

Astellas Showcases Scientific Advancements Across its Oncology Portfolio at 2024 ASCO Annual Meeting

16 abstracts feature new data and post-hoc analyses of pivotal trials across several types of hard-to-treat cancers

TOKYO, May 13, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, “Astellas”) will share new research from across its innovative portfolio of approved and investigational cancer therapies during the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting from May 31 - June 4. A total of 16 abstracts will be presented, including new data from pivotal trials supporting ongoing regulatory reviews. The volume of data being presented by Astellas reinforces its commitment to changing the course of cancer treatment through targeted therapies for hard-to-treat cancers like prostate, urothelial, and gastric/gastroesophageal junction (GEJ) cancers.

Tadaaki Taniguchi, MD, PhD, Chief Medical Officer, Astellas

“The data at ASCO demonstrate the strength and breadth of our growing oncology portfolio and provide new insights into our transformative therapies for patients living with some of the most devastating cancers. Recent regulatory achievements mean our oncology medicines are reaching more patients than ever worldwide, and we are continuing to pursue novel targets and invest in research to improve overall survival and raise quality of life.”

Highlights at the 2024 ASCO Annual Meeting include:

- Further data from the Phase 3 EV-302 trial evaluating enfortumab vedotin in combination with pembrolizumab versus chemotherapy in previously untreated locally advanced or metastatic urothelial carcinoma (la/mUC), including data in cisplatin-eligible and cisplatin-ineligible populations. These results support the combination as a landmark advancement in the care of patients with la/mUC, regardless of cisplatin eligibility, and serve as the basis of ongoing regulatory reviews by the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP), Japan’s Ministry of Health, Labour and Welfare (MHLW), and the China National Medical Products Administration (NMPA).
- Final overall survival (OS) results from the Phase 3 SPOTLIGHT study, evaluating the efficacy and safety of zolbetuximab – a first-in-class claudin (CLDN) 18.2-targeted monoclonal antibody approved by Japan’s MHLW and currently in review by multiple regulatory authorities for approval worldwide. In this abstract, zolbetuximab is evaluated in combination with mFOLFOX6 (a combination chemotherapy regimen that includes oxaliplatin, leucovorin, and fluorouracil) for the first-line treatment of patients with CLDN18.2 positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma. These results underpin the strength of the zolbetuximab clinical data supporting the pursuit of regulatory approvals worldwide.
- Two new post-hoc analyses of the Phase 3 EMBARK trial, which evaluated enzalutamide plus leuprolide, placebo plus leuprolide, and enzalutamide (single agent) in patients with nonmetastatic hormone- (or castration-) sensitive prostate

cancer (nmHSPC or nmCSPC) with high-risk biochemical recurrence (BCR), including an oral presentation on the impact of treatment suspension on health-related quality of life and a poster presentation on sexual activity patient-reported outcomes.

Astellas Presentations at 2024 ASCO Annual Meeting

Enfortumab Vedotin

Presentation Title	Lead Author	Presentation Details
Impact of exposure on outcomes with enfortumab vedotin in patients with locally advanced or metastatic urothelial cancer	D. Petrylak	Type: Oral Presentation Abstract Number: 4503 Date: June 3, 2024 8:00-11:00 AM CDT
Patient-reported outcomes (PROs) from a randomized, phase 3 trial of enfortumab vedotin plus pembrolizumab (EV+P) versus platinum-based chemotherapy (PBC) in previously untreated locally advanced or metastatic urothelial cancer (la/mUC)	S. Gupta	Type: Oral Presentation Abstract Number: 4502 Date: June 3, 2024 8:00-11:00 AM CDT
Enfortumab vedotin (EV) in triple-negative breast cancer (TNBC) and HR+/HER2-breast cancer (BC) cohorts of EV-202	A. Giordano	Type: Oral Presentation Abstract Number: 1005 Date: June 1, 2024 3:00-6:00 PM CDT
Enfortumab vedotin (EV) with pembrolizumab (P) versus chemotherapy (chemo) in previously untreated locally advanced or metastatic urothelial carcinoma (la/mUC): Analysis of cisplatin (cis)-eligible population from EV-302/KEYNOTE-A39	J. Bedke	Type: Poster Presentation Abstract Number: 4562 Date: June 2, 2024 9:00 AM-12:00 PM CDT
Enfortumab vedotin (EV) with pembrolizumab (P) versus chemotherapy (chemo) in previously untreated locally advanced or metastatic urothelial carcinoma (la/mUC): Analysis of the cisplatin (cis)-ineligible population from EV-302/KEYNOTE-A39	M. Van Der Heijden	Type: Poster Presentation Abstract Number: 4563 Date: June 2, 2024 9:00 AM-12:00 PM CDT

