture of drug substances through to finished product supply.

Moreover, in addition to building a global logistics and distribution network to develop the functions and capabilities which flexibly meet the various needs for products, including cold chains, Astellas is advancing logistics and trade compliance, including for imports and exports, to enhance the stable supply management.

Furthermore, in the area of commercial supply chain, Astellas has established a function at three locations: Japan, the Netherlands, and the US to continuously develop the supply chain process adapting to the environment changes and strengthened the management framework in global operations.

Shared Logistics for Stable Supply

One of the most important missions for a pharmaceutical company is to continuously improve BCP (Business Continuity Plan), and maintain and continue a stable supply of pharmaceutical products even when natural disasters occur. The Ministry of Health, Labour and Welfare released Japanese GDP (Good Distribution Practice) Guidelines which require greater strictness with respect to ensuring quality in storage and shipment under GDP. Meanwhile, MLIT (Ministry of Land, Infrastructure, Transport and Tourism), METI (Ministry of Economy, Trade and Industry), and MAFF (Ministry of Agriculture, Forestry and Fisheries) are promoting “White Logistics,” an initiative aimed at addressing working style reform, driver shortages, CO₂ reduction among other issues facing logistics. Under this initiative, consignors cooperate with logistics partners to implement activities for improvement and reform, and build sustainable logistics frameworks.

Under the environment changes surrounding logistics, Astellas, Takeda Pharmaceutical Company Limited, Teva Takeda Pharma Ltd. and Teva Takeda Yakuhin Ltd. have co-established a shared storage and joint distribution platform in Hokkaido, Japan. The platform aims to ensure a diverse and stable supply of pharmaceuticals with adequate contingency, even in the event of a large-scale natural disaster, as well as enhancing efficiency and quality management of product distribution. Astellas will continue initiatives that advance the sharing and standardization of the pharmaceutical logistics within the industry.

The joint distribution platform in Hokkaido has reduced costs. It has not only enabled us to set up a new logistics base but also has reduced the environmental burden through the reduction of carbon emissions. In recognition of these points, Astellas received the Minister of Economy, Trade and Industry Award in 2018 for the Green Logistics Excellent Business Award.

Measures to Prevent Medical Malpractice and to Improve the Distinguishability of Pharmaceuticals

Astellas strives to supply products from the users' perspective to ensure that healthcare professionals and patients do not mistake one pharmaceutical for another. We are working to prevent medical malpractice in this respect, through measures including printing product names directly on capsules and tablets, as well as printing product names and dosage on packaging sheets (blister sheets) so that the product name and dosage can be easily identified even after the blister sheet is split apart.

To prevent misreading of labeling on blister sheets, Astellas also endeavors to make products easier to identify visually by adopting easily discernible colors and font types for the blister sheets of certain products. We also adopt blister card packaging* for pharmaceuticals that require care with dosage frequency



from the perspective of preventing medical malpractice. For example, Evrenzo 20 mg / 50 mg / 100 mg tablets newly launched in 2019 are packaged in a set of three tablets in order to prevent taking more or less than the required dosage of three times per week. The size, color and labeling design are also differentiated to reflect the dosage size, to prevent taking the wrong tablet.

In addition, to improve patients' medication compliance and ease of swallowing, Astellas is also reducing the size of the tablet and changing the formulation. For example, the XTANDI 40 mg (10.1 mm dia.) / 80 mg (17.2 mm dia.) tablets launched in 2018 were smaller than the previously released XTANDI 40 mg (21 mm dia.). Moreover, as the number of tablets per dose is expected to be reduced, it will also reduce patients' burden when taking medications.

* Blister card packaging: Plastic packaging formed to fit the shape of the product.

Introducing Universal Design into Product Packaging

We have introduced universal design to certain product packaging. For example, the universal design packaging of Bonoteo 50 mg tablets, which is administered once every 4 weeks, features packaging with good openability. To prevent patients from forgetting to take the drug, there is an area provided on the packaging to write the day when the drug should be taken. A small sticker to be used on a calendar is also attached. In addition, the packaging uses a universal design font type for easy reading.



Universal design packaging of Bonoteo 50mg tablets

Relationship With Local Communities and Consideration for the Environment

To promote sustainable pharmaceutical manufacturing, Astellas arranges opportunities for dialogue with local residents and communities near its manufacturing sites. By proactively disclosing its initiatives, Astellas is working to build good relationships with them.

For 16 years at the Kerry Plant in Ireland, Astellas has been holding an event on an annual basis in which children from the local community draw pictures themed on protecting the environment, health and safety, and saving energy. These are made into a calendar which is sold locally, with all proceeds donated to the Irish Kidney Association. Every year, close to 1,000 entries are received from local schools, and the event has now developed into a regular community event. Various other initiatives are being carried out to deepen relationship with the local community, including cardiopulmonary resuscitation training in the community, science-themed awareness events with local schools, and dialogue meetings with experts on special themes such as dialogue with wildlife experts. During 2019 and 2020, Kerry Plant has won "Building Project of the Year" from SEAI*1, "Excellence in Environment" from Chambers Ireland*2 and "Sustainability Project of the Year" from Pharma Industry Awards*3. Furthermore, in recognition of these environmental activities in Ireland, Kerry Plant received the "Green Award"*4.

Astellas is also carrying out such activities at various business locations in Japan, including providing volunteer support for shoreline clean-ups and a summer festival at a facility for disabled persons, as well as holding plant tours as part of university work experience programs being held with the aim of promoting engineering careers in pharmaceutical related companies.

*1 SEAI: Sustainable Energy Authority of Ireland is an Irish government-affiliated organization supporting the reduction of CO2 emissions.

*2 Chambers Ireland: Ireland's largest business organization serving as a network of major-city chambers of commerce.

*3 Pharma Industry Awards: Award given to companies that contributed sustainable society in Ireland's pharmaceutical industry.

*4 Green Award: Award recognizing continuous dedication, leadership and platform for innovation in environmental activities in Ireland.

Response to Climate Change

In order to contribute to achieving sustainable society, Astellas recognizes that, among business activities carried out in harmony with the global environment, response to climate change and reduction of greenhouse gases are important corporate focuses. Accordingly, for some time now, we have actively implemented measures to reduce GHG emission, including the introduction of wind power generation and biomass boilers at manufacturing sites overseas, the use of renewable energy derived power, and the introduction of hybrid vehicles for sales staff in Japan and overseas.

Furthermore, in 2018, after backcasting*¹ from goals that society should aim for 2050, Astellas revised its targets for reducing GHG emissions in the medium to long term, and set a target by fiscal 2030 by a 30% compared with fiscal 2015 (baseline year: 221,000 tons). That target has been recognized as one that is grounded in science according to the Science Based Targets (SBT) initiative*².

As part of initiatives aimed at achieving medium- to long-term targets, from April 2020, the Tsukuba Research Center, Tsukuba Biotechnology Research Center and the Takahagi Chemistry & Technology Development Center in Japan have switched the energy supplier for all of their energy consumption, adopting the “Aqua Premium*³” plan provided by TEPCO Energy Partner, Incorporated. Through the adoption of Aqua Premium, the approximately 31,000 tons (2019 results) of GHG emission caused by the electric power consumption of those three facilities can be completely eliminated from fiscal 2020.

Going forward, Astellas will continue to contribute to the health of people all over the world by harmonizing its business activities with the global environment.

*1 Backcasting: A thinking method that starts with defining a desirable future and then working backwards to identify measures and actions.

*2 Science Based Targets (SBT) initiative: An organization jointly established in 2015 by four organizations: the CDP, the United Nations Global Compact, the World Resources Institute, and the World Wide Fund for Nature. An international initiative led by the organization is to encourage companies and national governments to set GHG reduction targets to achieve the “2 degrees Celsius target” as agreed under the Paris Agreement of 2015.

*3 Aqua Premium: A charging plan offered by TEPCO Energy Partner, Incorporated that allows customers to buy only hydroelectricity, which does not emit GHG at the time of generation.



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Provision of Product Information

Ensuring Proper Use

Astellas' Medical Representatives (MRs) provide information on appropriate usage based on on-label information to healthcare professionals to ensure that Astellas pharmaceutical products are used safely and effectively. In promotion of Astellas products, MRs act with high ethical standards and strictly comply with the applicable laws and regulations, industry codes and company policies including Astellas Group Code of Conduct.

Medical Science Liaisons (MSLs) engage with healthcare professionals to exchange scientifically based information to advance their understanding and the safe and effective use of our products in patient care. MSLs also act with high ethical standards and provide reliable, clear, fair, balanced and unbiased medical and scientific information. MSLs refrain from promotion of products, and observe high ethical standards, making compliance their top priority.

Responding to Inquiries

Astellas has a responsibility to provide truthful, balanced and unbiased medical information in response to inquiries regarding our products. By fulfilling this responsibility, Astellas supports the safe and effective use of our products.

In countries throughout the globe, we have Medical Information Call Centers that respond to a variety of inquiries. In our larger call centers, we have systems that allow for 24-hour responses to urgent inquiries, even on business holidays. In fiscal 2019, we responded to approximately 100,000 inquiries.

