R&D 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 Apr 2024

Underlined items indicate changes from the previous announcement in Feb 2024.

XTANDI and Strategic products (1/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
enzalutamide MDV3100 (XTANDI)	Small molecule	Androgen receptor inhibitor	Metastatic castration-sensitive prostate cancer	China Filed (Sep 2023)	Pfizer	
			Non-metastatic castration-sensitive prostate cancer	Europe Approved (Apr 2024)		
enfortumab vedotin ASG-22ME (PADCEV)	Antibody-drug conjugate (ADC)	Nectin-4 targeted ADC	Metastatic urothelial cancer, platinum-containing chemotherapy and PD-1/L1 inhibitor pretreated	China Filed (Mar 2023)	In-house [Co-development with Pfizer]	
			Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)	Europe Filed (Jan 2024) Japan Filed (Jan 2024) China Filed (Mar 2024)		
			Muscle-invasive bladder cancer (combo with pembrolizumab)	P-III		
			Other solid tumors	P-II		
			Non-muscle-invasive bladder cancer	P-I		
gilteritinib ASP2215 (XOSPATA)	Small molecule	FLT3 inhibitor	Post-chemotherapy maintenance acute myeloid leukemia	P-III	In-house	
			Post-hematopoietic stem cell transplant maintenance acute myeloid leukemia	P-III		
			Newly diagnosed acute myeloid leukemia with high intensity induction of chemotherapy	P-III		
			Newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy	P-I		
			Acute myeloid leukemia in pediatric patients	P-III		

XTANDI and Strategic products (2/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
zolbetuximab **IMAB362** **(VYLOY)**	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	Japan Approved (Mar 2024) US Filed (Jul 2023) Europe Filed (Jul 2023) China Filed (Jul 2023)	In-house (Ganymed)	
			Pancreatic adenocarcinoma	P-II		
fezolinetant **ESN364** **(VEOZAH***)**	Small molecule	NK3 receptor antagonist	Vasomotor symptoms due to menopause	China P-III Japan P-III	In-house (Ogeda)	
			Induced vasomotor symptoms in breast cancer patients on adjuvant endocrine therapy	P-III		
avacincaptad pegol **(IZERVAY)**	Pegylated RNA aptamer	Complement C5 inhibitor	Geographic atrophy secondary to age-related macular degeneration	Europe Filed (Aug 2023)		
			Stargardt disease	P-II		
resamirigene bilparvovec **AT132**	Gene therapy (AAV-based gene therapy)	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy	P-II	In-house (Audentes Therapeutics)	
roxadustat **ASP1517/FG-4592**	Small molecule	HIF-PH inhibitor	Anemia associated with chronic kidney disease in pediatric patients	Europe P-III	FibroGen	Astellas has rights in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.

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

Updates from the previous announcement (Feb 2024):
enzalutamide: Removed the description of the approval in US for non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis in Nov 2023. Approved in Europe in Apr 2024 for high risk biochemical recurrent non-metastatic hormone sensitive prostate cancer that is unsuitable for salvage radiotherapy.
enfortumab vedotin: Removed the description of the approval in US for locally advanced or metastatic urothelial cancer in the first-line setting in Dec 2023. Filed in China in Mar 2024 for locally advanced or metastatic urothelial cancer in the first-line setting.
zolbetuximab: Approved in Japan in Mar 2024 for CLDN18.2 positive, unresectable, advanced or recurrent gastric cancer.
fezolinetant: Removed the description of the approval in Europe for moderate to severe vasomotor symptoms associated with menopause in Dec 2023. Entered into Phase 3 for induced vasomotor symptoms in breast cancer patients on adjuvant endocrine therapy.

Projects with Focus Area approach (1/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
Immuno-oncology	**ASP1570**	Small molecule	DGKζ inhibitor	Cancer	P-I	In-house	
	ASP2138	Antibody	Anti-Claudin 18.2 and anti-CD3 bispecific antibody	Gastric and gastroesophageal junction adenocarcinoma, pancreatic adenocarcinoma	P-I	Xencor [Discovered through collaborative research]	
	ASP1002	Antibody	Bispecific antibody	Cancer	P-I	In-house	
	ASP1012	Oncolytic virus	Oncolytic virus encoding leptin-IL-2	Cancer	P-I	KaliVir	
	ASP2802	Cell therapy	Autologous CD20 *convertible* CAR-T	B-cell lymphoma	P-I	In-house (Xyphos Biosciences)	
Blindness and Regeneration	**ASP7317**	Cell therapy	Retinal pigment epithelium cells	Geographic atrophy secondary to age-related macular degeneration	P-I	In-house (Ocata Therapeutics)	

Projects with Focus Area approach (2/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
Genetic regulation	**resamirigene bilparvovec AT132 ***	Gene therapy (AAV-based gene therapy)	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy	P-II	In-house (Audentes Therapeutics)	
	zocaglusagene nuzaparvovec AT845	Gene therapy (AAV-based gene therapy)	GAA gene replacement to express GAA enzyme	Pompe disease	P-I	In-house (Audentes Therapeutics)	
	ASP2016	Gene therapy (AAV-based gene therapy)	FXN gene replacement to express frataxin	Cardiomyopathy associated with Friedreich Ataxia	P-I	In-house (Audentes Therapeutics)	
Targeted Protein Degradation	**ASP3082**	Small molecule	KRAS G12D degrader	Cancer	P-I	In-house	
	ASP4396	Small molecule	KRAS G12D degrader	Cancer	P-I	In-house	

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** Compounds with "In-house" in this column include ones discovered by collaborative research.
*** AT132 is also listed in "XTANDI and Strategic products".

Updates from the previous announcement (Feb 2024):
ASP2074: Discontinued the development for cancer in Phase 1.
ASP2802: Entered into Phase 1 for B-cell lymphoma.
ASP0367: Discontinued the development for primary mitochondrial myopathies in Phase 2 and Duchenne muscular dystrophy in Phase 1 based on its clinical data.
ASP2016: Entered into Phase 1 for cardiomyopathy associated with Friedreich Ataxia.
ASP4396: Entered into Phase 1 for cancer.

Others

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
mirabegron **YM178**	Small molecule	β_3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	Europe P-III	In-house	
peficitinib **ASP015K**	Small molecule	JAK inhibitor	Rheumatoid arthritis	China Filed (Aug 2022)	In-house	
abiraterone decanoate **PRL-02/ASP5541**	Small molecule	CYP17 lyase inhibitor	Prostate cancer	P-I	In-house (Propella Therapeutics)	

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

Updates from the previous announcement (Feb 2024):
isavuconazole: Removed the description of approval in US for invasive aspergillosis and invasive mucormycosis in pediatric patients in Dec 2023.

Rx+ Program

As of Apr 2024

Underlined items indicate changes from the previous announcement in Feb 2024.

Category	Program	Concept	Status*	Partner	Remarks
Digital health Other services	**BlueStar**	Digital therapeutics for adults with diabetes	Pivotal study (Japan)	Welldoc Roche Diabetes Care Japan	
	Z1608	Digital therapeutic plus remote patient monitoring for heart failure	Under development	Welldoc Eko	
Drug-device combination	**pudexacianinium chloride ASP5354**	Intraoperative ureter visualization for use in patients undergoing minimally invasive and open abdominopelvic surgeries	P-III	Stryker	

* The list shows the most advanced stage if the stages are different depending on the region.

Updates from the previous announcement (Feb 2024):
BlueStar: Entered into pivotal study in Japan.