VYLOY™ (ZOLBETUXIMAB) JAPAN REGULATORY UPDATE

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March 29, 2024 (JST)

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

In this material, 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 material is not intended to constitute an advertisement or medical advice.

The safety and efficacy of zolbetuximab has been assessed by the PMDA and approved for CLDN18.2 positive, unresectable, advanced or recurrent gastric cancer. VYLOY is used in combination with chemotherapy for patients whose tumors are human epidermal growth factor receptor 2 (HER2)-negative. In other markets, zolbetuximab is an investigational compound in clinical development. The safety and efficacy of zolbetuximab is being assessed by other Regulatory Authorities. There is no guarantee it will receive regulatory approval or become commercially available in all markets.

AGENDA

I **Gastric Cancer Disease State**

II **VYLOY Product Profile & Commercial Strategy**

III **Future Plans**

IV **Q&A**

Presenter

John Demaree
Head, Strategic Brand Marketing, Oncology

Q&A Participants

Tomoko Nakajima, Ph.D.
Asset Lead, zolbetuximab

Shelley Shaw
Global Brand Lead, zolbetuximab

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GASTRIC CANCER DISEASE STATE

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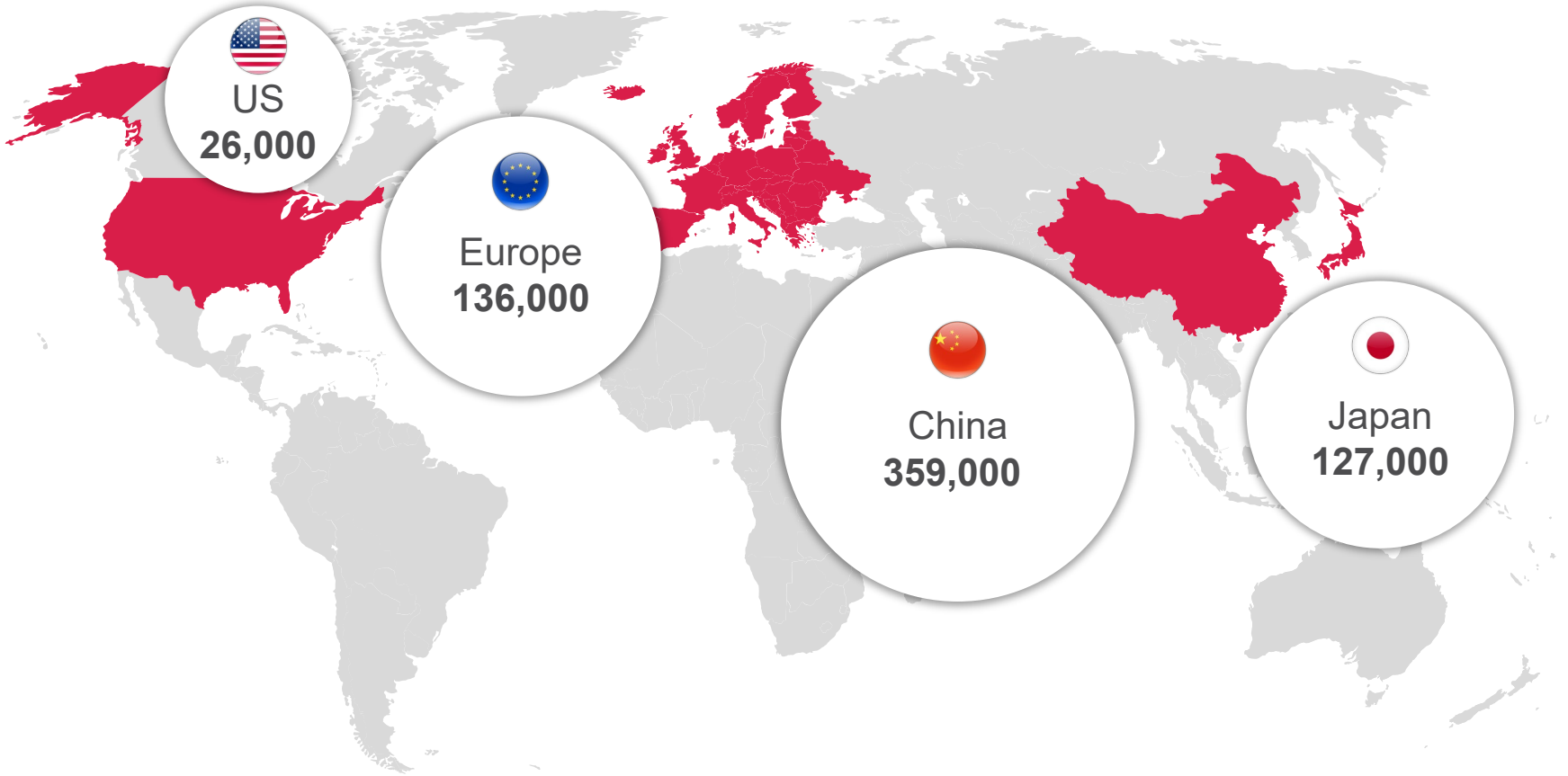
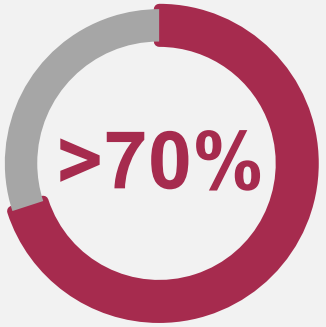
GASTRIC CANCER HAS A DEVASTATING IMPACT ON PATIENTS