Astellas makes continuous efforts to improve its medical information services, with the aim of providing accurate, appropriate and consistent information. As part of these efforts, a global medical information system is used where medical responses from group companies around the world are documented. This enables the responses to be communicated to our customers in a simple, swift and accurate manner. At the same time, we can analyze feedback from patients and medical professionals and communicate these insights to support the life cycle management of our products.

We have recently implemented a new global medical information system that sets the stage for new and improved services for our customers.



Close

Procurement

Sustainable Procurement Initiatives

Astellas considers it important to fulfill its social responsibilities across the entire supply chain. To achieve this goal, Astellas has formulated the [Astellas Business Partner Code of Conduct](#), which requires business partners to implement initiatives in accordance with social responsibilities and sign the Acknowledgement of Astellas Business Partner Code of Conduct.

Risk Assessments of Significant Business Partners

Astellas conducts a global assessment that includes an evaluation of sustainability risk in the selection process for significant business partners*, the business partners that have a particularly significant impact on Astellas' business continuity among others. The sustainability risk assessment involves judging a risk level based on a combination of the business partner's response to a questionnaire, external database information, a basic assessment by in-house experts on risks related to sustainability such as human rights, the environment, occupational health and safety and personal information protection, and, if necessary, the results of a local on-site audit carried out by an Astellas employee. The questionnaire has been updated in January 2019 to improve the accuracy of the risk assessment and been implemented in Japan, North America and Europe since February 2019. In addition, it has been expanded in stages to marketing subsidiaries in South America and Asia since March and April 2020, respectively.

If Astellas identifies a risk that can be improved during the business partner selection process, it encourages the business partner to make the improvement and monitors its initiatives. Astellas does not engage in business if it identifies a critical risk and it judges the risk is difficult to be improved.

Moreover, business divisions continue monitoring risk status even after business transactions have begun and the supplier's sustainability risk level is assessed once every two years through a questionnaire. If necessary, the assessment takes place even within the two-year period.

* Business partners that have a significant impact on Astellas' business continuity, such as suppliers of raw materials (regardless of whether they are direct or indirect materials), outsourcing companies, pharmaceutical wholesalers, sales alliance partners and banks.

On-Site Audits of Suppliers

In the year ended March 2020, Astellas employees conducted on-site audits at 13 companies in eight countries and assessed the risk related to wastewater treatment plants, employees' working environments and efforts to protect employees from exposure to chemical substances. In cases where items were pointed out, Astellas indicated an improvement proposal, requested a plan for corrective measures be drawn up and is currently following up on progress of the improvements based on the corrective measures plan.



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Our People, Our Organization

Astellas recognizes employees as important stakeholders. Astellas employees play the most valuable role in transforming the Company and in achieving enhanced levels of enterprise value. We are working to train employees and strengthen their competitiveness.

Astellas is fostering a corporate culture that aims to align the aspirations of its diverse employees in one direction to realize its business philosophy.

- [HR Vision](#)
- [Providing Opportunities for Employees to Succeed Globally](#)
- [Diversity Management](#)
- [Promoting Health Management](#)
- [Respect for Human Rights](#)

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HR Vision

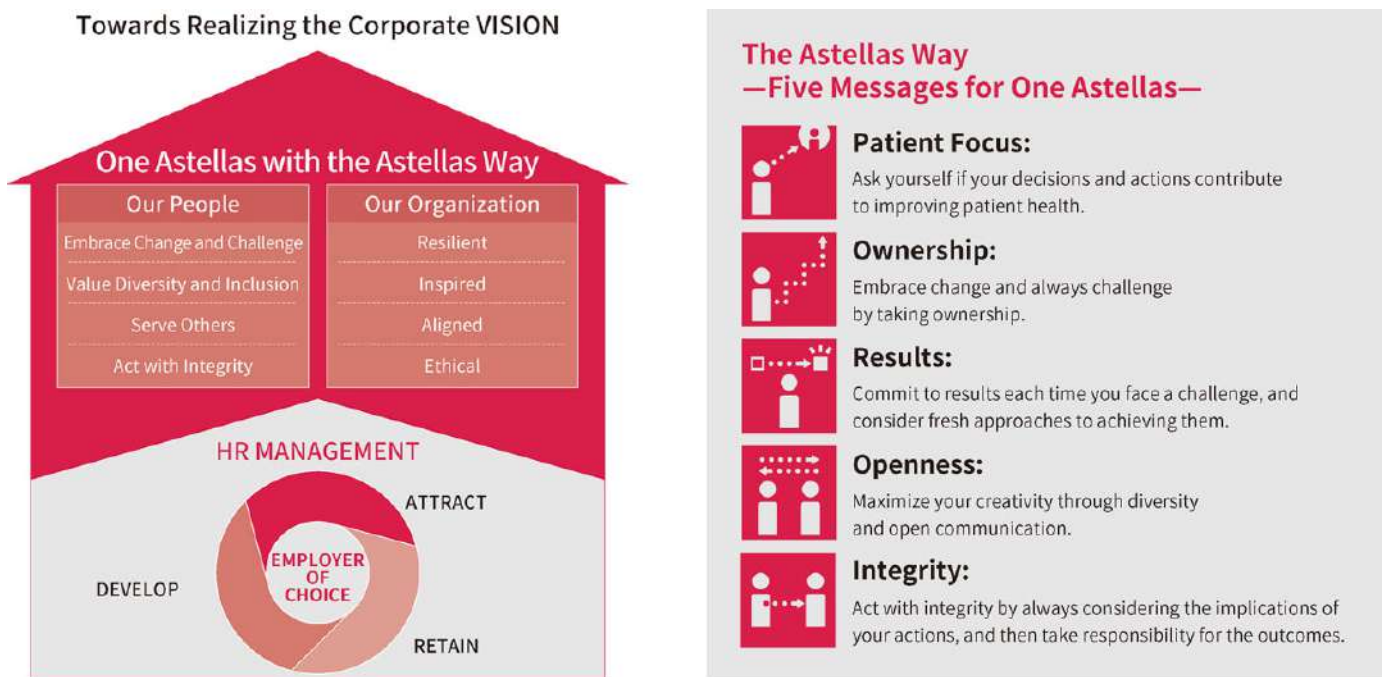
Astellas has formulated a Human Resources (HR) Vision, which represents its approach to “Our People, Our Organization,” and this vision is shared globally to define its aspirations for its human resources and its organization. To realize [Astellas’ VISION](#), employees should understand the HR Vision and act based on the Astellas Way.

As part of its activities to achieve these goals, Astellas is focusing on activities to disseminate the HR Vision. Specifically, this involved translating the HR Vision into various languages, conducting training and meetings for managers, and even reflecting the vision in talent development approach.

Moreover, as shown in the figure below, we have designed and implemented new HR system for the harmonization of many key HR processes that serve to attract, develop, and retain our talent at Astellas.

Astellas will increase the competitiveness of its human resources and organization by spreading and implementing the HR Vision and the Astellas Way. Moreover, Astellas will bring together individuals from diverse backgrounds within the Company to surmount national, regional and organizational barriers, foster mutual respect, and unite our people to continuously achieve innovation.

Overview of the HR Vision



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Providing Opportunities for Employees to Succeed Globally

Astellas provides employees with opportunities to succeed globally in variety of way. In particular, we have newly established a job-posting -system which is available for our employees worldwide since 2020. In Japan, we encourage our employees to succeed in roles at various overseas bases by proactively appointing employees from each division to be assigned abroad. Moreover, we accept long-term and short-term assignees from Group companies outside Japan. In these and other ways, we are working to promote global interaction among our employees at the divisional level.

In this way, having this foundational system for HR management in place helps to ensure we have the right person in the right position at the right time in a continuous and consistent way form global perspective.

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Diversity Management

Astellas is working to promote diversity so that diverse individuals can play a role, irrespective of race, nationality, gender, or age. Respecting the diverse values of our employees and reflecting their various perspectives in our business activities not only heightens creativity in our organization, but also helps to attract and retain talented people as employees and enhances our competitiveness.

Based on this recognition, Astellas implements measures led by its HR functions in each region to promote diversity in line with the current situation in the relevant region. For Astellas, promoting the career advancement of women in Japan is a high priority, particularly because the country has a low ratio of women in management positions compared to other regions, and the Company aims to develop a work environment and foster awareness among employees so that life events do not hinder career advancement.

The following engagements are unique efforts in Japan in promoting diversity.

In the year ended March 2019, Astellas acquired the Kurumin Certification as a company supporting employee child-raising from the Minister of Health, Labour and Welfare, based on the Act on Advancement of Measures to Support Raising Next-Generation Children. On top of this, Astellas has acquired the Platinum Kurumin Certification in October 2019 for our outstanding efforts. Moreover, Astellas has been selected by the Ministry of Economy, Trade and Industry and the Tokyo Stock Exchange as a Nadeshiko Brand company actively promoting women's success in the workplace.

