Press Release

Astellas Highlights Data on Advanced and Rare Cancers during 2022 ASCO Annual Meeting and EHA 2022 Hybrid Congress

Abstracts represent exciting research progress across four cancers where patients have limited treatment options

TOKYO, May 12, 2022 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") will share new research during the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting from June 3-7 and the European Hematology Association (EHA) 2022 Hybrid Congress from June 9-12. A total of 13 abstracts from the company's expanding portfolio of approved and investigational therapies will be presented across both meetings, underscoring the company's commitment to advancing treatment options for advanced and rare cancers, including prostate, pancreatic and urothelial cancer, as well as acute myeloid leukemia (AML).

"While a robust Phase 3 clinical trial program in gastric/gastroesophageal junction cancer for our investigational therapy zolbetuximab is well underway, the ASCO Annual Meeting will include the first trial-in-progress presentation from our expanded Phase 2 clinical trial in Claudin 18.2-positive pancreatic cancer," said Ahsan Arozullah, M.D., M.P.H., Senior Vice President and Head of Development Therapeutic Areas, Astellas. "The progress of these clinical studies reflects our enthusiasm to continue investigating the potential to benefit patients by targeting the emerging Claudin 18.2 biomarker."

"At Astellas, our mission is to not only advance innovative science, but to create value for patients and the oncology community," said Erhan Berrak, M.D., Vice President of Global Medical Affairs, Oncology, Astellas. "Our advanced prostate cancer data at ASCO, which range from new analyses of our ARCHES pivotal trial in metastatic hormone-sensitive prostate cancer to data on patient preferences and prescriber treatment decisions, will help inform discussions between patients and providers about novel hormone therapies."

Highlights at the 2022 ASCO Annual Meeting include:

- An overview of the expanded Phase 2 open-label, randomized study of zolbetuximab in combination with nab-paclitaxel and gemcitabine as an investigational first-line treatment for patients with Claudin 18.2-positive metastatic pancreatic cancer
- Long-term (24-month) data from the Phase 3 EV-301 trial, which evaluated enfortumab vedotin versus chemotherapy in adult patients with locally advanced or metastatic urothelial cancer who were previously treated with platinum-based chemotherapy and a PD-1/L1 inhibitor
- Four post-hoc analyses from the Phase 3 ARCHES study, which compared enzalutamide plus androgen deprivation therapy (ADT) versus placebo plus ADT in men with metastatic hormone-sensitive prostate cancer (mHSPC)

Highlights at the EHA 2022 Hybrid Congress include:

- Encore data from the COMMODORE Phase 3 confirmatory study of gilteritinib versus salvage chemotherapy in FLT3 mutation-positive relapsed or refractory AML in China and other countries
- An overview of the CLEVO non-interventional investigational study of FLT3 mutation frequency in patients with AML in Europe and the U.S.

Astellas Presentations at 2022 ASCO Annual Meeting

Enfortumab Vedotin

Presentation Title	Lead Author	Presentation Details
Long-term outcomes in EV-301: 24-month findings from the Phase 3 trial of enfortumab vedotin versus chemotherapy in patients with previously treated advanced urothelial carcinoma	J. Rosenberg	Type: Poster Discussion Abstract Number: 4516 Date: Saturday, June 4, 2022 Poster Session: Genitourinary Cancer – Kidney and Bladder Presentation: 1:15 – 4:15 p.m. CDT Poster Discussion Session: Genitourinary Cancer – Kidney and Bladder Presentation: 4:30 – 6 p.m. CDT
Benchmarking maintenance therapy survival in first-line advanced urothelial carcinoma using disease modeling	M. Galsky	Type: Poster Presentation Abstract Number: 4575 Date: Saturday, June 4, 2022 Poster Session: Genitourinary Cancer – Kidney and Bladder Presentation: 1:15 – 4:15 p.m. CDT
Real-world treatment patterns and clinical outcomes with first-line therapy in cisplatin-eligible and ineligible patients with advanced urothelial carcinoma	G. Sonpavde	Type: Poster Presentation Abstract Number: 4565 Date: Saturday, June 4, 2022 Poster Session: Genitourinary Cancer – Kidney and Bladder Presentation: 1:15 – 4:15 p.m. CDT
Study EV-103 Cohort H: Antitumor activity of neoadjuvant treatment with enfortumab vedotin monotherapy in patients with muscle-invasive bladder cancer who are cisplatin-ineligible	D. Petrylak	Type: Poster Presentation Abstract Number: 4582 Date: Saturday, June 4, 2022 Poster Session: Genitourinary Cancer – Kidney and Bladder Presentation: 1:15 – 4:15 p.m. CDT