~1 Million Cases of Gastric Cancer Diagnosed Globally in 2022[1]



3rd Deadliest Cancer in Japan[1]



Early Detection of Gastric Cancer in Japan[2]

Effective Treatment Options Are Limited

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PATIENTS WITH CLDN18.2 POSITIVE, UNRESECTABLE, ADVANCED OR RECURRENT GASTRIC CANCER NEED NEW TREATMENT OPTIONS

78% of 1L advanced gastric cancer population is HER2-negative[3]

In Japan, **chemotherapy ± CPI is the current standard of care**[4]

Oncologists are seeking new treatment options that may improve survival outcomes[5]

CPI: Checkpoint inhibitors

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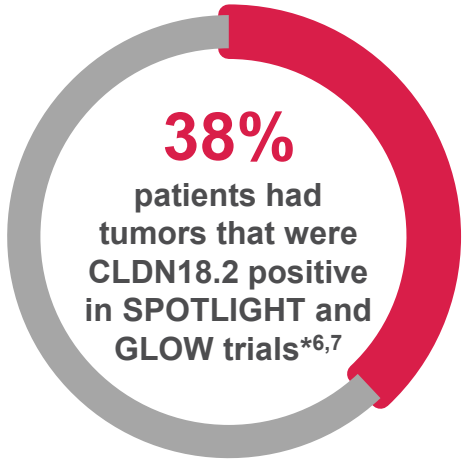
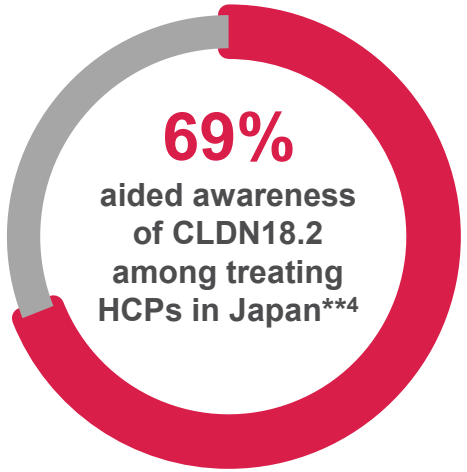
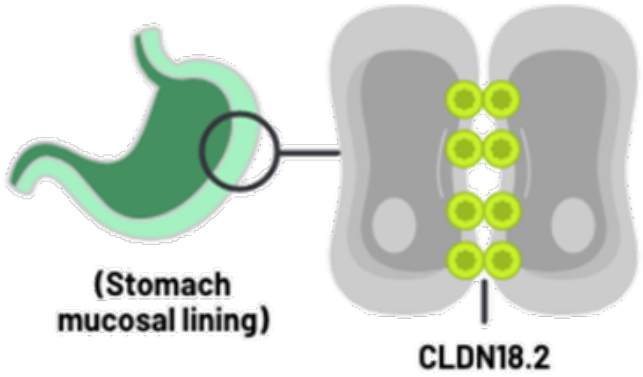
CLDN18.2 IS A NOVEL BIOMARKER IN ADVANCED GASTRIC CANCER

High prevalence and strength of clinical data provide strong reason to test for CLDN18.2 positivity

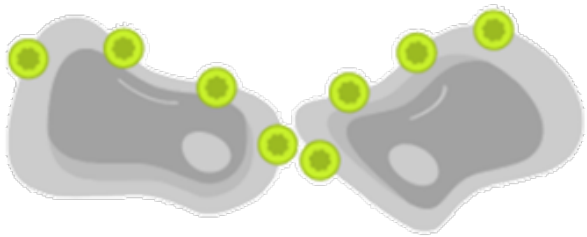




Confined in Healthy Tissue[8]



Retained and Exposed in Malignant Transformation[8]



Maintained in Metastatic Progression[8]

*CLDN18.2 positive is defined as ≥75% tumor cells showing moderate-to-strong membranous CLDN18 staining[6,7]
**Treating HCPs include oncologists, digestive surgeons and gastroenterologists