Furthermore, we have been promoting nationality diversity for the globalization of Astellas. In Japan we have employed non-Japanese new graduates since 2014.

The Astellas workplace environment is also well equipped to accommodate employees with disabilities. Aside from establishing Green Supply Support Office*¹, in order for employees to thrive at work, Astellas employs the usage of speech-to-text applications to support employees with hearing impairments. Moreover Astellas has taken part in Accessibility Consortium of Enterprises (ACE)*².

*1 Green Supply Support Office: function established in one of Japanese affiliated companies to support employees with disability by offering employment opportunities. Duties including planting, recycling, and cleaning are tailored to promote environmental sustainability.

*2 Accessibility Consortium of Enterprises (ACE): Japanese general incorporated association for model innovation of employment services for persons with disabilities.

Employee Ratio per Region and Ratio of Female Managers (The year ended March 2020) *³

	Established Markets* ⁴	Greater China* ⁵	International Markets* ⁶	Japan	United States	Average
Male	44.9%	41.2%	39.7%	70.7%	45.1%	53.0%
Female	55.1%	58.8%	60.3%	29.3%	54.9%	47.0%

	Established Markets*4	Greater China*5	International Markets*6	Japan	United States	Average
Ratio of female managers	50.9%	56.3%	49.7%	10.2%	51.3%	40.0%

*3 Expatriate employees seconded within the Astellas corporate group are included in the headcount of their current location. Expatriate employees seconded out of the Astellas corporate group are excluded from the headcount.

*4 Established Markets: Europe, Canada, Australia

*5 Greater China: China, Hong Kong, Taiwan

*6 International Markets: Russia, Latin America, the Middle East, Africa, Southeast Asia, South Asia, Korea

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Promoting Health Management

We believe, if each of our employees performs at a high productivity, creativity and self-fulfillment level, our organization will revitalize and grow as One Astellas. To keep our employees in the aforesaid work style, we prioritize their good health and well-being. Based on this thinking, Astellas in Japan is proactively promoting health management to ensure employee health in workplace.

Specifically, in cooperation with the health insurance association (“collaboration health”), the Company is promoting employee health improvement and disease prevention, as well as work style reform, mental health and smoke-free working policies.

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Respect for Human Rights

[The Astellas Charter of Corporate Conduct](#) and [the Astellas Group Code of Conduct](#) clearly state that members of the Astellas Group shall respect human rights and the personality and individuality of all its employees, observe all applicable international rules and local regulations, and embrace all cultures and customs. The recognition of the importance of respecting human rights is shared by Group companies worldwide.

Astellas disclosed its [Position on Human Rights](#) in April 2017. Wherever we operate, Astellas is committed to complying with internationally recognized basic human rights and labor standards as well as applicable local labor and employment laws, and to implementing and upholding the UN Guiding Principles on Business and Human Rights. Also, Astellas conducted a human rights impact assessment and has identified four human rights issues to which we pay particular attention as human rights in clinical trials and other research and development activities, product safety and counterfeit drugs, Access to Health and human rights in the workplace. Moreover, under the U.K. Modern Slavery Act 2015, we publish a Slavery and Human Trafficking Statement for each fiscal year, describing what steps we have taken to address this risk in our own operations or our supply chains.

We have established a system for swiftly responding to human rights issues that includes the setting up of external and internal helplines, as well as conducting training sessions for employees. In June and July 2019 Astellas conducted Global Ethics & Compliance 2019 Employee Survey to better understand the Astellas culture and behaviors covering a speaking up culture which includes human rights and fair labor matters and identify potential areas for enhancements to operational excellence and potential compliance risks. In the year ended March 2020, there were no critical human rights issues or other issues of common, worldwide concern reported in the survey.

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Ethics & Compliance

Astellas believes that acting in accordance with the highest ethical standards, which includes following the letter and spirit of the law, is the cornerstone of all our activities.

Based on this belief, the Astellas Charter of Corporate Conduct, which is shared globally, expresses the Company's ethical business philosophy in terms of corporate behavior. In addition, the Astellas Group Code of Conduct is a global code for everyone who works for Astellas in any location around the world and in any capacity whatsoever as a director, officer, employee, temporary worker, or otherwise, whether full-time or part-time, establishing that they are expected to perform their duties ethically and in compliance with laws and regulations. Also, we seek to ensure that third parties acting on behalf of Astellas comply with all relevant standards described in the Code.

To demonstrate this commitment, Astellas employees are evaluated annually, in part, on ethical and compliant behavior.

Astellas promotes compliance and maintains the highest ethical standards through the development, implementation and continuous enhancement of its policies, processes, and global compliance structures and thereby maintains the trust of patients and other stakeholders and enhances enterprise value.

- [Structured to Promote Ethics and Compliance](#)
- [Initiatives to Promote Compliance](#)
- [Helpline for Employees and Encouraging a Speak-Up Culture](#)
- [Astellas Anti-Bribery and Anti-Corruption Program](#)
- [Data Privacy](#)
- [Ensuring Fair Competition](#)

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Structured to Promote Ethics and Compliance

Astellas has been continuously enhancing the organizational structure for the Ethics & Compliance function. The global Ethics & Compliance operating model allows Astellas to continue to advance and apply a more consistent global standard while still being respectful of local cultural and legal differences.

The Compliance Excellence and Transformation team in the Ethics & Compliance function continues to drive consistency on a global basis for activities that are core to the Ethics & Compliance program, such as training, communications, risk assessments, monitoring, compliance policies/processes, transparency with respect to pharmaceutical company relationships with healthcare professionals and healthcare organizations, and investigation processes.

Our Ethics & Compliance professionals continue to partner with the business to reinforce the importance of integrating integrity, ethics and compliance into business processes as doing so is critical to the sustainable success of Astellas.

Global Compliance Structure (As of October , 2019)



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Initiatives to Promote Compliance

Compliance Training and Communications

Compliance training and communications targeted at the business are important to conducting business activities grounded on high ethical standards and integrity. Astellas regularly educates employees on both existing and emerging compliance risks as well as policies and processes that help us manage those risks.

The Ethics & Compliance function deploys multiple online and live training programs to continue to foster compliance awareness and understanding among employees. All employees, including new employees, are required to complete compliance training on topics such as the Astellas Group Code of Conduct, data privacy, anti-bribery and anti-corruption compliance, and conflicts of interest. In addition, global Ethics & Compliance training programs include a survey to determine training effectiveness. The results of these surveys assist Astellas in ensuring training programs are meeting the needs of employees and in turn, update the training to make it even more effective.

Astellas' Integrity in Action program reinforces the importance of taking responsibility, acting ethically and leading by example. As part of Astellas' ongoing commitment to this program, our training and communication materials continue to embed the Astellas Way values and a patient-focused mindset, so employees can see how policies and procedures help them live the Astellas mission.



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Continually Enhancing and Sustaining an Ethical and Compliant Culture at Astellas

Astellas leaders and managers are critical to the effective promotion and protection of the Astellas core values of integrity, ethics and compliance within their teams. Ethics & Compliance works closely with the business to engage in various initiatives designed to continually enhance and sustain an ethical and compliant culture at Astellas. This includes an ethical decision-making initiative with leader and manager workshops dedicated to providing insight into key ethical concepts that impact decision-making and the practical tools leaders and managers can use, as well as help their teams use, to support ethical decision-making.



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Compliance Risk Assessments

The ability to effectively assess compliance risk at local, regional and global levels is a foundational element of Astellas' compliance program. These assessments enable Astellas to more quickly identify and better respond to existing and emerging compliance risks.

The internal activities assessed in compliance risk assessments ("CRAs") continue to include transfers of value in any form to healthcare professionals, market access activities, interactions between the Company and government officials or healthcare professionals, and meals, gifts, or hospitality.

Astellas continues to conduct CRAs based on a globally consistent process, in a number of countries around the globe. The CRAs involve both the assessment of external environmental risk in each of the countries as well as assessment of internal risks within the affiliate arising from business operations. The results are discussed with the local management team to develop a Risk Mitigation Plan, which is then tracked until closure. The findings of the CRAs continue to help Astellas enhance compliance programs in each country and monitor trends in risks at the regional and global levels. The Ethics & Compliance function works closely with the business throughout the assessment process and helps develop and support any risk mitigation plans developed to address the identified risks.



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Compliance Monitoring

Compliance monitoring is a key component of any compliance program. Astellas monitors existing and emerging compliance risks and trends across a variety of activities. Doing so allows us to better anticipate potential issues before they become actual problems for the Company.

Astellas continues to enhance its monitoring program and activities in each region. Compliance monitoring yields results that not only informs our compliance program, but also provides management with insights to inform their decision-making on various process improvements. We continuously evaluate and improve our monitoring program to ensure that we provide the best tools for monitoring and the most useful information to our stakeholders.



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Conflicts of Interest

Another core element of an effective ethics and compliance program is how a company approaches its own conflicts of interest. That is because the foundation of an effective and robust ethics and compliance program is based on how a company manages its own internal behavior.