Enzalutamide

Presentation Title	Lead Author	Presentation Details
Radiographic progression in the absence of prostate-specific antigen (PSA) progression in patients with metastatic hormone-sensitive prostate cancer	A. Armstrong	Type: Poster Presentation Abstract Number: 5072 Date: Monday, June 6, 2022 Poster Session: Genitourinary Cancer—Prostate, Testicular, and Penile

(mHSPC): Post hoc analysis of ARCHES		Presentation: 1:15 – 4:15 p.m. CDT
Prevalence of DNA damage repair (DDR) alterations in patients with metastatic hormone-sensitive prostate cancer (mHSPC) receiving enzalutamide (ENZA) or placebo (PBO) plus androgen deprivation therapy (ADT): ARCHES post hoc analysis	A. Azad	Type: Poster Presentation Abstract Number: 5074 Date: Monday, June 6, 2022 Poster Session: Genitourinary Cancer—Prostate, Testicular, and Penile Presentation: 1:15 – 4:15 p.m. CDT
The association of germline *HSD3B1* genotype with outcomes in metastatic hormone-sensitive prostate cancer (mHSPC) treated with androgen deprivation therapy (ADT) with or without enzalutamide (ENZA) [ARCHES]	N. Sharifi	Type: Poster Presentation Abstract Number: 5022 Date: Monday, June 6, 2022 Poster Session: Genitourinary Cancer—Prostate, Testicular, and Penile Presentation: 1:15 – 4:15 p.m. CDT
Clinical outcomes and safety of enzalutamide (ENZA) plus androgen-deprivation therapy (ADT) in metastatic hormone-sensitive prostate cancer (mHSPC) in patients aged <75 and ≥75 years: ARCHES post hoc analysis	R. Szmulewitz	Type: Poster Presentation Abstract Number: 5069 Date: Monday, June 6, 2022 Poster Session: Genitourinary Cancer—Prostate, Testicular, and Penile Presentation: 1:15 – 4:15 p.m. CDT
Reasons for oncologist and urologist treatment choice in metastatic castration-sensitive prostate cancer (mCSPC): A physician survey linked to patient chart reviews in the United States	S. Freedland	Type: Poster presentation Abstract Number: 5065 Date: Monday, June 6, 2022 Poster Session: Genitourinary Cancer—Prostate, Testicular, and Penile Presentation: 1:15 – 4:15 p.m. CDT
Patient preferences for treatment and outcomes in hormone-sensitive prostate cancer (HSPC)	D. George	Type: Abstract publication Abstract Number: e18757

Zolbetuximab

Presentation Title	Lead Author	Presentation Details
Zolbetuximab plus gemcitabine and 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 Presentation Abstract Number: TPS4186 Date: Saturday, June 4, 2022 Poster Session: Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary Presentation: 8 – 11 a.m. CDT

Astellas Presentations at EHA 2022 Hybrid Congress

Gilteritinib

Presentation Title	Lead Author	Presentation Details
CLEVO: a non-interventional study to investigate clonal evolution of FMS-like tyrosine kinase 3 (FLT3) gene mutations during disease progression in patients with acute myeloid leukemia	P. Vyas	Type: Abstract publication Abstract Number: PB1834
Gilteritinib versus salvage chemotherapy for relapsed/refractory FLT3-mutated acute myeloid leukemia: a Phase 3, randomized, multicenter, open-label trial in Asia	J. Wang	Type: Poster session Abstract Number: P554

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

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.

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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