Press Release

Astellas Highlights Continued Delivery of Strong Cancer Portfolio and Pipeline at 2023 ASCO Annual Meeting

Data at meeting illustrate company's progress in addressing unmet needs in a broad range of hard-to-treat solid tumors and hematologic malignancies

TOKYO, May 25, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") will share new research from across its expanding portfolio of approved and investigational cancer therapies during the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting from June 2-6. A total of 15 abstracts, covering three approved medicines and one investigational therapy, will be presented underscoring the company's focus on pursuing targeted therapies for hard-to-treat cancers where few therapies exist, including prostate, urothelial, gastric/gastroesophageal junction (GEJ) and head & neck cancers, as well as acute myeloid leukemia (AML).

"The research presented at ASCO reflects our intense focus on how we are continuing to grow the breadth and utility of our oncology portfolio and pipeline for the oncology community and patients with cancer, particularly those with advanced disease," said Ahsan Arozullah, MD, MPH, Senior Vice President, Head of Oncology Development, Astellas. "Across our clinical development programs, these data add to the growing body of evidence and support our efforts to identify ways we can impact the course of disease, and redefine what is possible for patients who need it most."

Highlights at the 2023 ASCO Annual Meeting include:

- A rapid abstract update presentation of investigational data from the Phase 3 GLOW clinical trial, evaluating the efficacy and safety of zolbetuximab – an investigational first-in-class Claudin-18.2 (CLDN18.2) targeted monoclonal antibody – in combination with CAPOX (a combination chemotherapy regimen that includes capecitabine and oxaliplatin) for the first-line treatment of patients with CLDN18.2-positive, HER2-negative, locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma.
- The first clinical data from the Phase 1 EV-104 study evaluating intravesical administration of enfortumab vedotin, an antibody-drug conjugate developed in partnership with Seagen, in patients with non-muscle invasive bladder cancer.
- The first clinical data from the Phase 2 EV-202 study evaluating enfortumab vedotin monotherapy in previously treated advanced head & neck cancers.

"For the first time, we will present clinical data at ASCO investigating the potential of enfortumab vedotin as monotherapy in patients with previously treated advanced head and neck cancers, who have ongoing and unmet therapeutic needs," said Erhan Berrak, MD, Vice President, Medical Affairs, Oncology Therapeutic Area Head, Astellas. "Additionally, Astellas is pleased to share investigational data at ASCO that demonstrate continued progress for our zolbetuximab clinical development program in locally advanced or metastatic gastric and GEJ cancers, which have limited effective treatment options."

Astellas Presentations at 2023 ASCO Annual Meeting

Enfortumab Vedotin

Presentation Title	Lead Author	Presentation Details
A first-in-human trial of intravesical enfortumab vedotin (EV), an antibody-drug conjugate (ADC), in patients with non-muscle invasive bladder cancer (NMIBC): Interim results of a phase 1 study (EV-104)	A. Kamat	**Type**: Poster Presentation **Abstract Number**: 4596 **Date**: Sat. June 3, 8:00-11:00 am CDT **Poster Session**: Genitourinary Cancer – Kidney and Bladder
Study EV-103 dose escalation/cohort A: Long-term outcome of enfortumab vedotin + pembrolizumab in first-line (1L) cisplatin-ineligible locally advanced or metastatic urothelial carcinoma (la/mUC) with nearly 4 years of follow-up	S. Gupta	**Type**: Oral Presentation **Abstract Number**: 4505 **Date**: Mon. June 5, 12:54 pm CDT **Oral Abstract Session**: Genitourinary Cancer – Kidney and Bladder
Enfortumab vedotin in the previously treated advanced head and neck cancer (HNC) cohort of EV-202	P. Swiecicki	**Type**: Poster Presentation **Abstract Number**: 6017 **Date**: Mon. June 5, 5:04 pm CDT **Poster Session**: Head and Neck Cancer
EV-203: Phase 2 trial of enfortumab vedotin in patients with previously treated advanced urothelial carcinoma in China	S. Li	**Type**: Online-Only Abstract **Abstract Number**: e16574
Study EV-103: Neoadjuvant treatment with enfortumab vedotin monotherapy in cisplatin-ineligible patients (pts) with muscle invasive bladder cancer (MIBC): Updated results for Cohort H	T. Flaig	**Type**: Poster Presentation **Abstract Number**: 4595 **Date**: Sat. June 3, 8:00-11:00 am CDT **Poster Session**: Genitourinary Cancer – Kidney and Bladder
Enfortumab vedotin (EV) with or without pembrolizumab (P) in patients (pts) who are cisplatin-ineligible with previously untreated locally advanced or metastatic urothelial cancer (la/mUC): Additional 3-month follow-up on cohort K data	T. Friedlander	**Type**: Poster Presentation **Abstract Number**: 4568 **Date**: Sat. June 3, 8:00-11:00 am CDT

