Press Release

Astellas Highlights Data Advancing Cancer Care and Innovation for Patients with Hard-to-Treat Cancers at ESMO 2026

– PADCEV™ (enfortumab vedotin) plus pembrolizumab data highlight durable survival benefit in advanced bladder cancer –

– VYLOY™ (zolbetuximab) research reinforces the role of CLDN18.2 in shaping gastric cancer treatment decisions –

TOKYO, October 7, 2026 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced that 21 abstracts from its oncology portfolio will be presented at the European Society for Medical Oncology Congress 2026 (ESMO 2026), taking place October 23–27 in Madrid, Spain. The presentations span prostate, urothelial, gastric/gastroesophageal junction (GEJ), lung and pancreatic cancers, reflecting Astellas' commitment to advancing standards of care and pursuing new scientific approaches designed for cancers where significant unmet need remains.

Moitreyee Chatterjee-Kishore, Ph.D., MBA, Executive Vice President and Head of Oncology Development, Astellas:
"Standards of care do not change by accident. The data being presented at ESMO 2026 demonstrate how a deep understanding of disease biology and differentiated modalities is helping advance care for patients with bladder, gastric, and prostate cancers, including through approaches such as PADCEV™ (enfortumab vedotin) plus pembrolizumab, VYLOY™ (zolbetuximab), and XTANDI™ (enzalutamide). We are building upon this knowledge to develop the next generation of therapeutic options for cancers where unmet needs remain and look forward to engaging in discussions about this work at the congress."

Highlights from Astellas' ESMO 2026 presentations include:

- Enfortumab vedotin plus pembrolizumab presentations include the longest follow-up reported to date in locally advanced or metastatic urothelial cancer, along with analyses across patient subgroups and treatment settings. Additional presentations include trials in progress exploring bladder preservation in muscle-invasive bladder cancer.

- Zolbetuximab presentations examine CLDN18.2 assessment, patient identification and real-world use, reinforcing the growing body of evidence supporting CLDN18.2-guided treatment decisions in gastric and GEJ cancers.
- Pipeline presentations feature trials-in-progress across Astellas' investigational programs, including Phase 3 trials of setidegrasib in KRAS G12D-mutated pancreatic and non-small cell lung cancers, a Phase 1 trial of ASP5834 in KRAS-mutated or amplified solid tumors, and a Phase 1b/2 trial of ASP546C in CLDN18.2-expressing solid tumors. Together, these investigational studies illustrate Astellas' continued investment in advancing new approaches aimed at overcoming challenges that have limited progress in hard-to-treat cancers.

Additional details on Astellas' presentations at ESMO 2026 are included below.

Presentation Title	Lead Author	Presentation Details
Enfortumab vedotin		
EV-103 DE/Cohort A and Cohort K Final Analysis: Enfortumab vedotin with or without pembrolizumab as first-line treatment for cisplatin (cis)-ineligible locally advanced or metastatic urothelial carcinoma: long-term follow-up analysis from EV-103 cohorts DE/A and K	J. P. Maroto Rey	**Type:** Rapid oral **Abstract number:** 4740RO **Date/time:** Saturday, October 24, 10:15-11:45
EV-302 Comorbidities (DCO3): Enfortumab vedotin plus pembrolizumab for previously untreated locally advanced or metastatic urothelial carcinoma: updated exploratory analysis of EV-302 in older patients and those with comorbidities	S. S. Sridhar	**Type:** Poster **Abstract number:** 4761P **Date/time:** Friday, October 23, 15:15-16:00
EV-302 Clinical Subgroups (DCO3): Enfortumab vedotin + pembrolizumab in previously untreated locally advanced or metastatic urothelial cancer: exploratory analyses based on disease-related characteristics from EV-302	J. Bedke	**Type:** Poster **Abstract number:** 4760P **Date/time:** Friday, October 23, 15:15-16:00
EVOLVE 3: Real-world treatment patterns in patients with locally advanced and metastatic urothelial cancer in France	F. Joly	**Type:** ePoster
EV-303/KN-905 ITT3: Perioperative pembrolizumab or enfortumab vedotin plus pembro in participants with muscle-invasive	A. Ullén	**Type:** Proffered paper session **Abstract number:**

bladder cancer who are cisplatin-ineligible: ad hoc analysis from KEYNOTE-905		4733O **Date/time:** Friday, October 23, 13:30-15:00
EV-304/KN-B15 ctDNA: ctDNA analysis of the phase 3 KEYNOTE-B15 trial: neoadjuvant and adjuvant enfortumab vedotin + pembrolizumab for participants with muscle-invasive bladder cancer who are eligible for cisplatin	J. Chatzkel	**Type:** Proffered paper session **Abstract number:** 4734O **Date/time:** Friday, October 23, 13:30-15:00
EV-304/KN-B15 ePRO: Health-related quality of life with neoadjuvant and adjuvant enfortumab vedotin plus pembrolizumab in participants (pts) with muscle-invasive bladder cancer eligible for cisplatin in the phase 3 KEYNOTE-B15 study	A. Gómez De Liaño	**Type:** Rapid oral **Abstract number:** 4738RO **Date/time:** Saturday, October 24, 10:15-11:45
EV-209 TiP: EV-209: an open-label, single-arm, phase 2 study of enfortumab vedotin plus pembrolizumab for bladder preservation in patients with muscle-invasive bladder cancer eligible for radical cystectomy	Thomas Powles	**Type:** Poster **Abstract number:** 4769TiP **Date/time:** Friday, October 23, 15:15-16:00
EV-309 TiP: EV-309: an open-label, randomized, phase 3 study of enfortumab vedotin plus pembrolizumab for bladder preservation in patients with muscle-invasive bladder cancer	Matthew D. Galsky	**Type:** Poster **Abstract number:** 4770TiP **Date/time:** Friday, October 23, 15:15-16:00
Enzalutamide		
Adelpi REALIZE: High-risk biochemically recurrent (hrBCR) hormone sensitive prostate cancer (PC): European real-world (RW) evidence on risk stratification, PSMA PET use, and physician practices	A. Merseburger	**Type:** ePoster **Abstract number:** 2063eP **Date/time:** N/A
AMNOG NMA in mHSPC: Network meta-analysis (NMA) on the safety of androgen receptor pathway inhibitors (ARPIs) in patients with metastatic hormone-sensitive prostate cancer (mHSPC) from German AMNOG dossiers	C. Ohlmann	**Type:** Poster **Abstract number:** 2295P **Date/time:** Friday, October 23, 15:15-16:00