Conflicts of interest refer to situations where outside activities or other personal interests impair an employee's objectivity or judgment when performing their duties. Conflicts of interest also encompass situations where there is a potential conflict between the interests of an employee and Astellas. The Astellas Global Conflict of Interest Policy and accompanying training reinforces for our employees that they are expected to conduct their business activities with ethics and integrity even when no one is observing or there are no potential legal violations. Astellas believes that maintaining this baseline expectation regarding internal conflicts of interest contributes to our employees conducting their business with ethics and integrity when engaging with stakeholders outside the Company and where legal risks are involved. Engagement in the disclosure process and global training efforts continue to enhance the ability of internal stakeholders to identify potential conflicts, resulting in increased business ownership of compliance.



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Transparency

Astellas believes that the medical and scientific exchange between manufacturers and health care providers is essential to our provision of highly effective pharmaceuticals and contributes to improving the health of patients around the world. Advancing the field of science is rooted in supporting high-quality, independent medical education and global initiatives designed to improve the quality of medical care. To achieve this Astellas requires input and expertise from those such as healthcare professionals, patient organizations, academics, and healthcare organizations to drive medical innovation, focus on unmet needs, and educate providers and patients on therapeutic treatments.

An increasing number of countries and government organizations require transparency with respect to pharmaceutical company relationships with healthcare professionals, healthcare organizations and patient organizations. Astellas engages in appropriate relationships with healthcare professionals and organizations throughout the world. The disclosure of relevant financial relationships with healthcare professionals and organizations reflects our commitment to corporate accountability to both internal and external stakeholders. Astellas is committed to fulfilling its transparency requirements through the work of its global transparency team in coordination and collaboration with multiple business functions throughout the organization and across the globe.



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Helpline for Employees and Encouraging a Speak-Up Culture

Astellas continues to have helplines available globally so employees can report and receive advice on how to react in the event they discover actual or suspected misconduct. Reports may be made by employees or third parties and may be made anonymously where permitted by local law.



Astellas continues to foster an environment that encourages employees to use the helplines and speak up to report potential or actual violations of the Astellas Group Code of Conduct, as well as any other illegal or unethical behavior or business practices. In addition, Astellas strictly prohibits retaliation against anyone who raises a concern or reports a suspected compliance violation in good faith even if the concern or report is not substantiated after investigation. Astellas regularly reinforces the importance of speaking up and the responsibility that employees have in reporting concerns through Astellas' global Speak Up campaign which includes posters, communications, and

presentations supported by a visual theme.

Having the ability to centrally manage the reports of suspected non-compliance and the corresponding investigations also enhances Astellas' ability to analyze compliance trends globally. Compliance helpline statistics are analyzed and reported to the Regional and Global Compliance Committees on a regular basis.

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Astellas Anti-Bribery and Anti-Corruption Program

Astellas takes a strong stance against corruption. Astellas strictly prohibits bribery and corruption in any aspect of its business and is committed to complying with all applicable laws, including anti-corruption laws, consistent with its commitment to conducting its business with ethics and integrity.

This is a core commitment of Astellas embodied in the Astellas Group Code of Conduct and the Astellas Group Policy on Anti-Bribery and Anti-Corruption Compliance. In addition, Astellas is a signatory to the United Nations Global Compact, including its 10th Principle Against Corruption, and the Tokyo Principles for Strengthening Anti-Corruption Practices.

Astellas' Chief Ethics & Compliance Officer has overall responsibility for overseeing and implementing Astellas' global compliance program, including its anti-bribery and anti-corruption (ABAC) program, with the assistance of the Global Compliance Committee. The Chief Ethics & Compliance Officer, in turn, has designated Ethics and Compliance professionals with global and regional responsibilities for Astellas' ABAC program.

Astellas' ABAC program is designed to provide reasonable assurance of compliance with Astellas' commitment against corruption. The program consists of ABAC policies and procedures, trainings and communications, risk assessments, monitoring and auditing, reporting and investigation activities.

Astellas has ABAC policies and procedures that embody its commitment against corruption. These policies and procedures are consistent with the U.S. Foreign Corrupt Practices Act, the UK Bribery Act, and other applicable local anti-bribery and corruption laws and regulation. Astellas prohibits all forms of bribery and corruption, including facilitation payments.

Astellas requires all employees to complete annual ABAC training. This training is available in 22 languages. Astellas additionally provides specialized ABAC training to target audiences based on their functions or roles in the company, as well as where we have identified risks and needs.

As described above, Astellas conducts compliance risk assessments and compliance monitoring, including on aspects of its ABAC compliance program. Astellas Ethics & Compliance also works closely with the Astellas Legal Department to investigate potential incidents of ABAC non-compliance and with the Astellas Internal Audit Department on the audit of Astellas affiliates and third parties covering activities that may involve ABAC risks. Astellas continuously seeks to improve its ABAC program based on these activities to assure the program remains effective and up-to-date in addressing changing risk.

Astellas has established an internal control environment designed to comply with J-SOX regulatory requirements to ensure financial reporting integrity as well as fraud prevention and detection. Its financial controls provide complementary assurance of compliance with its anti-corruption commitment.

A core principle of our ABAC compliance program is to prohibit third parties from engaging in activities that we prohibit for our own employees. This principle is embodied in the Astellas Group Policy on Anti-Bribery and Anti-Corruption Compliance and the Astellas Business Partner Code of Conduct. To adhere to this principle and mitigate and manage the risk arising from third parties providing services on our behalf, Astellas has established a process to conduct bribery and corruption compliance due diligence assessments on third parties interacting with healthcare professionals or

government officials on our behalf. In addition, Astellas periodically exercises audit rights over third parties, and has risk-based ABAC clauses for contractual arrangements with third parties.

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Data Privacy

Astellas is committed to conducting its business throughout the world in accordance with applicable laws and high ethical standards. That commitment extends to how we obtain and use personal information that is essential for our business.

Healthcare professionals, patients, suppliers and employees share their personal information with Astellas, and entrust us to keep that information safe, use it appropriately and handle it with care. To ensure we always handle personal information in a compliant and appropriate way, Astellas has incorporated key privacy principles into its policies and practices.

Specifically, personal information must be

- (1) processed lawfully, fairly, and transparently;
- (2) collected for specific, legitimate, and explicit purposes;
- (3) adequate, relevant, and limited to what is necessary;
- (4) accurate, and where possible, kept up to date;
- (5) retained only for as long as necessary; and
- (6) kept secure and protected against loss or inappropriate access or disclosure.

We have a robust Privacy Program in place which incorporates key systems & controls to ensure we meet our regulatory privacy obligations globally.

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Ensuring Fair Competition

Astellas is committed to conducting its business in a fair and competitive environment and does not reach any agreements with its competitors regarding sales conditions, such as prices, sales plans and strategies, and market and customer shares. We limit our engagement with competitors and avoid any conversation concerning these topics when engagement is necessary, so that such interactions are not construed to reflect the existence of such an agreement.

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Access to Health

Position on Access to Health

Astellas regards the situation where there still remains barriers for many people who have difficulty accessing the healthcare they need due to the lack of available treatments, poverty, healthcare system challenges and insufficient healthcare information. Astellas recognizes this problem as the Access to Health issue. To improve Access to Health, Astellas has identified four areas where we can leverage our strengths and technologies, and is working to solve issues, making full use of external partnerships. These areas are “creating innovation,” “enhancing availability,” “strengthening healthcare system” and “improving health literacy.”

We believe that undertaking initiatives for the improvement of Access to Health will contribute to the enhancement of the sustainability of society while the relationships of trust with external partners and various local governments cultivated through activities will also lead to the enhancement of the sustainability of Astellas at the same time.

For further information on Position on Access to Health, please visit [here](#).

Annual Report 2020

Research Activities on Tuberculosis and Malaria

Collaborative Research on New Drugs for the Treatment of Tuberculosis and Malaria

Astellas is pursuing collaborative research to discover new drugs for the treatment of tuberculosis and malaria, which are infectious diseases that cause tremendous suffering among people in developing countries.

In 2018 10 million incidences of tuberculosis were observed with 1.5 million* deaths, and more than 200 million incidences of malaria were observed with 405,000 deaths. Both tuberculosis and malaria have led to serious social problems, underscoring the urgent need for innovative drugs to treat these diseases.

Considering these backgrounds, in October 2017, Astellas entered into a new collaborative research agreement with TB Alliance for the exploration of new drugs for the treatment of tuberculosis and a screening collaboration agreement with Medicines for Malaria Venture (MMV) to discover new drugs for malaria.

Under these agreements, Astellas provides its original library of compounds, while TB Alliance and MMV conduct screenings of the library to discover hit compounds to be used in the research and development of new tuberculosis and malaria drugs, respectively.

These research programs are funded by the Global Health Innovative Technology Fund (“GHIT Fund”).

*Figure includes 0.25 million people infected with HIV.

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Research Activities on NTDs

Participation in the Neglected Tropical Diseases Drug Discovery Booster

In March 2018, Astellas participated in the Neglected Tropical Diseases Drug Discovery Booster^{*1}, a consortium whose purpose is to identify lead compounds^{*2} for leishmaniasis and Chagas disease, both of which are neglected tropical diseases (NTDs). The consortium is supported by funding from the Global Health Innovative Technology Fund (“GHIT Fund”).