		Poster Session: Genitourinary Cancer – Kidney and Bladder
Real-world use, dose intensity, and adherence to an antibody-drug conjugate (ADC) in metastatic urothelial cancer (mUC)	K. Tsingas	**Type**: Online-Only Abstract **Abstract Number**: e16567
KEYNOTE-905/EV-303: A phase 3 study to evaluate the efficacy and safety of perioperative pembrolizumab or pembrolizumab plus enfortumab vedotin (EV) for muscle-invasive bladder cancer (MIBC)	A. Necchi	**Type**: Poster Presentation **Abstract Number**: TPS4601 **Date**: Sat. June 3, 8:00-11:00 am CDT **Poster Session**: Genitourinary Cancer – Kidney and Bladder

Enzalutamide

Presentation Title	Lead Author	Presentation Details
Longitudinal transcriptome profiling of localized hormone-sensitive tumors in treatment-naïve ENACT patients with prostate cancer with and without enzalutamide (ENZA)	A. Ross	**Type**: Poster Presentation **Abstract Number**: 5026 **Date**: Sat. June 3, 8:00-11:00 am CDT **Poster Session**: Genitourinary Cancer –Prostate, Testicular, and Penile
Outcomes of patients (pts) with de novo metastatic hormone-sensitive prostate cancer (mHSPC) who progressed to metastatic castration-resistant prostate cancer (mCRPC): a post-hoc analysis of the TRUMPET registry	D. Shevrin	**Type**: Online-Only Abstract **Abstract Number**: e17085
Real-world baseline characteristics and first-line (1L) treatment (Tx) in patients (pts) with de novo metastatic castration-sensitive prostate cancer (mCSPC) by disease volume	S. Freedland	**Type**: Online-Only Abstract **Abstract Number**: e17081

Zolbetuximab

Presentation Title	Lead Author	Presentation Details
Zolbetuximab + CAPOX in 1L claudin-18.2+ (CLDN18.2+)/HER2− locally advanced (LA) unresectable or metastatic gastric or gastroesophageal junction (mG/GEJ) adenocarcinoma: Primary phase 3 results from GLOW (Rapid abstract update presentation following March 22 Plenary Series session)	R. Xu	**Type**: Rapid Oral **Abstract Number**: N/A **Date**: Sat. June 3, 1:06 pm CDT **Session**: ASCO Plenary Series: Rapid Abstract Updates
Phase 2 trial of zolbetuximab in combination with mFOLFOX6 and nivolumab in patients with advanced or	K. Shitara	**Type**: Poster Presentation

metastatic claudin 18.2-positive, HER2-negative gastric or gastroesophageal junction adenocarcinomas		**Abstract Number**: TPS4173 **Date**: Mon. June 5, 8:00-11:00 am CDT **Poster Session**: Gastrointestinal Cancer – Gastroesophageal, Pancreatic, and Hepatobiliary
Global prevalence of CLDN18.2 positivity in tumor samples from patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma: Biomarker analysis of two zolbetuximab phase 3 studies (SPOTLIGHT and GLOW)	K. Shitara	**Type**: Poster Presentation **Abstract Number**: 4035 **Date**: Mon. June 5, 8:00-11:00 am CDT **Poster Session**: Gastrointestinal Cancer – Gastroesophageal, Pancreatic, and Hepatobiliary

Gilteritinib

Presentation Title	Lead Author	Presentation Details
Work Absenteeism and Disability Days after Diagnosis among Patients with AML and Caregivers	T. LeBlanc	**Type**: Online-Only Abstract **Abstract Number**: e19002

About Enfortumab Vedotin and the Astellas and Seagen Collaboration
Astellas and Seagen are co-developing enfortumab vedotin under a 50:50 worldwide development and commercialization collaboration. In the United States, Astellas and Seagen co-promote enfortumab vedotin. In the Americas outside the U.S., Seagen holds responsibility for commercialization activities and regulatory filings. Outside of the Americas, Astellas holds responsibility for commercialization activities and regulatory filings.

About the Astellas, Seagen and Merck Collaboration
Astellas and Seagen entered a clinical collaboration agreement with Merck to evaluate the combination of Astellas' and Seagen'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.

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 U.S. 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 agents discussed herein are under investigation and have not been established. There is no guarantee that the agents will receive regulatory approval and become commercially available for uses 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.

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