Press Release

Astellas to Present New Oncology Data at the 2018 ASCO Genitourinary Cancers (GU) Symposium

– A total of 10 abstracts and one trial in progress (TIP) across various cancers to be presented during oral and poster sessions –

TOKYO – January 26, 2018 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") today announced new data to be presented at the 2018 Genitourinary Cancers Symposium of the American Society of Clinical Oncology (ASCO GU) taking place on February 8-10 in San Francisco. Among the data being presented are findings for men with non-metastatic Castration-Resistant Prostate Cancer (CRPC) taking enzalutamide*; and for patients with locally advanced or metastatic urothelial cancer taking enfortumab vedotin**, an investigational antibody-drug conjugate (ADC).

"We are poised to announce our largest presence to date at this year's ASCO GU meeting," said Steven Benner, M.D., senior vice president and global therapeutic area head, Oncology Development, Astellas. "We're pleased to showcase additional work in our oncology franchise, investigating new indications and uses where possible for patients through expanded indications and tumor types in areas of high unmet need."

The following abstract will be featured during an oral presentation session for enzalutamide:

> ***Title:*** PROSPER: A phase 3, randomized, double-blind, placebo (PBO)-controlled study of enzalutamide (ENZA) in men with nonmetastatic castration-resistant prostate cancer (M0 CRPC)
>
> *Presenter:* Maha Hussain, M.D.
> - Oral Presentation Abstract Session A: Prostate Cancer; Abstract Number: 3
> - Session Date/Time: Thursday, February 8, 1:00 p.m.- 2:30 p.m. PST

In addition to the oral presentation, the following six abstracts will be presented during the poster sessions for enzalutamide:

> ***Title:*** Hepatic effects assessed by review of safety data in enzalutamide castration-resistant prostate cancer (CRPC) trials
>
> *Lead Author:* Tomasz M. Beer, M.D.
> - Poster Session A: Prostate Cancer; Abstract Number: 199
> - Session Date/Time: Thursday, February 8, 11:30 a.m.-1:00 p.m.; 5:15 p.m.- 6:15 p.m. PST

Title: Impact of enzalutamide (ENZA) vs. bicalutamide (BIC) on health-related quality of life (HRQoL) of patients (pts) with castration-resistant prostate cancer (CRPC): STRIVE study

Lead Author: Raoul Concepcion, M.D.

- Poster Session A: Prostate Cancer; Abstract Number: 234
- Session Date/Time: Thursday, February 8, 11:30 a.m.-1:00 p.m.; 5:15 p.m. - 6:15 p.m. PST

Title: Comparison of enzalutamide and bicalutamide in patients with non-metastatic castration resistant prostate cancer: Number needed to treat to achieve one additional patient free of clinical progression events

Lead Author: Lawrence Ivan Karsh, M.D.

- Poster Session A: Prostate Cancer Abstract Number: 228
- Session Date/Time: Thursday, February 8, 11:30 a.m.-1:00 p.m.; 5:15 p.m.- 6:15 p.m. PST

Title: Treatment duration and utilization patterns in metastatic castration-resistant prostate cancer patients receiving enzalutamide or abiraterone acetate

Lead Author: Vahan Kassabian, M.D.

- Poster Session A: Prostate Cancer; Abstract Number: 229
- Session Date/Time: Thursday, February 8, 11:30 a.m.-1:00 p.m.; 5:15 p.m.- 6:15 p.m. PST

Title: Health care resource utilization and costs in metastatic castration-resistant prostate cancer patients treated with enzalutamide or abiraterone acetate

Lead Author: Vahan Kassabian, M.D.

- Poster Session A: Prostate Cancer; Abstract Number: 232
- Session Date/Time: Thursday, February 8, 11:30 a.m.-1:00 p.m.; 5:15 p.m.- 6:15 p.m. PST

Title: Safety of continued administration of enzalutamide in patients with prostate cancer who showed benefit from prior exposure: A Phase 2 open-label extension study

Lead Author: Elaine Tat Lam, M.D.

- Poster Session B: Prostate Cancer, Urothelial Carcinoma, and Penile, Urethral, and Testicular Cancers; Abstract Number: 303
- Session Date/Time: Friday, February 9, 12:15 p.m.-1:45 p.m.; 6 p.m. - 7 p.m. PST

Astellas will present the following three abstracts during poster sessions for enfortumab vedotin, which include updated Phase 1 data in metastatic urothelial cancer patients with prior CPI treatment and trials in progress (TIP) for the EV-201 and EV-103 studies.

Title: Enfortumab vedotin (EV) in patients (Pts) with metastatic urothelial carcinoma (mUC) with prior checkpoint inhibitor (CPI) failure: A prospective cohort of an ongoing phase 1 study

Lead Author: Daniel P. Petrylak, M.D.

- Poster Session B: Prostate Cancer, Urothelial Carcinoma, and Penile, Urethral, and Testicular Cancers; Abstract Number 431
- Session Date/Time: Friday, February 9, 12:15 p.m.-1:45 p.m.; 6:00 p.m.-7:00 p.m. PST

Title: 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

Lead Author: Jonathan E. Rosenberg, M.D.

- Trials in Progress Poster Session B: Prostate Cancer, Urothelial Carcinoma, and Penile, Urethral, and Testicular Cancers; Abstract Number TPS542
- Session Date/Time: Friday, February 9, 12:15 p.m.-1:45 p.m.; 6:00 p.m.-7:00 p.m. PST

Title: EV-103 study: A phase 1b dose-escalation and dose-expansion study of enfortumab vedotin in combination with immune checkpoint inhibitor (CPI) therapy for treatment of patients with locally advanced or metastatic urothelial cancer

Lead Author: Christopher J. Hoimes, D.O.

- Trials in Progress Poster Session B: Prostate Cancer, Urothelial Carcinoma, and Penile, Urethral, and Testicular Cancers; Abstract Number TPS532
- Session Date/Time: Friday, February 9, 12:15 p.m.-1:45 p.m.; 6:00 p.m.-7:00 p.m. PST

*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 Enfortumab Vedotin

Enfortumab vedotin is an investigational Antibody-Drug Conjugate (ADC), composed of an anti-Nectin-4 monoclonal antibody attached to a microtubule-disrupting agent, monomethyl auristatin E (MMAE), using Seattle Genetics' proprietary, industry-leading linker technology. Enfortumab vedotin targets Nectin-4, a cell adhesion molecule identified as an ADC target by Astellas, which is expressed on many solid tumors.

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.

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 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:

United States:
Media inquiries: Tarsis Lopez
TEL: +1-847-224-8374
E-MAIL: tarsis.lopez@astellas.com

Japan:
Media and Investor Relations inquiries:
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473