NTDs are mainly parasitic, bacterial, viral or fungal infections prevalent among people living in poverty in developing nations in tropical and subtropical regions. At least 1 billion people worldwide are reported to be infected with the 20 NTDs listed by the World Health Organization (WHO), many of which cause serious social difficulties.

Through the consortium, Astellas will contribute to the discovery of new drugs for patients suffering from leishmaniasis and Chagas disease.

^{*1} Neglected Tropical Diseases Drug Discovery Booster: A consortium launched by the Drugs for Neglected Diseases *initiative* (DNDI), a not-for-profit organization engaged in the development of new treatments for neglected diseases. In addition to Astellas, seven pharmaceutical companies, specifically Eisai Co., Ltd., Shionogi & Co., Ltd., Takeda Pharmaceutical Company Limited, AstraZeneca plc., Celgene Corporation, Merck KGaA, and AbbVie, also participate in the consortium as partners.

^{*2} Lead compound: A compound with confirmed pharmacological activity against a target disease. Optimization research (for improvement of activity, physical properties, pharmacokinetics, toxicity, etc.) is conducted based on lead compounds.

Advisory to the collaborative research for discovery of new drugs against Chagas disease

From October 2018 until March 2020, Astellas was engaged as an advisor to the collaborative research project, “Exploratory research aiming to determine target molecules for discovery of new drugs against Chagas disease.” The project has been conducted by Institute of Tropical Medicine, Nagasaki University (NEKKEN) together with the National Institute of Advanced Industrial Science and Technology (AIST), High Energy Accelerator Research Organization (KEK), and London School of Hygiene and Tropical Medicine (LSHTM).

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Development of Pediatric Formulation for Schistosomiasis



Schistosomiasis is one of the most prevalent parasitic diseases in developing countries, notably in Africa and South America. The economic and health impacts of schistosomiasis are considerable. If it is left untreated, schistosomiasis causes anaemia, stunted growth, reduced ability to learn, and chronic inflammation of the organs, which can be fatal^{*1}. The disease has a particularly high incidence among children.

The existing “standard of care” treatment for schistosomiasis is praziquantel. However, at present, the group of infected preschool-age children, including infants and toddlers, is left untreated in public health programs due to lack of relevant clinical data and a missing appropriate child-friendly formulation of the drug. Young children cannot swallow the existing tablet because of its large size and bitter taste.

Within a consortium of partners, involving pharmaceutical companies, research institutions and international non-profit organizations, Astellas has developed a pediatric formulation of praziquantel.

The pediatric formulation newly developed by Astellas uses proprietary drug formulation technology to create a smaller, orally dispersible tablet of reduced bitterness that can be taken with or without water. The pediatric formulation has also been designed for manufacturing at reduced cost using simple production technology, yielding tablets that are stable even in hot and humid tropical climates. To facilitate production of materials for clinical trials and help build local pharmaceutical manufacturing capabilities for future supplies, Astellas has transferred to consortium partners in Germany and Brazil the technology and expertise needed to develop the pediatric formulations and produce the tablets.

After successful completion of the Phase II clinical study, the consortium program is currently running the pivotal Phase III clinical trials in Kenya and Ivory Coast to gain data for registration and facilitate access to a novel orally dispersible tablet formulation for young children (below six years of age). Astellas is committed to providing the consortium with all necessary technical expertise. As a member of the consortium, Astellas is working with the partners aiming to have the product available for launch in the first endemic country in Africa in a few years.

For more information on the Consortium program and the partners, please visit:

<https://www.pediatricpraziquantelconsortium.org/>

*1 <https://www.who.int/en/news-room/fact-sheets/detail/schistosomiasis>

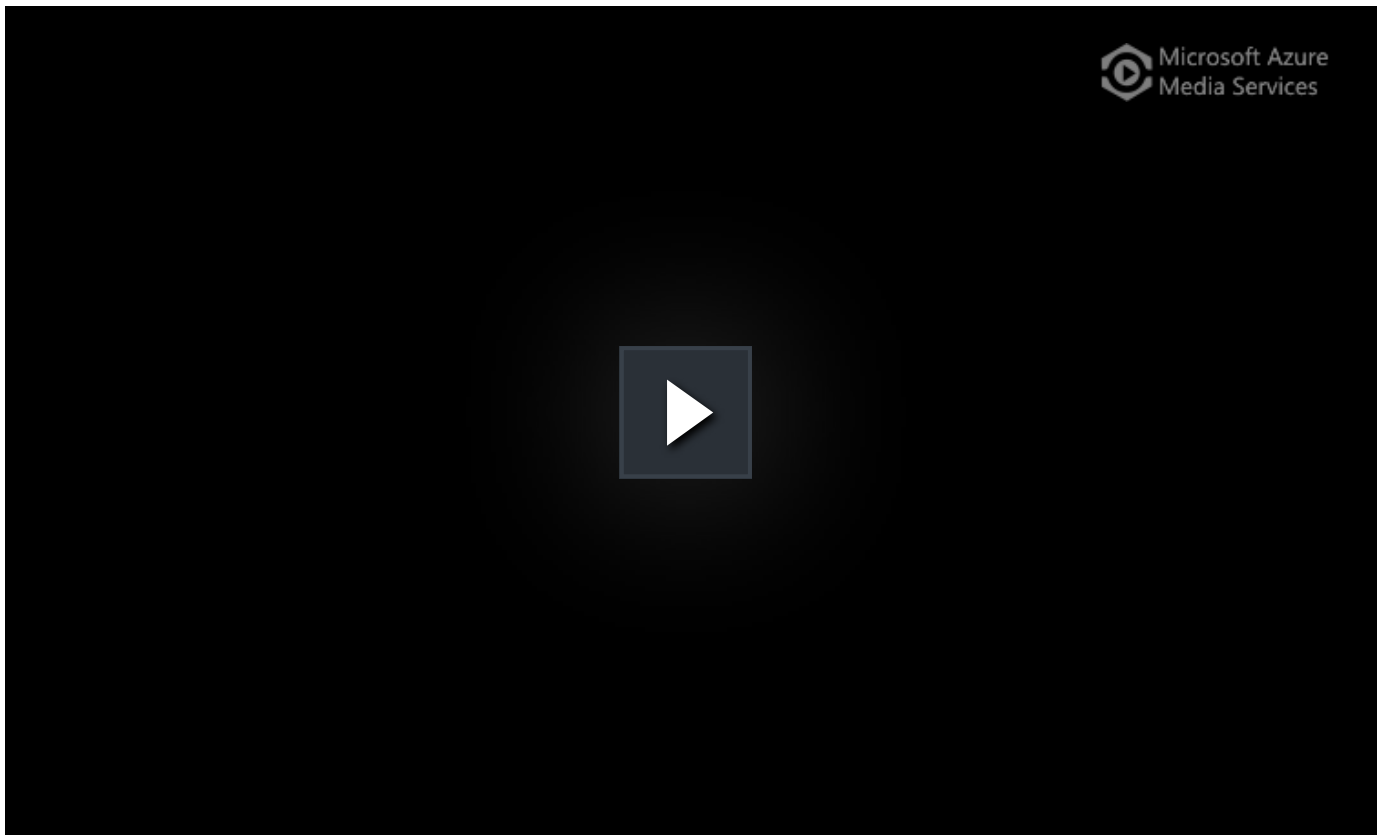
*Consortium activities are currently supported by grants from the Global Health Innovative Technology (GHIT) Fund and the European and Developing Countries Clinical Trials Partnership (EDCTP).



Newly developed pediatric formulation (top) and existing tablet (bottom)



Pediatric Praziquantel Consortium partners and project contributors
©Lygature



*This movie was created by GHIT Fund on July 2019.

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Access Accelerated



Access Accelerated^{*1} is a global initiative aimed at improving access to non-communicable diseases (NCDs) prevention, diagnosis and treatment in low- and middle-income countries. More than 20 international pharmaceutical companies are partners in the program, working alongside organizations such as the World Bank, City Cancer Challenge Foundation, PATH, NCD Alliance and World Heart Federation. Astellas has participated in Access Accelerated since January 2017, which is when it was launched.

NCDs are any diseases not caused by human-to-human transmission of an infectious agent. Leading NCDs include cancer, cardiovascular disease, chronic respiratory disease and diabetes. Many NCDs are caused by unhealthy eating, lack of exercise, smoking or excessive drinking, and could be prevented by lifestyle improvement. NCDs are not just on the increase in developed countries, but the number of patients suffering from NCDs is also increasing in developing countries. The rising incidence of NCDs not only puts pressure on the healthcare budgets of developing countries, but also leads to economic losses when patients cannot work due to illness.

*1 For details about Access Accelerated, please visit the following website:

- [Access Accelerated Website](#)

 [Link to Press Release released by Access Accelerated \(pdf 428KB\)](#)

Our Commitment



*This information describes Astellas' support for the initiative as of January 18, 2017.