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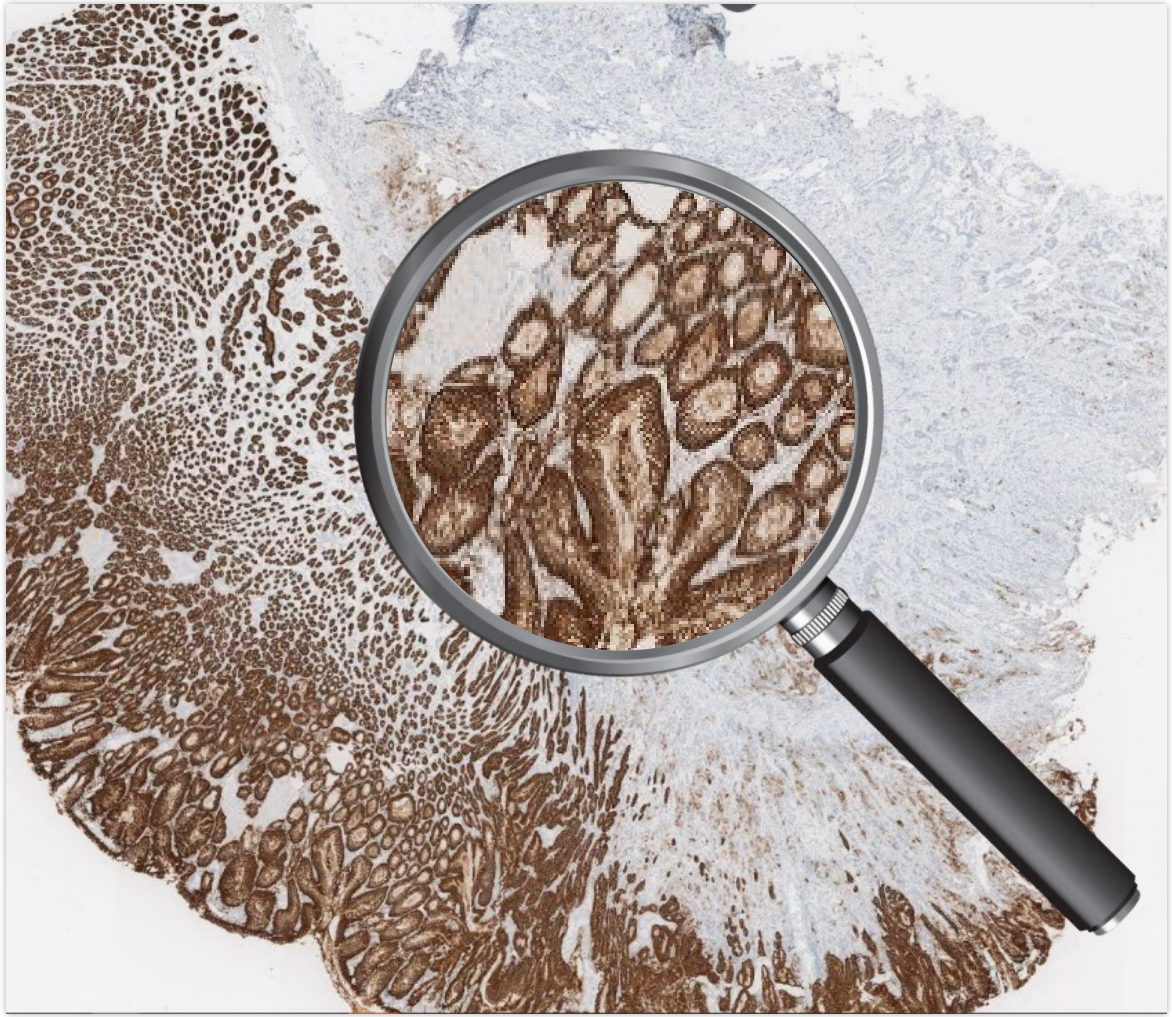
DIAGNOSTIC TESTING EDUCATION RESOURCES TO SUPPORT PATHOLOGISTS

