

Astellas to Present New Clinical Data Across Its Gastrointestinal Cancers Portfolio at 2026 ASCO GI Cancers Symposium

*- Data reflect new insights and precision oncology advancements in
portfolio and pipeline -*

*- Cohort results from Phase 2 ILUSTRO study evaluating a
zolbetuximab triplet combination regimen in first-line advanced gastric
and gastroesophageal junction (GEJ) cancer featured in late-breaking
oral presentation -*

TOKYO, DECEMBER 11, 2025 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, “Astellas”) today announced it will present data on potential treatments for pancreatic and gastric/gastroesophageal junction (G/GEJ) cancer at the 2026 American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium taking place January 8-10, 2026 in San Francisco, California. Highlights include a late-breaking oral presentation of cohort results from the Phase 2 ILUSTRO study of first-line zolbetuximab in combination with chemotherapy and immunotherapy in claudin 18.2-positive, HER2-negative, locally advanced or metastatic G/GEJ cancer, as well as new Phase 1 data from ASP3082 (setidegrasib), an investigational KRAS G12D targeted protein degrader, in pancreatic cancer.

Moitreyee Chatterjee-Kishore, Ph.D., M.B.A., Head of Oncology Development, Astellas

“At Astellas, we are harnessing next-generation treatment modalities and a precision biomarker-driven approach to deliver treatments that make a meaningful difference for patients with gastrointestinal cancers. We’re excited to share data at ASCO GI from our growing portfolio of assets in GI cancers – which showcase our commitment to better understanding how to treat these diseases – including emerging data from zolbetuximab as well as progress on ASP3082 (setidegrasib), our investigational KRAS G12D targeted protein degrader. Together with the passionate GI cancer community of patients, physicians, and advocates, we are working to transform outcomes for patients and pave the future of cancer care.”

Astellas Presentations at ASCO GI 2026

Zolbetuximab

Presentation Title	Presenter	Presentation Details
Phase 2 ILUSTRO trial of first-line zolbetuximab plus mFOLFOX6 and nivolumab in patients with claudin	K. Shitara	Type: Oral presentation Abstract Number: LBA284

18 isoform 2-positive, human epidermal growth factor receptor 2-negative, locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma		Date: January 8, 2026, 8:47 a.m. - 8:57 a.m. PST
Determinants of biomarker testing and treatment selection by oncologists caring for patients with gastric or gastroesophageal junction adenocarcinoma	R. Fuldeore	Type: Poster Abstract Number: 453 Date: January 8, 2026, 11:30 a.m. - 1:00 p.m.; 6:00 p.m. - 7:00 p.m. PST
Zolbetuximab + pembrolizumab and chemotherapy as first-line treatment for patients with CLDN18.2-positive, HER2-negative, PD-L1-positive locally advanced unresectable or metastatic G/GEJ adenocarcinoma: Phase 3, double-blind, randomized trial (LUCERNA)	K. Shitara	Type: Poster Abstract Number: TPS473 Date: January 8, 2026, 11:30 a.m. - 1:00 p.m.; 6:00 p.m. - 7:00 p.m. PST
Assessment of the impact of proton pump inhibitor exposure on survival outcomes in patients with gastric or gastroesophageal junction adenocarcinoma treated with zolbetuximab plus chemotherapy	A. Yamada	Type: Poster Abstract Number: 349 Date: January 8, 2026, 11:30 a.m. - 1:00 p.m.; 6:00 p.m. - 7:00 p.m. PST
A real-world study of claudin 18.2 association with molecular subtypes, mutations/biomarkers, immune landscapes, and gene signatures and prognostic value in pancreatic ductal adenocarcinoma	G. Zhang	Type: Poster Abstract Number: 744 Date: January 9, 2026, 11:30 a.m. - 1:00 p.m.; 5:00 p.m. - 6:00 p.m. PST
Treatment patterns and outcomes of patients diagnosed with metastatic pancreatic adenocarcinoma	R. Fuldeore	Type: Poster Abstract Number: 685 Date: January 9, 2026, 11:30 a.m. - 1:00 p.m.; 5:00 p.m. - 6:00 p.m. PST

ASP3082 (setidegrasib)