 [Link to Press Release released by Astellas \(pdf 292KB\)](#)

Astellas' activities for Access Accelerated

Under Access Accelerated, Astellas supports ACTION ON FISTULA™^{*2}. Since this program began in 2014, 11 doctors who can perform surgery for obstetric fistula were trained, the fistula treatment network was established, and a system that provides routine surgery at multiple cooperating hospitals was prepared. As a result of this program, a total of over 6,200 obstetric fistula patients received surgery and their quality of life was improved. Furthermore, 22 support groups were established that take care of patients' mental well-being, provide economic support and employment support so that patients who have received treatment can reintegrate into society.

Additionally, in the field of oncology, Astellas launched a new initiative in India structured according to patients' income levels, with the aim of improving their access to its anticancer products since 2017. Moreover, Astellas supported City Cancer Challenge initiative at Cali city, Colombia. Astellas will continue to push ahead with activities that improve patients' access to the prevention, diagnosis, and treatment of NCDs in low- and middle-income countries.

^{*2} ACTION ON FISTULA™: A program launched by the Fistula Foundation. Astellas Pharma Europe Ltd., which is a European subsidiary of Astellas, provided funds for the Fistula Foundation, aiming to treat a total of over 4,500 patients by 2020.

^{*3} At the end of the program, a total of 6,223 patients accessed fistula treatment.

Achievements of Access Accelerated

Access Accelerated annual reports introduce achievements of Access Accelerated. Since its launch on January 18, 2017, over 100 programs have carried out newly or continued by participated companies. ACTION ON FISTULA™, a program to transform the lives of obstetric fistula patients in Kenya, is also introduced in this report.

Through participation in Access Accelerated, Astellas is working to achieve the United Nations Sustainable Development Goal to reduce premature deaths from NCDs by one-third by 2030, in collaboration with various partners.

- [Access Accelerated Year One Report](#)
- [Access Accelerated Year Two Report](#)
- [Access Accelerated Year 3 Report](#)

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ACTION ON FISTULA™

ACTION ON FISTULA™ was conceived, built and is run by the Fistula Foundation. The six-year programme started in 2014 by a grant given to the Fistula Foundation from an affiliate of Astellas, Astellas Pharma Europe Ltd. By 2020, the programme aimed to help 4,500 patients to access fistula treatment. In total, since 2014, 6,223^{*1} surgeries have been carried out at 7 hospitals, transforming the lives of women in Kenya who are suffering with obstetric fistula^{*2}.

Through continued efforts contributing towards ending obstetric fistula, Fistula Foundation's ACTION ON FISTULA carried out interventions in Kenya via the organisation's outreach and treatment partners. From inception to at the end of the programme, 11 surgeons have been trained at Gynocare Women's and Fistula Hospital, expanding to include surgeons beyond Kenya to build capacity across sub-Saharan Africa and Southeast Asia. A total of 19 nurses have also been trained at this facility.

In April 2019, the number of programme outreach partners increased to five. These community outreach teams are critical to the success of the programme and, to date, almost 2 million community members were reached with fistula messages through outreach activities. This Community Mobilisation Programme trains Community Health Volunteers, sensitises local and traditional leaders, and utilises radio and media programmes to raise awareness of fistula and help identify and refer women with fistula for treatment.

In addition, ACTION ON FISTULA helped fistula patients who have undergone treatment with psychological support, and economic empowerment opportunities so that they can return to their communities. To this end, the programme established 22 support groups to reach and assist survivors.

*1 At the end of the programme

*2 An obstetric fistula is a hole between the vagina and rectum or bladder that is caused by prolonged obstructed labour when emergency care is unavailable, causing faecal and/or urinary incontinence. Although it has been virtually eradicated in developed countries, the UNFPA estimates 3,000 new cases of obstetric fistula occur annually in Kenya. Women with obstetric fistula are often subject to severe social stigma due to odour, which is constant and humiliating, often driving the patients' family, friends and neighbours away. Stigmatised, these women are also often denied access to education and employment and live in isolation and poverty.



A fistula survivor participating in Beyond Fistula, a skills-building and empowerment programme offered to patients waiting for or recovering from surgery at the Gynocare Women’s & Fistula Hospital in Eldoret, Kenya. Photography: ©Georgina Goodwin



A patient listening to an advocate who is addressing patients at the Gynocare Women’s and Fistula Hospital in Kenya.

Progress in ACTION ON FISTULA™ (May 2014 – at the end of the programme)

Patients successfully treated with reconstructive surgery	6,223 surgeries
Surgeons trained at Gynocare Women’s and Fistula Hospital (expanding to include surgeons beyond Kenya to build capacity across sub-Saharan Africa and Southeast Asia)	11 surgeons
Hospitals in the Fistula Treatment Network (new)	7 hospitals
FIGO ^{*1} -accredited fistula training center	Established Gynocare Women’s and Fistula Hospital in Eldoret, Kenya
Kenyan counties ^{*2} reached	47 counties
Trained community outreach workers	424 outreach workers
Conducted outreach activities	20,050 activities
Community members reached with fistula messages	1,964,452 community members

*1 FIGO: International Federation of Gynecology and Obstetrics

*2 47 counties have been established in Kenya, which are in charge of local governments. Under counties, the following divisions have been established: sub-counties, wards and villages.

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Social Contribution

Policy on Social Contribution

Astellas' raison d'être is to contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Our company Charter of Corporate Conduct further states that as good corporate citizens, we shall actively engage in charitable and other activities that benefit society. Astellas believes that we need to enhance our sustainability through earning trust from society for both Astellas and our products.

Astellas aims to conduct all of our activities strategically to ensure they create sustainable, long-term benefit for our patients and communities around the world. Astellas will utilize our resources (e.g., people, skills, expertise) to implement our social contributions effectively. Astellas will partner with industry associations, charitable organizations and other stakeholders to contribute to addressing healthcare-related challenges that cannot be solved by a single entity. Astellas evaluates and measures the impact of our social contribution activities based on well-accepted, identifiable metrics and will modify and adjust future goals where appropriate. Astellas will report on our activities in an appropriate manner to our stakeholders.

Based on the relevance to Astellas' core business and societal expectation of Astellas, we will focus our resources for social contribution in three areas listed below in order of priority.

- 1st priority: Addressing [Access to Health issues](#)
- 2nd priority: Advancement of Medical Sciences
- 3rd priority: Philanthropy/Community Development

For further information on Policy on Social Contribution, please visit [here](#).

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AECEP Overseas Volunteer Program

Astellas has run a social contribution program called the Astellas Emerging Countries Empowerment Program (AECEP) since fiscal 2016.

The AECEP is a program that allows Astellas employees to utilize individual specialist expertise, skills and experience to help address societal issues in emerging countries in partnership with local enterprises and non-governmental organizations (NGO). After completing a 1.5-month preparation period, employees volunteering as AECEP participants are assigned for a limited period of 3.5 months to work at a partner enterprise or NGO engaged in projects to develop solutions benefiting society in the recipient country.

Partners are selected from among local enterprises and NGOs involved in addressing medical, health and safety issues or environmental problems. Gaining a valuable learning experience through the cooperation of committed leaders and community members when addressing local social issues, participants can also contribute to building and improving partners' systems by leveraging their personal experience and abilities to help maximize the effectiveness of their activities. The reciprocal and equal nature of this relationship is the key characteristic of the AECEP in terms of contributing to society.

In the year ended March 2020, the fourth year of the program, two employees were selected as participants. One was assigned to an organization in Cambodia that is involved in planning and holding medical-related events to disseminate proper medical knowledge to patients through doctors and nurses. By understanding a different culture and working out methods to communicate, the participant increased teamwork with the local co-workers and worked with them to hold business seminars for the doctors or medical staffs as well as medical check-up events for citizens. Consequently, the medical knowledge of audiences was enhanced and the expansion of the range of the organization's activities was achieved.

The other participant was assigned to an organization in India that is working on a comprehensive approach for healthcare and public health for the impoverished and the socially vulnerable. The participant contributed by creating a self-medication manual for issues related to the prevention of diseases that have been revealed from patients' examination environment field surveys. The participant delivered results while running into the large wall that is differences between the participant and colleagues who have gathered from various countries regarding how to proceed with work and the sense of values, and received warm words of gratitude from members of his assigned organization.

The invaluable experiences that can be obtained through AECEP—getting away from daily work and pursuing one's own potential in an emerging country while newly creating value for society—also have major significance for Astellas from the standpoint of human resource development.

"Embrace Change and Challenge" is included in the "Our People" section of our HR Vision, and Astellas will also continue promoting AECEP for this reason: to help develop human resources with a long-term, strategic thinking ability who are truly capable of taking on challenges with a sense of ownership. Astellas will work to solve social issues faced by people around the world while working together with various stakeholders.



Astellas employee involved in the operation of events aiming to spread team members and doctors in Cambodia (center)



Astellas employee working on healthcare issues for the impoverished with staff members from the organization in India (second from the left in the back row)

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Support for Patients

Astellas conducts a variety of activities to provide assistance to patients fighting illnesses, and to their family members, on a global basis.