Claudin182.JP

Unique peer-to-peer education platform on biomarker testing for pathologists



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VYLOY PRODUCT PROFILE & COMMERCIAL STRATEGY

THE JOURNEY OF VYLOY

Completion of Phase 2 FAST Trial

Astellas Acquisition of Ganymed

Completion of 2 Global Pivotal Phase 3 SPOTLIGHT and GLOW Trials*

Global Regulatory Submissions**

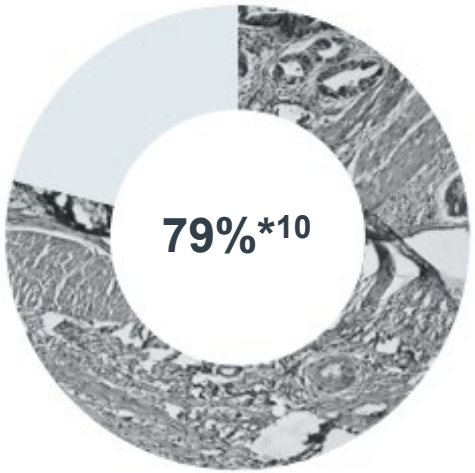
First Approved Targeted Treatment for CLDN18.2 Positive, Unresectable, Advanced or Recurrent Gastric Cancer

*Phase 1 and Phase 2 studies were conducted previously
**Global regulatory submissions to date include U.S., Japan, China, Europe, among other markets

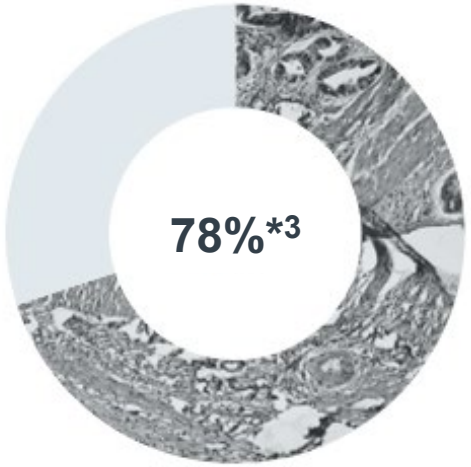
IDENTIFYING POTENTIAL CANDIDATES FOR VYLOY

There are approximately 400,000[9] patients diagnosed globally with Stage IV mGC/GEJ**

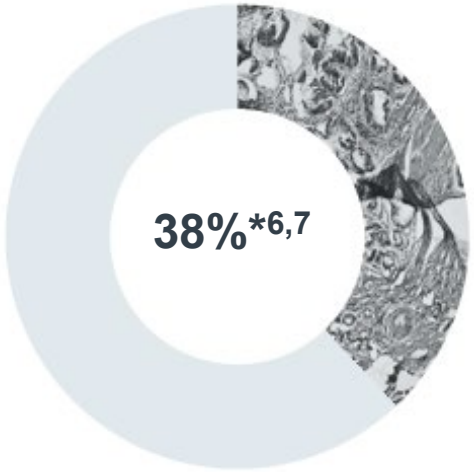
Biomarker Testing	HER2 Status	CLDN18.2 Status



Tested for HER2 (and CLDN18.2 in future)



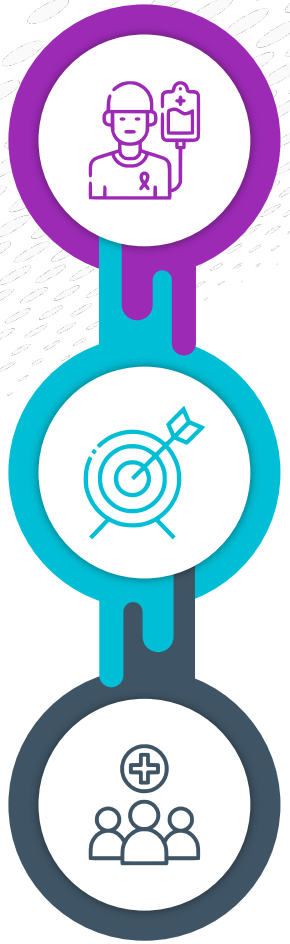
HER2-negative



CLDN18.2 positive

*Percentages represent global weighted averages
**In Japan, the gastric cancer indication includes gastroesophageal junction (GEJ) adenocarcinoma

