Press Release

Astellas to Share New Data Across Hard-to-Treat Cancers During ESMO Congress 2023

Data include three late-breaking abstracts, underscoring Astellas' efforts to potentially redefine expectations for patients across its oncology portfolio

TOKYO, Oct 15, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") will share new research results during the European Society for Medical Oncology (ESMO) Congress 2023 from October 20-24, showcasing the company's focus on making a meaningful difference for people living with hard-to-treat cancers. A total of 13 abstracts will be presented, highlighting data from two established medicines and one investigational therapy, across prostate, urothelial and gastric/gastroesophageal junction (GEJ) cancers.

Ahsan Arozullah, MD, MPH, Senior Vice President and Head of Oncology Development, Astellas
"At Astellas, we're working to change the course of cancer care, including through scientific advancements to address pressing unmet needs. We look forward to sharing our latest investigational data at ESMO, including data from the Phase 3 EV-302 study of enfortumab vedotin, which is developed in partnership with Seagen, in combination with Merck's pembrolizumab in patients with previously untreated locally advanced or metastatic urothelial cancer in a late-breaking presentation. We will also present expanded data from a Phase 3 study investigating enzalutamide plus leuprolide in patients with nonmetastatic hormone-sensitive prostate cancer with high-risk biochemical recurrence."

Moitreyee Chatterjee-Kishore, PhD, MBA, Senior Vice President and Head of Immuno-Oncology Development, Astellas
"Over the last several months, Astellas has demonstrated considerable progress in our efforts to make a purposeful impact in the care of patients with advanced gastric cancer through regulatory submissions for our investigational therapy, zolbetuximab, across the U.S., Asia, and Europe. During ESMO, we will share updated data from two Phase 3 clinical studies, highlighting important clinical data of zolbetuximab in gastric and GEJ cancer patients whose tumors are CLDN18.2-positive."

Other highlights at the ESMO Congress 2023 include:

- Data from Cohort L of the EV-103 study evaluating enfortumab vedotin monotherapy in cisplatin-ineligible patients with muscle invasive bladder cancer (MIBC)
- Health-related quality of life (HRQoL) data from the Phase 3 SPOTLIGHT and GLOW trials, evaluating zolbetuximab as a first-line treatment in patients with HER2-negative, locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma whose tumors are CLDN18.2-positive
- HRQoL data in nonmetastatic hormone-sensitive prostate cancer (nmHSPC) patients with high-risk biochemical recurrence (BCR) from the EMBARK study evaluating enzalutamide plus leuprolide, leuprolide plus placebo and enzalutamide monotherapy

Astellas Presentations at ESMO Congress 2023

Enfortumab Vedotin

Presentation Title	Speaker	Presentation Details
EV-302/KEYNOTE-A39: Open-label, randomized Phase 3 study of enfortumab vedotin in combination with pembrolizumab (EV+P) vs chemotherapy (chemo) in previously untreated locally advanced metastatic urothelial carcinoma (la/mUC)	T. B. Powles	**Type:** Presidential 2 **Abstract Number**: LBA6 **Date**: Sunday, October 22
Study EV-103 Cohort L: Perioperative treatment w/ enfortumab vedotin (EV) monotherapy in cisplatin (cis)-ineligible patients (pts) w/ muscle invasive bladder cancer (MIBC)	S. Sridhar	**Type:** Mini Oral **Abstract Number**: 2365MO **Date**: Sunday, October 22

Enzalutamide

Presentation Title	Speaker	Presentation Details
Health-related quality of life in nonmetastatic hormone-sensitive prostate cancer patients with high-risk biochemical recurrence from the EMBARK study	S. Freedland	**Type:** Mini Oral **Abstract Number**: 1766MO **Date**: Sunday, October 22
Treatment of high-risk biochemically recurrent prostate cancer with enzalutamide in combination with leuprolide acetate: Secondary endpoints from EMBARK	N. Shore	**Type:** Poster **Abstract Number**: 1778P **Date**: Sunday, October 22
Enzalutamide monotherapy for the treatment of prostate cancer with high-risk biochemical recurrence: EMBARK secondary endpoints	U. F. De Giorgi	**Type:** Poster **Abstract Number**: 1777P **Date**: Sunday, October 22
Real-world overall survival with enzalutamide and abiraterone acetate in patients with chemotherapy-naïve metastatic castration-resistant prostate cancer	S. Freedland	**Type:** Poster **Abstract Number**: 1827P **Date**: Sunday, October 22
China ARCHES: a multicenter, Phase 3, randomized, double-blind, placebo-controlled efficacy and safety trial of enzalutamide + androgen deprivation therapy (ADT) vs placebo + ADT in Chinese patients with metastatic hormone-sensitive prostate cancer	G. Zeng	**Type:** Poster **Abstract Number**: 1795P **Date**: Sunday, October 22
Blood based biomarkers identify metastatic castration-resistant prostate cancer with the greatest benefit from continuing enzalutamide beyond progression in combination with docetaxel: a pre-specified biomarker study of the phase 3b PRESIDE trial	M. Ruiz Vico	**Type:** Poster **Abstract Number**: 1836P **Date**: Sunday, October 22

Zolbetuximab

Presentation Title	Speaker	Presentation Details
Updated efficacy and safety results from phase 3 GLOW study evaluating zolbetuximab + CAPOX as first-line (1L) treatment for patients with claudin-18 isoform 2-positive (CLDN18.2)+, HER2−, locally advanced (LA) unresectable or metastatic gastric or gastroesophageal junction (mG/GEJ) adenocarcinoma	F. Lordick	**Type:** Mini Oral **Abstract Number**: LBA81 **Date**: Saturday, October 21
Updated efficacy and safety results from phase 3 SPOTLIGHT study evaluating zolbetuximab + mFOLFOX6 as first-line (1L) treatment for patients with claudin-18 isoform 2-positive (CLDN18.2+), HER2−, locally advanced (LA) unresectable or metastatic gastric or gastroesophageal junction (mG/GEJ) adenocarcinoma	J. A. Ajani	**Type:** Mini Oral **Abstract Number**: LBA82 **Date**: Saturday, October 21
Health-related quality of life (HRQoL) in patients with claudin-18 isoform 2-positive (CLDN18.2+) locally advanced (LA) unresectable or metastatic gastric or gastroesophageal junction (mG/GEJ) adenocarcinoma: results from SPOTLIGHT and GLOW	F. Lordick	**Type:** Poster **Abstract Number**: 1530P **Date**: Monday, October 23
Effects of antiemetics on zolbetuximab-induced gastric injury and emesis frequency in ferrets	J. Wang	**Type:** Poster **Abstract Number**: 38P **Date**: Sunday, October 22
Real-world practices and physician perspectives on biomarker testing and treatment patterns in patients with locally advanced unresectable or metastatic (la/m) gastric/gastroesophageal junction (G/GEJ) adenocarcinoma in the US	K. Lewis	**Type:** Poster **Abstract Number**: 160P **Date**: Saturday, October 21

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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