CASPER: Outcomes of enzalutamide (ENZ) and apalutamide (APA) in metastatic hormone-sensitive prostate cancer (mHSPC): a Canadian real-world (RW) study	B. Shayegan	**Type:** ePoster **Abstract number:** 2329eP **Date/time:** N/A
ARCHES/ARANOTE indirect safety comparison: Indirect safety comparison of enzalutamide (ENZA) and darolutamide (DARO) with androgen-deprivation therapy (ADT) in metastatic hormone-sensitive prostate cancer (mHSPC)	S. Shariat	**Type:** Poster **Abstract number:** 2294P **Date/time:** Friday, October 23, 15:15-16:00
EMBARK deep PSA response: Deep prostate-specific antigen (PSA) response by prior definitive treatment (tx) in patients (pts) with high-risk biochemically recurrent prostate cancer (hrBCR): EMBARK post hoc analysis	S. Freedland	**Type:** Poster **Abstract number:** 2293P **Date/time:** Friday, October 23, 15:15-16:00
Zolbetuximab		
SPOTLIGHT ctDNA: ctDNA Assessment in Patients with CLDN18.2+, HER2−, Locally Advanced Unresectable or Metastatic (la/m) Gastric or Gastroesophageal Junction Adenocarcinoma (G/GEJ a) in SPOTLIGHT	K. Shitara	**Type:** Poster **Abstract number:** 2882P **Date/time:** Sunday, October 25, 12:00-12:45
Canadian PSP: Real-World Use of Zolbetuximab Plus Chemotherapy (CTx) in Patients with CLDN18.2+, HER2−, Locally Advanced (LA) Unresectable or Metastatic Gastric or Gastroesophageal Junction Cancer (mGC/GEJC) in a Canadian Patient Support Program (PSP)	H. Karachiwala	**Type:** Poster **Abstract number:** 2941P **Date/time:** Sunday, October 25, 12:00-12:45
Pipeline		
Phase 3 PDAC TiP: A Phase 3, double-blind, randomized trial of setidegrasib + mFOLFIRINOX or NALIRIFOX as first-line treatment for patients with metastatic pancreatic ductal adenocarcinoma (PDAC) harboring KRAS G12D mutations: Trial in progress	T. Macarulla	**Type:** Poster **Abstract number:** 3190TiP **Date/time:** Sunday, October 25, 12:00-12:45
Phase 3 NSCLC TiP: Phase 3, randomized, open-label trial of setidegrasib	F. Skoulidis	**Type:** ePoster **Abstract number:**

vs docetaxel in patients with KRAS G12D-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) that progressed on or after platinum-based chemotherapy and checkpoint inhibitor (CPI) therapy: Trial in progress		2871eTiP **Date/time:** N/A
Phase 1b/2 TiP: Phase 1b/2 study of ASP546C, a Claudin 18.2-targeting antibody-drug conjugate with a topoisomerase 1 inhibitor payload, in patients with Claudin 18.2-expressing unresectable locally advanced or metastatic solid tumors	T. Macarulla	**Type:** ePoster **Abstract number:** 1133eTiP **Date/time:** N/A
FiH TiP: A phase 1 study of ASP5834 in patients with locally advanced or metastatic solid tumors with Kirsten rat sarcoma viral oncogene homologue (KRAS) mutations or amplifications	S. Sen	**Type:** ePoster **Abstract number:** 1145eTiP **Date/time:** N/A
Combination clinical data for mss CRC: A phase 1/2 study of ASP1570 for locally advanced/metastatic microsatellite-stable (MSS) colorectal cancer (CRC)	V. Boni	**Type:** ePoster **Abstract number:** 1090eP **Date/time:** N/A

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 PADCEV and the Pfizer, Astellas and MSD Collaboration

Seagen and Astellas previously entered a clinical collaboration agreement with MSD to evaluate the combination of Seagen's and Astellas' PADCEV™ (enfortumab vedotin) and MSD's KEYTRUDA® (pembrolizumab) in patients with urothelial cancer. Pfizer Inc. successfully completed its acquisition of Seagen on December 14, 2023. KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA (known as MSD outside of the United States and Canada).

About XTANDI and the Pfizer/Astellas Collaboration

In October 2009, Medivation, Inc., which is now part of Pfizer (NYSE:PFE), and Astellas (TSE: 4503) entered into a commercial agreement to jointly develop and commercialize XTANDI® (enzalutamide) in the United States, while Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing the product outside the United States. Pfizer receives alliance revenues as a share of U.S. profits and receives royalties on sales outside the U.S.

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.

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