VYLOY PROVIDES A TARGETED TREATMENT OPTION



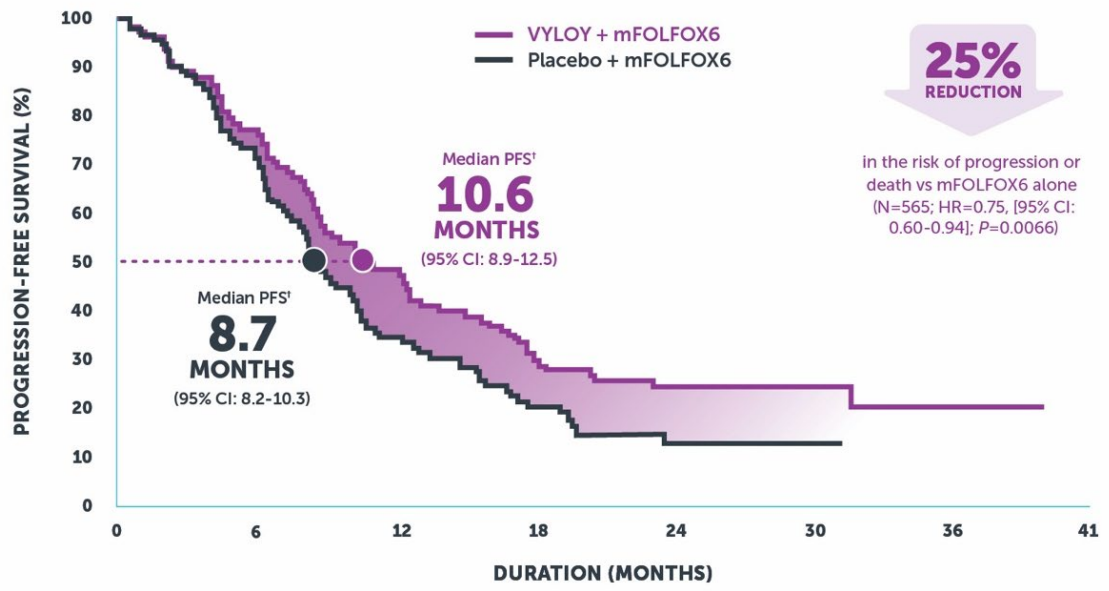
1. VYLOY is indicated for CLDN18.2 positive, unresectable, advanced or recurrent gastric cancer

2. VYLOY is **first and only approved** CLDN18.2-targeted therapy

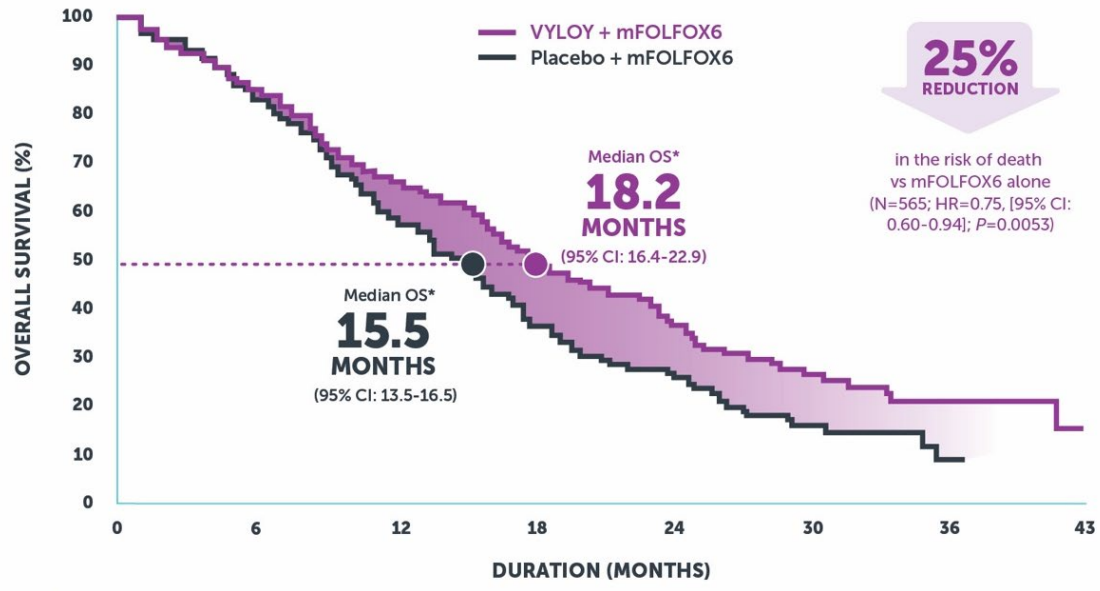
3. VYLOY can be used in eligible patients **regardless of combined positive score** (CPS)

DATA FROM PIVOTAL PHASE 3 TRIALS SUPPORTED APPROVAL: SPOTLIGHT[6]

PROGRESSION-FREE SURVIVAL (PRIMARY ENDPOINT, ITT)*



OVERALL SURVIVAL (KEY SECONDARY ENDPOINT, ITT)

