Press Release

Astellas Announces Abstracts Highlighting Growing Oncology Portfolio to be Presented at 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

TOKYO – May 16, 2018 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") announced today that a wide selection of abstracts highlighting the Company's diverse oncology portfolio across a broad range of cancers have been accepted for oral and poster presentation at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting, June 1-5 in Chicago. Highlights of the data and studies being presented include findings for: men with non-metastatic Castration-Resistant Prostate Cancer (CRPC) taking enzalutamide* and androgen deprivation therapy; patients with locally advanced or metastatic urothelial cancer taking enfortumab vedotin**, an investigational antibody-drug conjugate (ADC); and patients taking gilteritinib in Phase 3 trial in FLT3 mutation-positive (FLT3mut+) acute myeloid leukemia (AML).

"The Astellas abstracts accepted for presentation at this year's ASCO meeting demonstrate the depth and breadth of our growing leadership in oncology across a broad range of cancers," said Steven Benner, M.D., senior vice president and global therapeutic area head, Oncology Development, Astellas. "These data demonstrate the strength and progress of our oncology pipeline driven by investment in R&D and collaborative partnerships."

The following will be presented during an oral presentation:

Title: (Abstract 4504) Updated Results from the enfortumab vedotin Phase 1 (EV-101) Study in Patients with Metastatic Urothelial Cancer (mUC)

Presenter: Jonathan E. Rosenberg, MD

- Session Date/Time: June 3, 9:12 AM – 9:24 AM CDT
- Oral Abstract Session: Genitourinary (Nonprostate) Cancer
- Location: Arie Crown Theater

Additionally, the following data will be shared during poster presentations:

Title: (Abstract TPS4590) EV-201 Study: A Single-Arm, Open-Label, Multicenter Study of enfortumab vedotin for Treatment of Patients with Locally Advanced or Metastatic Urothelial Cancer who previously Received Immune Checkpoint Inhibitor Therapy

Presenter: Jonathan E. Rosenberg, MD

- Session Date/Time: June 2, 8:00 AM – 11:30 AM CDT
- Poster Session: Genitourinary (Nonprostate) Cancer
- Location: Hall A

Title: (Abstract 5010) Health-Related Quality of Life (HRQoL) Deterioration and Pain Progression in Men with Non-Metastatic Castration-Resistant Prostate Cancer (M0-CRPC): Results from the PROSPER study

Presenter: Gerhardt Attard, MD, PhD

- Session Date/Time: June 2, 1:15 PM – 4:45 PM CDT
- Poster Session: Genitourinary (Prostate) Cancer
- Location: Hall A
- Poster Discussion Session on June 2, 2018, 4:45 PM - 6:00 PM CDT, at S406

Title: (Abstract 5043) Association Between Health-Related Quality of Life (HRQoL) and clinical outcomes in non-metastatic castration-resistant prostate cancer (M0 CRPC): Results from the PROSPER study

Presenter: Gerhardt Attard, MD, PhD

- Session Date/Time: June 2,1:15 PM – 4:45 PM CDT
- Poster Session: Genitourinary (Prostate) Cancer
- Location: Hall A

Title: (Abstract TPS7075) A Phase 3, Trial of Gilteritinib, as Maintenance Therapy after Allogeneic Hematopoietic Stem Cell Transplantation in Patients with FLT3-ITD + AML

Presenter: Mark J. Levis, MD, PhD

- Session Date/Time: June 4, 8:00 AM – 11:30 AM CDT
- Poster Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant
- Location: Hall A

*Enzalutamide is developed through a collaboration between Pfizer and Astellas and commercialized under the brand name XTANDI®.
**Enfortumab vedotin is developed through a collaboration between Seattle Genetics and Astellas

About Astellas
Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

Astellas Forward-Looking Statement
In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forwardlooking 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. 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.

About XTANDI® (enzalutamide) capsules

XTANDI (enzalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with metastatic castration-resistant prostate cancer.