Astellas supports the self-reliance and independent development of patient associations in Japan as “Starlight Partners Activities.” As one aspect of that, Astellas provided approximately 6 million yen in activity funding to 32 organizations through a public application process in the year ended March 2020. Peer Support Training Session activities are held for a wide range of participants, including patients and their families. In these training sessions, activities include programs for participants to learn attentive listening skills, which enable peers who have faced the same issues or have experienced the same problems to serve as consulting partners to one another. In the year ended March 2020, a training session was held in Tokyo (headquarters) and 22 people from 14 organizations attended. Astellas also sent instructors to 5 organizations for Peer Support Training Sessions organized by patient associations where a total of 150 people attended. In addition, Astellas donated stationery to another 36 events organized by patient associations.

Over the last five years, Astellas in the United States has encouraged field-based employees to volunteer at local Ronald McDonald House Charities (RMHC) Chapters, helping the organizations provide comfort and care to millions of families with ill or injured family members who have to travel far from home for the care they need. Employees are responsible for scheduling events, recruiting team members to participate, purchasing supplies and working with teams to prepare and serve meals. In the year ended March 2020, nearly 100 Astellas employees prepared and served 400 meals to patients’ families at Ronald McDonald House events across the U.S. to comfort families caring for a sick child.

Additionally, Astellas’ Military Employee Impact Group has been working with the Fisher House Foundation over the last several years as part of their commitment to the community. A Fisher House is “a home away from home” for family members, caregivers or loved ones of patients receiving medical care at major military and VA medical centers. It is a temporary residence and is not a treatment facility, hospice or counseling center. As part of Changing Tomorrow Day and Martin Luther King Junior events in the United States, employees spent time at local Fisher Houses, serving meals, cleaning and organizing. In 2019, more than 175 employees have served meals to families at Fisher House locations across the United States.

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Astellas Foundations

Astellas Foundation for Research on Metabolic Disorders

Astellas Foundation for Research on Metabolic Disorders, established in 1969, contributes to public health, medical progress, and development of therapeutic drugs.

The Foundation contributes to medical and life sciences through the awarding of grants for the research initiatives which will open up the next generation, as well as the discovery and nurturing of brilliant young talent and support for researchers by providing training and an opportunity to study abroad. Astellas supports their activities.

To learn more about Astellas Foundation for Research on Metabolic Disorders, please visit

<https://astellas-swift.secure.force.com/byoutai/>

Astellas Global Health Foundation

The Astellas Global Health Foundation is a tax-exempt, non-profit corporation that awards grants to support charitable purposes with a focus on improving access to health in underserved global communities in order to make a sustainable impact on the health of people around the world.

Key areas of focus for the Astellas Global Health Foundation are neglected tropical and communicable diseases, children's health and mental health in low-income communities and low-and middle-income countries where Astellas does not have a commercial presence.

Additionally, the Astellas Global Health Foundation funds programs that build healthier communities and provide disaster preparedness and relief in these same geographies.

In 2019, the Astellas Global Health Foundation awarded four grants across its areas of focus including a grant in the amount of \$750,000 to the END Fund, a philanthropic organization combating the five most common neglected tropical diseases (NTDs) worldwide. Additionally, the Astellas Global Health Foundation announced a grant providing \$1.35 million over three years to the Academic Model Providing Access to Healthcare (AMPATH), a partnership of Kenyan and North American academic health centers, under the direction of the Indiana University Center for Global Health, to support increased access to mental health initiatives for people in need in western Kenya. The Astellas Global Health Foundation provided nearly \$700,000 over two years to UNICEF USA to support its Mothers and Babies in Good Care initiative in the Dominican Republic. Finally, the Astellas Global Health Foundation provided a \$600,000 community resilience/disaster support grant to Americares in support of the Americares Rural El Salvador Health and Resiliency Initiative project, a community resilience effort focused on strengthening resilience for underserved Salvadorans through clinical, community health and disaster preparedness support.

In April 2020, the Astellas Global Health Foundation opened a request for proposal process, soliciting invited organizations to apply for funding to aid in the fight against COVID-19. More information about the grants awarded is

available on the Astellas Global Health Foundation website.

To learn more about the Astellas Global Health Foundation please visit

www.astellasglobalhealthfoundation.org.

*Astellas Foundation for Research on Metabolic Disorders and the Astellas Global Health Foundation are independent organizations from Astellas.

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Group-Wide Volunteer Activities for Changing Tomorrow Day

Astellas encourages group employees around the world to conduct a diverse range of volunteer activities as part of Changing Tomorrow Day based on the themes of promoting healthcare and maintaining the environment, thereby contributing to their local communities. In the year ended March 2020, more than 4,800 employees participated.

Changing Tomorrow Day Held in the year ended March 2020

Region	Participants	Volunteering hours	Number of locations	Number of countries
Established Markets*1	411	2,212	24	12
Greater China*2	144	675	3	3
International Markets*3	350	1,894	20	10
Japan	1,615	1,941	83	1
United States	2,355	8,689	29	3
Total	4,875	15,411	159	29

*1 Established Markets: Europe, Canada, Australia.

*2 Greater China: China, Hong Kong, Taiwan.

*3 International Markets: Russia, Latin America, the Middle East, Africa, Southeast Asia, South Asia, Korea.

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EHS ; Environment, Health & Safety

In Search of EHS EXCELLENCE

Astellas has embraced the sustainable enhancement of enterprise value as its corporate mission. To fulfill this mission, Astellas seeks to be a chosen and trusted enterprise by all stakeholders, including customers, shareholders, employees, and the global community. The Astellas Charter of Corporate Conduct contains the following principles on Environment, Health and Safety (EHS): "We shall respect employees' human rights, individuality, and differences; promote diversity in the workplace; and provide a safe and rewarding work environment" and "Recognizing that harmony between the global environment and our business activities is a prerequisite to our corporate existence, we shall take proactive measures to conserve the global environment." These principles require employees to conduct themselves based on high ethical standards in EHS fields, among other areas.

EHS Management

Astellas' basic stance toward the environment as well as the health and safety of its employees is outlined in the Astellas EHS Policy. Moreover, Astellas is working organizationally and continuously toward achieving this stance as described in the Astellas EHS Guidelines. In addition, Astellas has set medium-term targets for the key priorities in its EHS Action Plan and is working to achieve those targets.

Environment

Astellas has set specific numerical targets related to climate change, water resources, waste disposal management and biodiversity as its environmental action plan, and implements initiatives continuously to achieve these.

Please refer to [the Environment section](#) on the corporate website for details. (The parts of performance indicators have been assured independently by third party.)

Occupational Health & Safety

Astellas is working to reduce the severity rate of work-related injuries and carry out the risk assessments as part of its occupational health and safety action plan, and implements initiatives continuously to minimize work injuries through prevention of accidents and ensuring maintenance of safe work environments.

Please refer [to the Occupational Health & Safety section](#) on the corporate website for details. (The parts of performance indicators have been assured independently by third party.)

EHS Report

Please refer to [the EHS Reports](#) (Printer-friendly version) about Astellas' EHS activities.

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Financial Information



Financial Summary

Review Astellas' consolidated business results, forecasts and financial data, etc

[Read More](#)

Business Results

Financial results, announcement materials and other supplemental documents

[Read More](#)

Consolidated Financial Statements and Footnotes

Find the Consolidated Financial Statements and footnotes under IFRS with Independent Auditor's Report.

[Read More](#)

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Financial Summary

Financial Highlights

Find summaries of Consolidated Business Results and Forecasts.

[Read More](#)

Financial Data (Annual Data)

Find annual financial information such as Statement of Income, Statement of Financial Position, Statement of Cash Flows and Per share data.

[Read More](#)

Financial Data (Quarterly Data)

Find quarterly financial information such as Statement of Income, Balance Sheet and Statement of Cash Flows.

[Read More](#)

Sales of Major Products

Find information about sales of our Major Products.

[Read More](#)

Revenue by Region

Find information about our sales broken out by region.