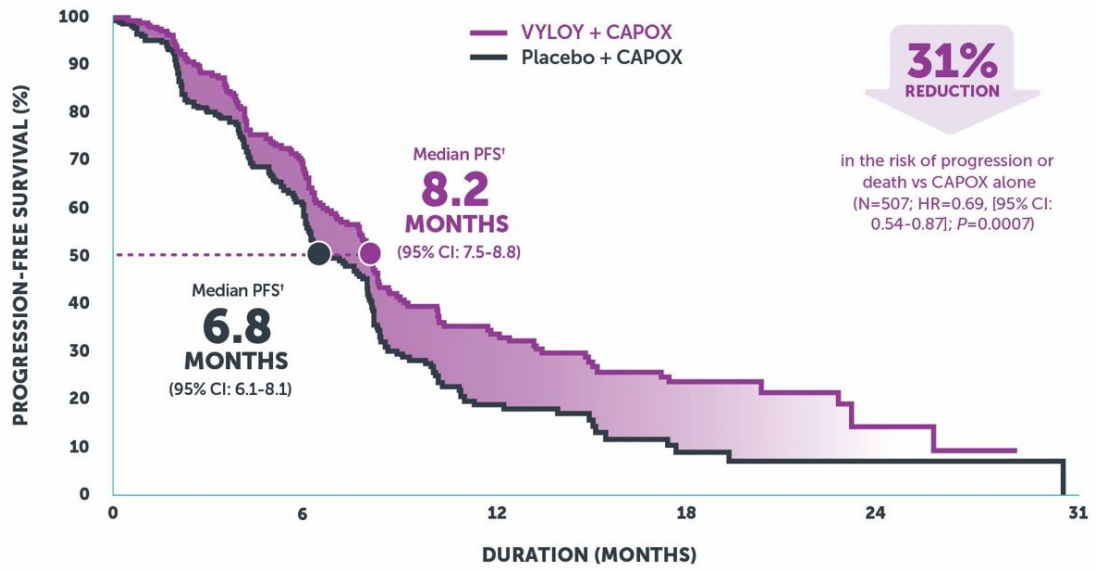


Median OS was the longest OS observed in a global Phase 3 trial in this patient population.[11,12]

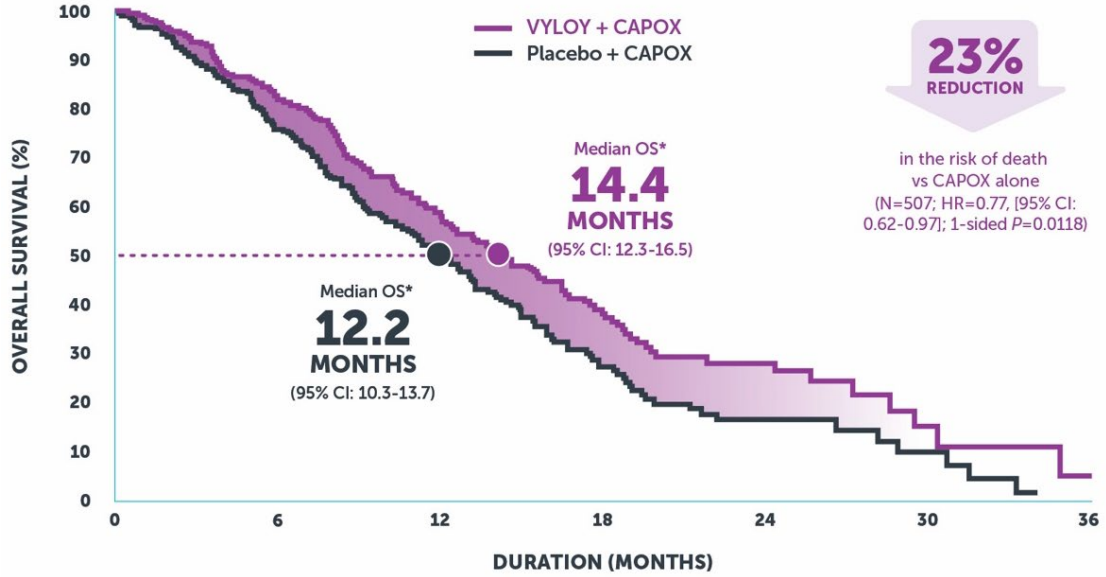
*PFS was assessed per RECIST v1.1 by IRC
mFOLFOX6: 5-FU, leucovorin and oxaliplatin; PFS: Progression-free survival; OS: Overall survival

DATA FROM PIVOTAL PHASE 3 TRIALS SUPPORTED APPROVAL: GLOW[7]

PROGRESSION-FREE SURVIVAL (PRIMARY ENDPOINT, ITT)*



OVERALL SURVIVAL (SECONDARY ENDPOINT, ITT)



SPOTLIGHT and GLOW had similar overall survival hazard ratios, validating the effectiveness of zolbetuximab combined with chemotherapy.[6,7]