Important Safety Information

Contraindications
XTANDI is not indicated for women. XTANDI can cause fetal harm and potential loss of pregnancy.

Warnings and Precautions
Seizure occurred in 0.5% of patients receiving XTANDI in clinical studies. In a study of patients with predisposing factors, seizures were reported in 2.2% of patients. See section 5.1 of the Prescribing Information for the list of predisposing factors. It is unknown whether anti-epileptic medications will prevent seizures with XTANDI. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

Posterior Reversible Encephalopathy Syndrome (PRES)
In post approval use, there have been reports of PRES in patients receiving XTANDI. PRES is a neurological disorder which can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably MRI. Discontinue XTANDI in patients who develop PRES.

Adverse Reactions
The most common adverse reactions (≥ 10%) that occurred more commonly (≥ 2% over placebo) in the XTANDI patients from the two placebo-controlled clinical trials were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypertension, and dizziness/vertigo. In the bicalutamide-controlled study of chemotherapy-naïve patients, the most common adverse reactions (≥ 10%) reported in XTANDI patients were asthenia/fatigue, back pain, musculoskeletal pain, hot flush, hypertension, nausea, constipation, upper respiratory tract infection, diarrhea, and weight loss.

In the placebo-controlled study of patients taking XTANDI who previously received docetaxel, Grade 3 and higher adverse reactions were reported among 47% of XTANDI patients and 53% of placebo patients. Discontinuations due to adverse events were reported for 16% of XTANDI patients and 18% of placebo patients.
In the placebo-controlled study of chemotherapy-naïve patients, Grade 3-4 adverse reactions were reported in 44% of XTANDI patients and 37% of placebo patients. Discontinuations due to adverse events were reported for 6% of both study groups.
In the bicalutamide-controlled study of chemotherapy-naïve patients, Grade 3-4 adverse reactions were reported in 38.8% of XTANDI patients and 37.6% of bicalutamide patients. Discontinuations due to adverse events were reported for 7.6% of XTANDI patients and 6.3% of bicalutamide patients.

Lab Abnormalities: In the two placebo-controlled trials, Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% Grade 3-4) and 6% of placebo patients (0.5% Grade 3-4). Grade 1-4 thrombocytopenia occurred in 6% of XTANDI patients (0.3% Grade 3-4) and 5% of placebo patients (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of XTANDI patients (0.2% Grade 3-4) and 16% of placebo patients (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients (0.1% Grade 3-4) and 2% of placebo patients (no Grade 3-4).

Infections: In the study of patients taking XTANDI who previously received docetaxel, 1% of XTANDI patients compared to 0.3% of placebo patients died from infections or sepsis. In the study of chemotherapy-naïve patients, 1 patient in each treatment group (0.1%) had an infection resulting in death.

Falls (including fall-related injuries) occurred in 9% of XTANDI patients and 4% of placebo patients in the two placebo-controlled trials. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in XTANDI patients, and included non-pathologic fractures, joint injuries, and hematomas.

Hypertension occurred in 11% of XTANDI patients and 4% of placebo patients in the two placebo-controlled trials. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of patients in each arm.

Drug Interactions
Effect of Other Drugs on XTANDI Avoid strong CYP2C8 inhibitors, as they can

increase the plasma exposure to XTANDI. If co-administration is necessary, reduce the dose of XTANDI.

Avoid strong CYP3A4 inducers as they can decrease the plasma exposure to XTANDI. If co-administration is necessary, increase the dose of XTANDI.

Effect of XTANDI on Other Drugs Avoid CYP3A4, CYP2C9, and CYP2C19 substrates with a narrow therapeutic index, as XTANDI may decrease the plasma exposures of these drugs. If XTANDI is co-administered with warfarin (CYP2C9 substrate), conduct additional INR monitoring.

Please see Full Prescribing Information for **additional safety information**

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