Presentation Title	Presenter	Presentation Details
Efficacy and safety of setidegrasib (ASP3082) monotherapy or in	A. Kasi	Type: Poster Abstract Number: 704

combination with mFOLFIRINOX in patients with pancreatic ductal adenocarcinoma		Date: January 9, 2026, 11:30 a.m. - 1:00 p.m.; 5:00 p.m. - 6:00 p.m. PST
Phase 1 evaluation of setidegrasib (ASP3082), a first-in-class selective protein degrader, in patients with KRAS G12D-mutant pancreatic ductal adenocarcinoma: Pharmacokinetics and biomarker insights	W. Park	Type: Poster Abstract Number: 775 Date: January 9, 2026, 11:30 a.m. - 1:00 p.m.; 5:00 p.m. - 6:00 p.m. PST

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About Astellas

Astellas is a global life sciences company committed to turning innovative science into VALUE for patients. We provide transformative therapies in disease areas that include oncology, ophthalmology, urology, immunology and women's health. Through our research and development programs, we are pioneering new healthcare solutions for diseases with high unmet medical need. Learn more at www.astellas.com.

About VYLOY (zolbetuximab)

VYLOY (zolbetuximab) is a first-in-class monoclonal antibody (mAb) specifically designed to target tumor cells that express claudin 18.2 (CLDN18.2), a transmembrane protein. By binding to CLDN18.2, VYLOY (zolbetuximab) induces cancer cell death and inhibits tumor growth by activating two distinct immune system pathways - antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC), as demonstrated in preclinical studies.

VYLOY (zolbetuximab) was the first CLDN18.2-targeted therapy to receive regulatory approval anywhere in the world and is currently the only approved treatment, in combination with chemotherapy, for CLDN18.2-positive (HER2-negative) gastric or gastroesophageal junction (GEJ) cancer in several countries, including China, the European Union, Japan, and the United States.

In both the SPOTLIGHT and GLOW Phase 3 clinical trials, which assessed the efficacy and safety of zolbetuximab plus chemotherapy in patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma, approximately 38% of patients screened had tumors that were CLDN18.2 positive, defined as $\geq 75\%$ of tumor cells demonstrating moderate to strong membranous CLDN18.2 immunohistochemical staining. This represents a substantial patient group that could benefit from targeted first-line therapy.^{1,2}

Astellas collaborated with Roche on the Ventana™ CLDN18 (43-14a) RXDX assay, which, where approved, can be used by pathologists or laboratories to identify patients eligible for targeted treatment with VYLOY (zolbetuximab).

Astellas is exploring zolbetuximab in combination with pembrolizumab and chemotherapy as a first-line treatment for patients with CLDN18.2-positive, HER2-negative, PD-L1-positive locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma in the investigational Phase III LUCERNA study. For more information, visit clinicaltrials.gov with identifier [NCT06901531](https://clinicaltrials.gov/ct2/show/study/NCT06901531).

About ASP3082 (setidegrasib)

ASP3082 is a selective protein degrader discovered fully in-house that targets mutated KRAS G12D, which is found in approximately 40% of pancreatic ductal adenocarcinomas.³ A potential first-in-class therapy, ASP3082 is currently being evaluated in a Phase 1 clinical trial for patients with metastatic or locally advanced unresectable solid tumors with KRAS G12D mutations. In addition, Astellas is advancing ASP4396 which also targets mutated KRAS G12D and is in Phase 1 study. For more information, visit clinicaltrials.gov with identifier [NCT05382559](https://clinicaltrials.gov/ct2/show/study/NCT05382559) (ASP3082) or [NCT06364696](https://clinicaltrials.gov/ct2/show/study/NCT06364696) (ASP4396).

The safety and efficacy of the agents under investigation have not been established for the uses being considered. There is no guarantee that the agents will receive regulatory approval and become commercially available for the uses being investigated.

Cautionary Notes

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

References

¹ Shitara K, et al. Zolbetuximab plus mFOLFOX6 in patients with CLDN18.2-positive, HER2-negative, untreated, locally advanced unresectable or metastatic gastric or gastro-oesophageal junction adenocarcinoma (SPOTLIGHT): a multicentre, randomised, double-blind, phase 3 trial. *Lancet*. 2023;401(10389):1655-1668.

² Shah MA, et al. Zolbetuximab plus CAPOX in CLDN18.2-positive gastric or gastroesophageal junction adenocarcinoma: the randomized, phase 3 GLOW trial. *Nat Med*. 2023;29(8):2133-2141.

³ Lee, JK et al. Comprehensive pan-cancer genomic landscape of KRAS altered cancers and real-world outcomes in solid tumors. *NPJ Precis Oncol*. 2022;9;6(1):91.

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