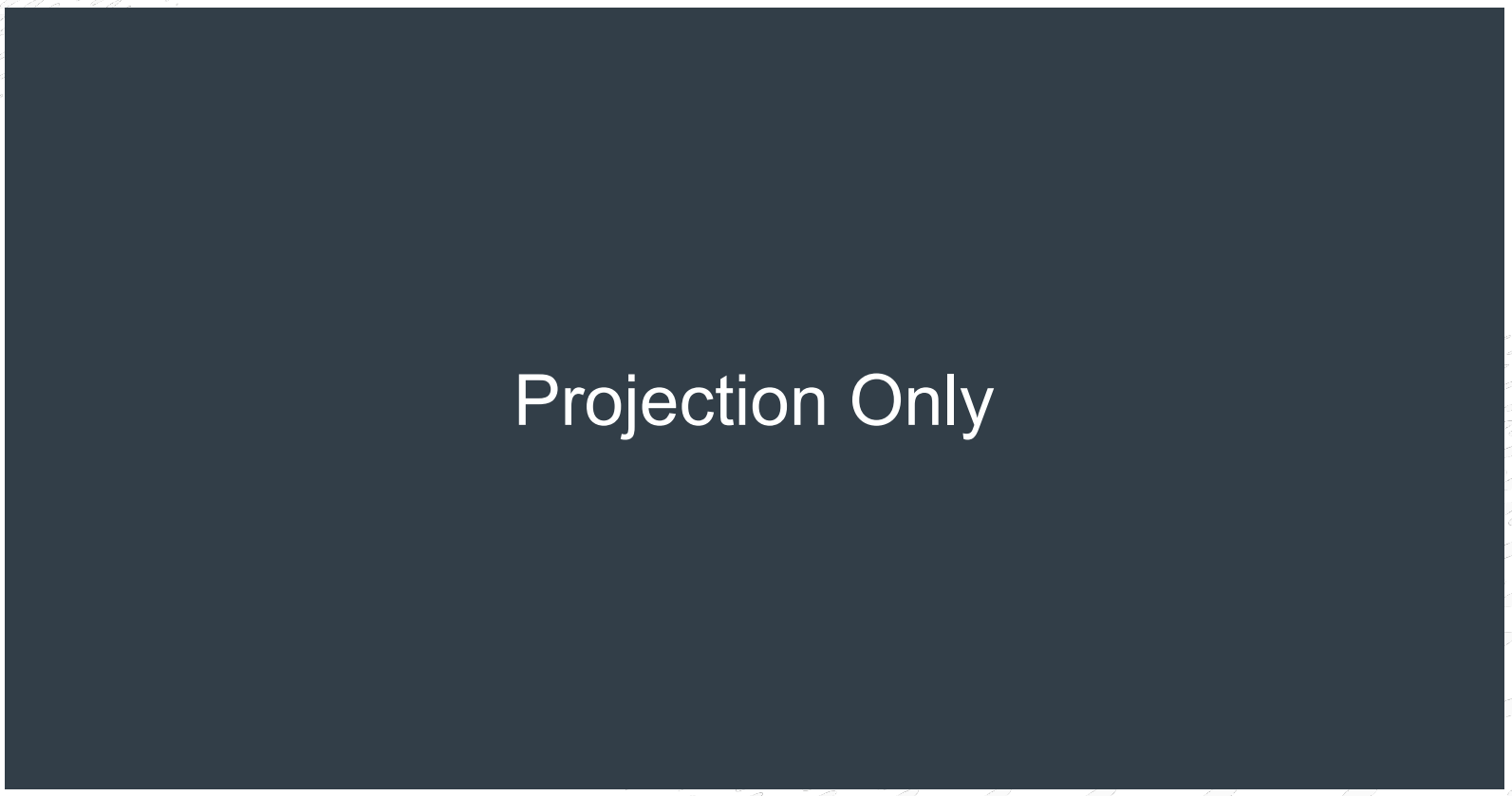
*PFS was assessed per RECIST v1.1 by IRC
CAPOX: Capecitabine and oxaliplatin; PFS: Progression-free survival; OS: Overall survival

SAFETY DATA FROM SPOTLIGHT AND GLOW

SPOTLIGHT	GLOW
Incidence of serious TEAEs* was similar between both arms (44.8% vs. 43.5%)[6]	Incidence of serious TEAEs was similar between both arms (47.2% vs. 49.8%)[7]
Most frequent TEAEs in the VYLOY versus control arms: • Nausea (82.4% vs. 60.8%) • Vomiting (67.4% vs. 35.6%) • Decreased appetite (47.0% vs. 33.5%)	Most frequent TEAEs in the VYLOY versus control arms: • Nausea (68.5% vs. 50.2%) • Vomiting (66.1% vs. 30.9%) • Decreased appetite (41.3% vs. 33.7%)

*Treatment emergent adverse events

DR. KOHEI SHITARA DISCUSSES SIGNIFICANCE OF MHLW APPROVAL OF VYLOY



MAXIMIZING THE VALUE OF VYLOY: LEVERAGING ONCOLOGY EXPERTISE

- **Successfully launching oncology products into areas of high unmet need**
- **Building market leadership**
- **Creating strong relationships in oncology**
- **Preparing experienced, knowledgeable, and agile sales force for readiness upon launch**

PADCEV®
enfortumab vedotin
Injection for IV infusion 20 mg & 30 mg vials

Xtandi®
(enzalutamide)

XOSPATA®
gilteritinib 40mg tablets

ACTIVATING LABS FOR IMMEDIATE TESTING FOR CLDN18.2 POSITIVITY IN JAPAN

Recently, VENTANA® CLDN18 (43-14A) RxDx Assay, developed by Roche, was approved as an IHC companion diagnostic.