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Corporate Data



Current Share Status

Basical information about current share holders

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Corporate Information

Summary of Astellas' corporate profile

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Subsidiaries & Locations

List of Astellas' office locations and major subsidiaries

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Current Share Status

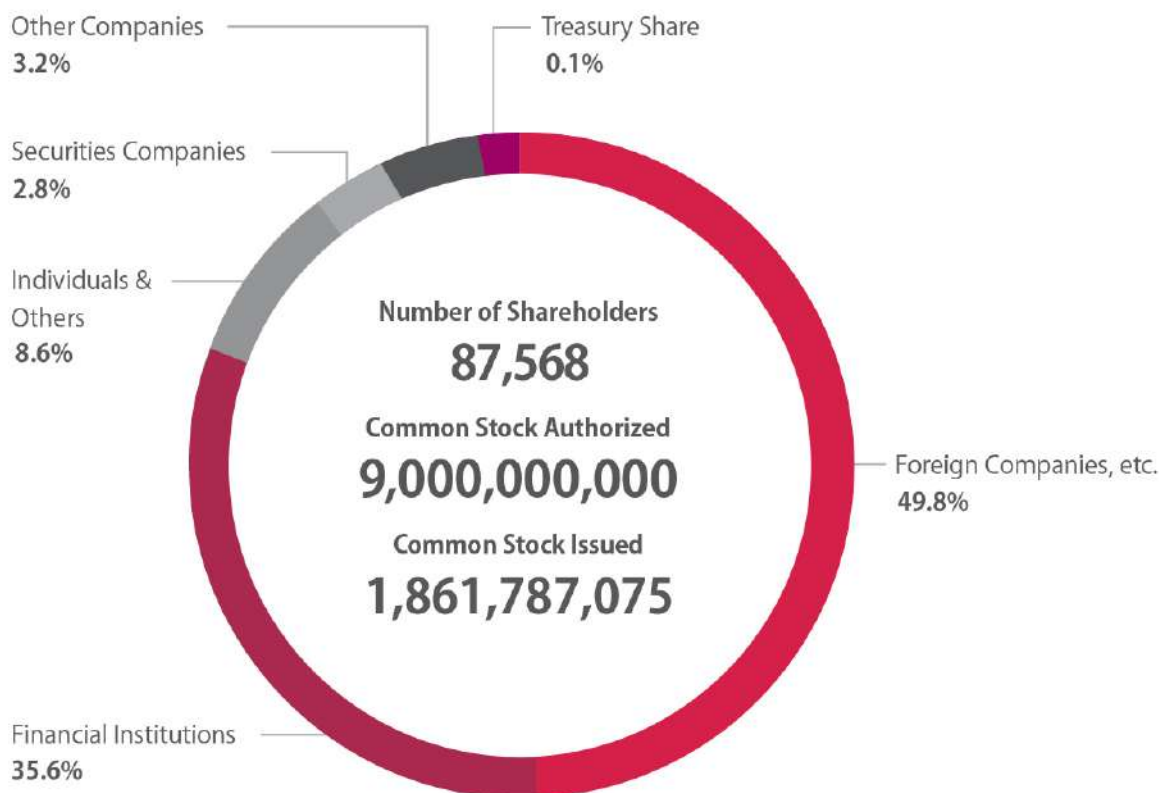
(as of March 31, 2020)

Number of shareholders: 87,568

Common stock Authorized: 9,000,000,000

Common stock Issued: 1,861,787,075

Breakdown of Shareholders by Type



Top ten (10) principal shareholders in the register of shareholders:

	Name of shareholders	Number of shares held (Thousand)	Percentage of shares held (%)
1	The Master Trust Bank of Japan, Ltd. (trust account)	210,258	11.30
2	Japan Trustee Services Bank, Ltd. (trust account)	113,716	6.11
3	Nippon Life Insurance Company	64,486	3.46
4	Japan Trustee Services Bank, Ltd. (trust account 7)	52,498	2.82
5	State Street Bank and Trust Company 505001	49,996	2.68
6	SSBTC CLIENT OMNIBUS ACCOUNT	38,226	2.05
7	JP Morgan Chase Bank 385151	37,440	2.01
8	Japan Trustee Services Bank, Ltd. (trust account 5)	35,314	1.89
9	JP Morgan Chase Bank 385632	35,121	1.88
10	STATE STREET BANK WEST CLIENT - TREATY 505234	30,300	1.62

※ Number of shares held are presented by discarding the numbers down to the thousand, and percentage of shares are presented by discarding the numbers down to the third decimal.

※ The Company holds 1,294,076 shares of treasury share, but it is not included in the above list of principal shareholders.

Annual Report 2020

Corporate Information

Company Name

Astellas Pharma Inc.

Headquarters

2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan

Tel. +81-3-3244-3000

[Headquarters Access Map \(Google Maps\)](#)

[Headquarters Annex Access Map \(Google Maps\)](#)

Foundation

1923

Capital

103,001 million yen (March 2019)

Representative Director

Kenji Yasukawa (President and Chief Executive Officer)

Employees

15,883 (Consolidated basis, March 2020)

Business Description

Manufacturing, marketing and import/export of pharmaceuticals.

Organization Chart

As of October 1, 2020

 [Organization Chart \(pdf 172KB\)](#)

Annual Report 2020

Subsidiaries & Locations

Office Locations

As of May 2014

Headquarters

2-5-1, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan

Tel.:+81-3-3244-3000

[Access Map \(Google Maps\)](#)

[Headquarters Annex Access Map \(Google Maps\)](#)

Takahagi Chemistry & Technology Development Center

160-2, Akahama, Takahagi-shi, Ibaraki 318-0001, Japan

Tsukuba Research Center

21, Miyukigaoka, Tsukuba-shi, Ibaraki 305-8585, Japan

Tsukuba Biotechnology Research Center

5-2-3, Tokodai, Tsukuba-shi, Ibaraki 300-2698, Japan

Yaizu Pharmaceutical Research Center

180, Ozumi, Yaizu-shi, Shizuoka 425-0072, Japan

Major Subsidiaries

Japan

Manufacturing base

[Astellas Pharma Tech Co., Ltd.](#)

Other

[Astellas Green Supply, Inc.](#)

Americas

The company holds business locations for R&D, manufacturing and sales & marketing in Americas under the name Astellas U.S. Holding.

Holding company in North America

Astellas US Holding, Inc.

Regional headquarters

[Astellas US LLC](#)

R&D bases

Astellas Pharma Global Development, Inc.

[Astellas Institute for Regenerative Medicine \(AIRM\)](#)

Astellas Research Institute of America LLC

[Astellas Innovation Management LLC](#)

[Astellas Venture Management LLC](#)

Sales bases

[Astellas Pharma US, Inc.](#)

[Astellas Pharma Canada, Inc. \(Canada\)](#)

[Astellas Farma Brasil Importação e Distribuição de Medicamentos Ltda. \(Brazil\)](#)

[Astellas Farma Colombia SAS \(Colombia\)](#)

Other

Astellas US Technologies, Inc.

EMEA

The company holds business locations for R&D, manufacturing and sales & marketing also in EMEA, under the name Astellas B.V.

Holding company in EMEA

Astellas B.V.

Regional headquarters (Astellas EMEA operations)

[Astellas Pharma Europe Ltd.](#)

R&D and manufacturing bases

Astellas Pharma Europe B.V. (R&D and manufacturing, Netherlands)

Astellas Ireland Co., Limited (Development and manufacturing, Ireland)

Sales bases

[Astellas Pharma Ges.m.b.H \(Austria\)](#)

[Astellas Pharma B.V. \(Belgium\)](#)

Astellas Pharma s.r.o (Czech Republic)

[Astellas Pharma A/S \(Denmark\)](#)

[Astellas Pharma S.A.S \(France\)](#)

[Astellas Pharma GmbH \(Germany\)](#)

[Astellas Pharmaceuticals AEBE \(Greece\)](#)

[Astellas Pharma Kft. \(Hungary\)](#)

[Astellas Pharma Co., Limited \(Ireland\)](#)

[Astellas Pharma S.p.A. \(Italy\)](#)

[Astellas Pharma B.V. \(Netherlands\)](#)

[Astellas Pharma Sp.zo.o. \(Poland\)](#)

[Astellas Farma Limitada \(Portugal\)](#)

[JSC Astellas Pharma \(Russia\)](#)

[Astellas Pharma d.o.o. \(Slovenia\)](#)

Astellas Pharma(Proprietary), Ltd. (South Africa)

[Astellas Pharma S.A. \(Spain\)](#)

[Astellas Pharma A.G. \(Switzerland\)](#)

[Astellas Pharma ilaç Ticaret ve Sanayi A.Ş. \(Turkey\)](#)

Astellas Pharma DMCC (United Arab Emirates)

[Astellas Pharma Ltd. \(United Kingdom\)](#)

Asia/Oceania

The company holds sales & marketing and manufacturing functions in China, and sales offices in Hong Kong, Taiwan, South Korea, the Philippines, Thailand, Indonesia, India, Australia and Singapore.

Sales and other bases

[Astellas Pharma China, Inc. \(Sales and manufacturing, China\)](#)

[Astellas Pharma Hong Kong Co., Ltd. \(Hong Kong\)](#)

[Astellas Pharma Taiwan, Inc. \(Taiwan\)](#)

[Astellas Pharma Korea, Inc. \(Korea\)](#)

[Astellas Pharma Philippines, Inc. \(Philippines\)](#)

[Astellas Pharma \(Thailand\) Co., Ltd. \(Thailand\)](#)

[P.T. Astellas Pharma Indonesia \(Indonesia\)](#)

[Astellas Pharma India Private Limited \(India\)](#)

[Astellas Pharma Australia Pty Ltd. \(Australia\)](#)

[Astellas Pharma Singapore Pte. Ltd. \(Singapore\)](#)

[Astellas Pharma Malaysia Sdn. Bhd. \(Malaysia\)](#)

[The Representative Office of Astellas Pharma Singapore Pte. Ltd. in Vietnam \(Vietnam\)](#)