Press Release

Astellas to Present Data from Expanding Oncology Portfolio During the 2021 ASCO Annual Meeting

Astellas' ambitious innovation and committed collaboration support new research on investigational and approved therapies in hard-to-treat cancers

TOKYO, May 17, 2021 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") will share new data across its oncology portfolio during the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting from June 4-8, 2021. Covering three approved treatments and one investigational therapy, the 12 Astellas-sponsored abstracts underscore the company's commitment to advancing treatment options for difficult-to-treat cancers, including bladder, prostate and gastric/gastroesophageal junction (GEJ) cancers, as well as acute myeloid leukemia (AML).

"While oncology has seen incredible advancements over the last decade, there are still many patients whose disease has few or no effective treatments. Astellas is determined to change that reality," said Andrew Krivoshik, M.D., Ph.D., Astellas Senior Vice President and Oncology Therapeutic Area Head. "Our data suggest that progress is possible, and we are committed to working with physicians, patients and others in the cancer community to change the course of hard-to-treat forms of cancer."

"The latest investigational research supported by Astellas reflects our commitment to understanding unmet needs in cancer care and our mission to turn innovative science into treatments that are truly valued by patients and healthcare professionals," said Erhan Berrak, M.D., Astellas Vice President of Medical Affairs, Oncology. "For example, research to be presented at ASCO includes a closer look at real-world treatment patterns in several clinical states of advanced prostate cancer, including the use of advanced treatments across racial groups – a topic closely aligned with the ASCO 2021 theme of equity."

Astellas will share data across its portfolio and investigational therapies, with highlights including:

- Quality of life results from the Phase 3 EV-301 trial of enfortumab vedotin (EV) and an updated analysis of efficacy and safety data from EV-201 cohort 2 of EV; updated durability and long-term outcomes from the EV-103 clinical trial of EV and pembrolizumab – all in advanced types of urothelial cancer
- Research on racial disparities in advanced prostate cancer treatment, as well as real-world treatment patterns for patients with advanced prostate cancer

- Follow-up data from the Phase 3 ADMIRAL trial evaluating gilteritinib in patients with relapsed or refractory (resistant to treatment) AML with a FLT3 mutation
- Data from the Phase 2 study of zolbetuximab plus mFOLFOX6 in claudin 18.2-positive (CLDN18.2+) locally advanced or metastatic gastric or GEJ adenocarcinoma

Astellas Presentations at ASCO21

Enfortumab Vedotin

Presentation Title	Lead Author	Presentation Details
Enfortumab vedotin in cisplatin-ineligible patients with locally advanced or metastatic urothelial cancer who received prior PD-1/PD-L1 inhibitors: An updated analysis of EV-201 Cohort 2	B. McGregor	Type: Poster Abstract Number: 4524
Study EV-103: Update on durability results and long-term outcome of enfortumab vedotin + pembrolizumab in first line locally advanced or metastatic urothelial carcinoma (la/mUC)	T. Friedlander	Type: Poster Abstract Number: 4528
Quality of life, functioning, and symptoms in patients with previously treated locally advanced or metastatic urothelial carcinoma from EV-301: A randomized phase 3 trial of enfortumab vedotin vs chemotherapy	R. Mamtani	Type: Poster Abstract Number: 4539
KEYNOTE-B15/EV-304: Randomized phase 3 study of perioperative enfortumab vedotin plus pembrolizumab versus chemotherapy in cisplatin-eligible patients with muscle-invasive bladder cancer (MIBC)	C. Hoimes	Type: Poster Abstract Number: TPS4587
Opioid use in locally advanced or metastatic urothelial carcinoma patients and matched non-cancer controls	S. Grewal	Type: Publication Only Abstract Number: e16517

Enzalutamide

Presentation Title	Lead Author	Presentation Details
The efficacy of enzalutamide (ENZA) plus androgen deprivation therapy (ADT) on bone oligometastatic hormone-sensitive prostate cancer: A post hoc analysis of ARCHES	A. Armstrong	Type: Poster Abstract Number: 5071
Real world first-line (1L) treatment patterns in patients (pts) with metastatic castration-sensitive prostate cancer (mCSPC) in a U.S. health insurance database	U. Swami	Type: Poster Abstract Number: 5072
Real-world utilization of advanced therapies and racial disparity among patients with metastatic castration-sensitive prostate cancer (mCSPC): A Medicare database analysis	S. Freedland	Type: Poster Abstract Number: 5073
Real-world treatment patterns among patients diagnosed with metastatic castration-sensitive prostate cancer (mCSPC) in community oncology settings	D. George	Type: Poster Abstract Number: 5074

Gilteritinib

Presentation Title	Lead Author	Presentation Details
Follow-up of patients with *FLT3*-mutated R/R AML in the phase 3 ADMIRAL trial	A. Perl	Type: Poster Abstract Number: 7013

Press Release

Zolbetuximab

Presentation Title	Lead Author	Presentation Details
Phase 2 study of zolbetuximab plus mFOLFOX6 in claudin 18.2-positive locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma (G/GEJ): ILUSTRO cohort 2	S. Klempner	Type: Publication Only Abstract Number: e16063
Effect of ethnicity and chemotherapy (mFOLFOX6) on zolbetuximab pharmacokinetics in patients with claudin 18.2+ locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma (G/GEJ)	K. Lee	Type: Publication Only Abstract Number: e16078

The ASCO 2021 Annual Meeting abstracts are available at the ASCO Meeting Library.

###

Enfortumab Vedotin Collaborations
Astellas and Seagen Inc. 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 US, Seagen holds responsibility for commercialization activities and regulatory filings. Outside of the Americas, Astellas holds responsibility for commercialization activities and regulatory filings.

Astellas and Seagen entered a clinical collaboration agreement with Merck to evaluate the combination of enfortumab vedotin 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., Kenilworth, NJ, USA.

Enzalutamide 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 global agreement to jointly develop and commercialize enzalutamide. The companies jointly commercialize enzalutamide in the United States and Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing enzalutamide outside the United States.

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.

Press Release

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.

###

Contacts for inquiries or additional information:
Astellas Pharma Inc. Corporate Advocacy & Relations
TEL: +81-3-3244-3201

Astellas Portfolio Communications
Chris Goldrick
TEL: +1 847-224-3014
chris.goldrick@astellas.com