Astellas and Seattle Genetics Initiate Phase 1b Trial of Enfortumab Vedotin in Combination with Immune Checkpoint Inhibitor Therapies in Locally Advanced or Metastatic Urothelial Cancer

-ADC Combination Study Focuses on First-Line Treatment-

TOKYO and BOTHELL, Wash. – November 8, 2017 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") and Seattle Genetics, Inc. (NASDAQ: SGEN) today announced dosing of the first patient in EV-103, a phase 1b clinical trial evaluating the safety and tolerability of enfortumab vedotin in combination with pembrolizumab or atezolizumab, two types of immune checkpoint inhibitor (CPI) therapies, for first- or second-line treatment of patients with locally advanced or metastatic urothelial cancer. Enfortumab vedotin is an investigational antibody-drug conjugate (ADC) designed to deliver the cell-killing agent monomethyl auristatin E (MMAE) to the target Nectin-4.

"The initiation of EV-103 is an important step in investigating the utility of enfortumab vedotin in earlier lines of therapy, including the first-line setting, for locally advanced and metastatic urothelial cancer, where patients ineligible for cisplatin-based chemotherapy continue to have limited treatment options," said Jonathan Drachman, M.D., Chief Medical Officer and Executive Vice President, Research and Development at Seattle Genetics. "This study represents Seattle Genetics' third ADC under clinical evaluation in combination with CPIs, highlighting our vision that ADCs could be the preferred partners for immuno-oncology agents for patients with solid tumors and hematological cancers."

The EV-103 study is a single arm, open label multicenter trial that will enroll up to 85 patients with locally advanced or metastatic urothelial cancer who are ineligible for first line cisplatin-based chemotherapy or have progressed following treatment with a regimen containing platinum-based chemotherapy. Enfortumab vedotin will be administered during weeks one and two of every three-week cycle, and pembrolizumab or atezolizumab will also be administered during week one of this period. The primary objective of the trial is to assess the safety and tolerability of enfortumab vedotin in combination with CPI therapy. Secondary endpoints include the recommended dose in combination with CPIs, overall response rate (ORR), duration of response (DOR), progression-free survival (PFS), and overall survival (OS), among other measures.

"We are pleased to be moving forward with evaluating enfortumab vedotin in combination with CPI therapy, as we look to further investigate the potential of this agent in some of the hardest-to-treat cancers," said Steven Benner, M.D., senior vice president and global therapeutic area head, oncology development at Astellas. "Many patients do not respond to or relapse after treatment with CPIs, and we are committed to exploring additional ways to potentially address the unmet needs of the urothelial cancer community.

Enfortumab vedotin is also being studied as monotherapy in a pivotal clinical trial for patients with advanced urothelial cancer who have received prior CPI therapy, called EV-201 (NCT03219333), to support potential registration under the U.S. Food and Drug Administration's (FDA) accelerated approval regulations.

For more information about the EV-103 clinical trial, please visit www.clinicaltrials.gov.

About Urothelial Cancer
Urothelial cancer is most commonly found in the bladder (90 percent). According to the American Cancer Society, approximately 79,000 people in the U.S. will be diagnosed with bladder cancer during 2017 and almost 17,000 will die from the disease. Outcomes are poor for patients diagnosed with metastatic disease, with a five-year survival rate of five percent.

About Enfortumab Vedotin
Enfortumab vedotin is an investigational ADC composed of an anti-Nectin-4 monoclonal antibody attached to a microtubule-disrupting agent, 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 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 https://www.astellas.com/en.

About Seattle Genetics
Seattle Genetics is an innovative biotechnology company dedicated to improving the lives of people with cancer through novel antibody-based therapies. The company's industry-leading antibody-drug conjugate (ADC) technology harnesses the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells. Seattle Genetics commercializes ADCETRIS® (brentuximab vedotin) for the treatment of several types of CD30-expressing lymphomas. The company is also advancing a robust pipeline of novel therapies for solid tumors and blood-related cancers designed to address significant unmet medical needs and improve treatment outcomes for patients. More information can be found at www.seattlegenetics.com and follow @SeattleGenetics on Twitter.

About the Astellas and Seattle Genetics Collaboration
Astellas and Seattle Genetics entered into the ADC collaboration in January 2007 and expanded it in November 2009. Under the collaboration, the companies are co-developing and have options to globally co-commercialize enfortumab vedotin.

Seattle Genetics Forward Looking Statement
Certain of the statements made in this press release are forward looking, such as those, among others, relating to the therapeutic potential of enfortumab vedotin, its possible safety, efficacy, and therapeutic uses and anticipated development activities including future clinical trials and intended regulatory actions. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the inability to show sufficient activity in the clinical trials and risk of adverse events as enfortumab vedotin advance in clinical trials even after promising results in earlier clinical trials. In addition, as our drug candidates or those of our collaborators advance in clinical trials, adverse events and/or regulatory actions may occur which affect the future development of those drug candidates and possibly other compounds using similar

technology. More information about the risks and uncertainties faced by Seattle Genetics is contained under the caption "Risk Factors" included in the company's Quarterly Report on Form 10-Q for the quarter ended Nov. 6, 2017 filed with the Securities and Exchange Commission. Seattle Genetics disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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 agent discussed herein are under investigation and have not been established. There is no guarantee that the agent will receive regulatory approval and become commercially available for the 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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