Enfortumab vedotin (EV) in non-squamous and squamous non–small cell lung cancer (NSCLC) cohorts of EV-202	K. Muro	Type: Poster Presentation Abstract Number: 8585 Date: June 3, 2024 1:30-4:30 PM CDT
Enfortumab vedotin (EV) in previously treated gastric/esophageal cancers cohorts of EV-202	K. Muro	Type: Poster Presentation Abstract Number: 4046 Date: June 1, 2024 1:30-4:30 PM CDT
Study EV-103: Neoadjuvant treatment with enfortumab vedotin monotherapy in cisplatin-ineligible patients with muscle invasive bladder cancer (MIBC): 2-year event-free survival and safety data for Cohort H	P. O'Donnell	Type: Poster Presentation Abstract Number: 4564 Date: June 2, 2024 9:00 AM-12:00 PM CDT
Enfortumab vedotin and pembrolizumab as first-line treatment in recurrent or metastatic head and neck squamous cell carcinoma: a cohort of the EV-202 trial	P. Swiecicki	Type: Poster Presentation Abstract Number: TPS6116 Date: June 2, 2024 9:00 AM-12:00 PM CDT
Systematic Literature Review and Network Meta-Analysis of First-Line Therapies for Locally Advanced/Metastatic Urothelial Carcinoma	L. Bloudek	Type: Online publication Abstract Number: e16547
Real-world first-line treatment patterns and outcomes in patients with locally advanced or metastatic urothelial carcinoma in the United States	R. Chen	Type: Online Publication Abstract Number: e23287

Enzalutamide

Presentation Title	Lead Author	Presentation Details
EMBARC post-hoc analysis of impact of treatment suspension (TxS) on health-related quality of life (HRQoL)	S. Freedland	Type: Oral Presentation Abstract Number: 5005 Date: June 1, 2024 3:00-6:00PM CDT
EMBARC post hoc analysis of sexual activity (SA) patient-reported outcomes (PROs) in patients	S. Freedland	Type: Poster Presentation Abstract Number: 5084 Date: June 2, 2024 9:00 AM-12:00 PM CDT

(pts) who were sexually active or interested in sex at baseline (BL)		
Physicians use of first-line treatment intensification in metastatic castration-sensitive prostate cancer (mCSPC): A discrete choice experiment	S. Loeb	Type: Poster Presentation Abstract Number: 5087 Date: June 2, 2024 9:00 AM-12:00 PM CDT
Characteristics and treatment (Tx) patterns (TxP) of high-risk biochemically recurrent (HR-BCR) non-metastatic castration-sensitive prostate cancer in the real-world by race, age, and prostate-specific antigen (PSA) doubling time (PSADT)	A. Morgans	Type: Online-Only Abstract Abstract Number: e17071

Zolbetuximab

Presentation Title	Lead Author	Presentation Details
Final overall survival results from phase 3 SPOTLIGHT study evaluating zolbetuximab + mFOLFOX6 as first-line (1L) treatment for patients (pts) with claudin 18 isoform 2 (CLDN18.2)+, HER2-, locally advanced (LA) unresectable or metastatic gastric or gastroesophageal junction (mG/GEJ) adenocarcinoma	K. Shitara	Type: Poster Presentation Abstract Number: 4036 Date: June 1, 2024 1:30-4:30 PM CDT

About PADCEV and the Astellas, Pfizer and Merck Collaboration

Astellas and Pfizer have a clinical collaboration agreement with Merck to evaluate the combination of Astellas' and Pfizer's PADCEV™ (enfortumab vedotin-ejfv) and Merck'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.

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>.

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

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.

###

Contacts for inquiries or additional information:

For Media

Brianna Wilkins
+1 513-633-4593
brianna.wilkins@astellas.com

For Investors

Astellas Pharma Inc.
Corporate Communications
+81-3-3244-3202