At VYLOY launch, strategic partnerships with the top 3 central labs and major cancer centers will ensure national availability to testing for all patients, providing coverage throughout Japan.

Post-VYLOY launch, both HQ and sales team will collaborate with labs to increase awareness of and broaden local access to testing.

FUTURE PLANS

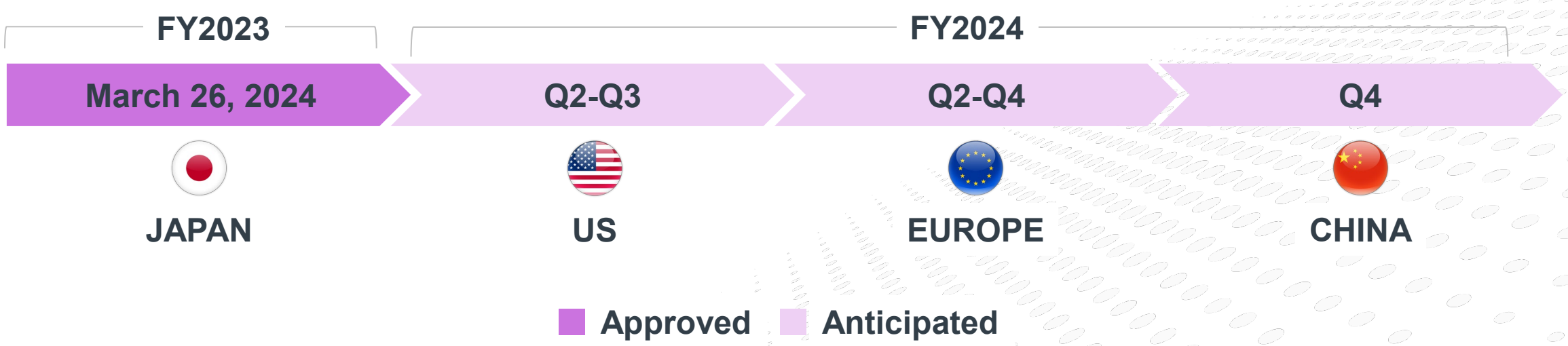
GLOBAL LAUNCH PLAN

Global Launch:
VYLOY + Roche VENTANA CDx

~50 VYLOY country launches planned[13]

Multiple launches in Asian countries where disease incidence is highest[1]

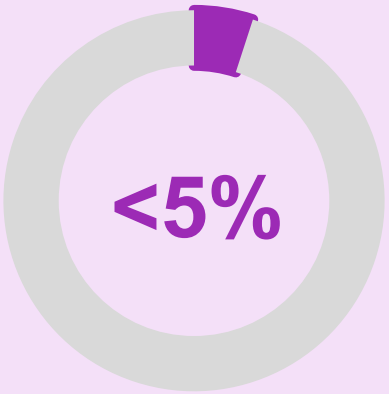
Anticipated Approval Timings*



*Global regulatory submissions to date include U.S., China, and Europe, among others

LOOKING AHEAD TO A POTENTIAL PANCREATIC CANCER INDICATION

Leading cause of cancer death in Japan[14]



5-year survival globally for patients at the metastatic stage[15]

Phase 2 registrational trial in metastatic pancreatic adenocarcinoma is in progress[16]

Potential pancreatic cancer indication represents significant upside potential for the VYLOY global sales forecast

*Claudin 18.2 positive is defined as ≥75% tumor cells showing moderate-to-strong membranous CLDN18 staining

KEY TAKEAWAYS

CLDN18.2 is a novel and highly prevalent predictive biomarker in advanced gastric cancer that can be readily detected via IHC[6,7]

VYLOY is approved for patients with HER2-negative, CLDN18.2 positive, unresectable, advanced or recurrent gastric cancer, which is the third deadliest in Japan[1]

VENTANA CLDN18 (43-14A) RxDx Assay developed by Roche is approved as an IHC companion diagnostic for VYLOY to help determine CLDN18.2 status

VYLOY is also being evaluated in pancreatic cancer,[16] which is expected to remain the fourth deadliest cancer in Japan[14]

Thank You

APPENDIX

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