Press Release

Astellas Presents Scientific Progress in Advanced and Hard-to-Treat Cancers at ESMO 2024

- Eight abstracts, including two oral presentations, feature new clinical data from Astellas' oncology portfolio and two lead pipeline programs across a broad range of cancer types -

TOKYO, September 11, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") will highlight new data from across its approved and investigational cancer therapies during the 2024 European Society for Medical Oncology (ESMO) Congress being held in Barcelona, Spain on 13-17 September. Eight abstracts across a broad range of cancer types will be presented, reinforcing Astellas' commitment to making a meaningful difference to people living with advanced and hard-to-treat cancers. Six abstracts include data spanning prostate, urothelial, gastric and gastroesophageal junction (GEJ), and pancreatic cancers. Two abstracts feature Phase 1 data presented for the first time from immuno-oncology and targeted protein degradation assets.

Tadaaki Taniguchi, MD, PhD, Chief Medical Officer, Astellas:
"The data presented at ESMO are an exciting demonstration of the strength of our portfolio and the transformative potential of our pipeline to help deliver outcomes that matter for patients. Astellas has made a long-term commitment to helping people living with hard-to-treat cancers by both investing in next-generation modalities like targeted protein degradation and immuno-oncology, and by maximizing the number of patients that could benefit from our approved medicines."

Highlights at the ESMO Congress 2024 include:

- Data from the Phase 3 EV-302 study, evaluating Nectin-4 expression and response to first-line treatment of **enfortumab vedotin** in combination with pembrolizumab in previously untreated locally advanced or metastatic urothelial cancer (la/mUC). These results support the combination as a first-line advancement across la/mUC patient subgroups, regardless of Nectin-4 expression.
- Five-year follow-up data from the Phase 1/2b EV-103 DE/A study, analyzing durable responses and meaningful survival to **enfortumab vedotin** in combination with pembrolizumab in patients with first-line cis-ineligible la/mUC. These results further support the broad suitability, regardless of cis-eligibility, and long-term benefits of this regimen in la/mUC.
- Final pooled overall survival data from the Phase 3 SPOTLIGHT and GLOW trials, evaluating **zolbetuximab** plus chemotherapy as a first-line treatment in patients with HER2-negative, locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma whose tumors are Claudin 18.2-positive.

- Updates involving a Phase 2 trial in progress assessing **zolbetuximab** in combination with gemcitabine and nab-paclitaxel (GN) versus GN therapy as first-line treatment of Claudin 18.2-positive metastatic pancreatic cancer.
- Phase 3 EMBARK post-hoc analyses, evaluating **enzalutamide** in combination with leuprolide and as monotherapy versus leuprolide alone in patients with high-risk biochemical recurrent non-metastatic hormone-sensitive prostate cancer. These results support the benefits of enzalutamide both in combination with leuprolide and as monotherapy in patients aged <70 and ≥70 years.
- **Clinical data from lead pipeline assets:** Phase 1 data from **ASP3082**, the first protein degrader targeting KRAS G12D mutant to enter clinical trials, in patients with advanced pancreatic, colorectal, and non-small cell lung cancer; and preclinical, translational/early clinical data from **ASP1570**, a novel DGKζ inhibitor, in patients with advanced solid tumors. The results support continued study of these investigational therapies for the treatment of various cancer types.

Astellas Presentations at 2024 ESMO Congress

Enfortumab Vedotin

Presentation title	**Speaker**	**Presentation details**
EV-302: Exploratory Analysis of Nectin-4 Expression and Response to 1L Enfortumab Vedotin (EV) + Pembrolizumab (P) in Previously Untreated Locally Advanced or Metastatic Urothelial Cancer (la/mUC)	T. Powles	**Type:** Mini Oral Session **Abstract Number:** 1966MO **Date:** September 15
Study EV-103 Dose Escalation/Cohort A (DE/A): 5y Follow-Up Of First-Line (1L) Enfortumab Vedotin (EV) + Pembrolizumab (P) in Cisplatin (cis)-Ineligible Locally Advanced Or Metastatic Urothelial Carcinoma (la/mUC)	J. Rosenberg	**Type:** Poster **Abstract Number:** 1968P **Date:** September 15
Epidemiology and treatment patterns of patients with locally advanced or metastatic urothelial cancer in France: a non-interventional database study	F. Joly	**Type:** Poster **Abstract Number:** 2001P **Date:** September 15

Zolbetuximab

Presentation title	Speaker	Presentation details
First-line (1L) zolbetuximab + chemotherapy in patients (pts) with claudin 18.2 (CLDN18.2) +, HER2–, locally advanced (LA) unresectable or metastatic gastric or gastroesophageal junction (mG/GEJ) adenocarcinoma: A pooled final analysis of SPOTLIGHT + GLOW	Y-K Kang	**Type:** Poster **Abstract Number:** 1438P **Date:** September 16
Zolbetuximab With Gemcitabine + Nab-Paclitaxel (GN) in First-Line Treatment of Claudin 18.2–Positive Metastatic Pancreatic Cancer (mPC): Phase 2, Open-Label, Randomized Study	W. Park	**Type:** Poster **Abstract Number:** 1532TiP **Date:** September 16

Enzalutamide

Presentation title	Speaker	Presentation details
Enzalutamide (enza) with or without leuprolide in patients (pts) with high-risk biochemically recurrent (hrBCR) prostate cancer (PC): EMBARK post-hoc analysis by age	N. D. Shore	**Type:** Poster **Abstract Number:** 1638P **Date:** September 15

Pipeline

Presentation title	Speaker	Presentation details
Phase 1/2 Trial of ASP1570, a Novel Diacylglycerol Kinase ζ Inhibitor, in Patients With Advanced Solid Tumors	D. Olsen	**Type:** Poster **Abstract Number:** 1004P **Date:** September 14
Preliminary safety and clinical activity of ASP3082, a first-in-class, KRAS G12D selective protein degrader in adults with advanced pancreatic (PC), colorectal	W. Park	**Type:** Proffered Paper Session **Abstract Number:** 608O **Date:** September 15

(CRC), and non-small cell lung cancer (NSCLC)		

About Astellas
Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into VALUE for patients. For more information, please visit our website at https://www.astellas.com/en.

About PADCEV and the Astellas, Pfizer and MSD Collaboration
Astellas and Pfizer have a clinical collaboration agreement with MSD to evaluate the combination of Astellas' and Pfizer's PADCEV™ (enfortumab vedotin-ejfv) and MSD's KEYTRUDA® (pembrolizumab) in patients with previously untreated metastatic urothelial cancer. 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.

Astellas 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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