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Seattle Genetics and Astellas Announce Progress in Enfortumab Vedotin Urothelial Cancer Clinical Development Program

-Enrollment of EV-201 Pivotal Trial Cohort Designed to Support Potential Expedited Registration Pathway in the U.S. Completed-

-First Patient Dosed in Phase 3 Global Confirmatory Trial-

BOTHELL, Wash., and TOKYO, July 9, 2018 – Seattle Genetics, Inc. (Nasdaq:SGEN) and Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced completion of enrollment for the enfortumab vedotin EV-201 pivotal phase 2 clinical trial cohort of patients with locally advanced or metastatic urothelial cancer who have been previously treated with both platinum chemotherapy and a checkpoint inhibitor (PD-L1 or PD-1). Enfortumab vedotin is an investigational antibody-drug conjugate (ADC) that targets Nectin-4.

The companies expect to report topline efficacy and safety results from this first cohort of the EV-201 trial, which is intended to support potential registration under the U.S. Food and Drug Administration's (FDA) accelerated approval pathway, in the first half of 2019.

The companies also today announced dosing of the first patient in EV-301, a global, randomized phase 3 clinical trial evaluating enfortumab vedotin in patients with previously treated locally advanced or metastatic urothelial cancer. The EV-301 trial is intended to support a broader global registration strategy and to serve as the confirmatory randomized trial in the U.S. for EV-201. Enfortumab vedotin has been granted Breakthrough Therapy Designation by the FDA for patients with locally advanced or metastatic urothelial cancer who were previously treated with checkpoint inhibitors.

"With enfortumab vedotin, we have the opportunity to address some of the unmet need in advanced urothelial cancer," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics. "With our partners Astellas, we are pleased to advance the enfortumab vedotin

clinical trial program with the vision of bringing a new treatment option to patients with advanced urothelial cancer worldwide."

"Despite recent treatment advances, the unfortunate reality is that many patients with metastatic urothelial cancer currently find that their disease will progress after anti-PD-1 or PD-L1 therapy, highlighting the need to identify additional therapeutic options," said Steven Benner, M.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development, Astellas. "Following encouraging results from our ongoing phase 1 study, we and our partners at Seattle Genetics decided to proceed with these registrational trials. We look forward to future clinical development milestones for enfortumab vedotin."

In addition to EV-201 and EV-301, enfortumab vedotin is also under evaluation in a phase 1 clinical trial (EV-103) in combination with pembrolizumab (Keytruda®) in cisplatin-ineligible first-line patients with locally advanced or metastatic urothelial cancer.

About EV-201 Trial
EV-201 is an ongoing single-arm, single-agent pivotal phase 2 clinical trial of enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who have been previously treated with a checkpoint inhibitor, including those who had also been treated with a platinum chemotherapy (first cohort) and those who were cisplatin ineligible / platinum naïve (second cohort). Approximately 120 patients were enrolled in the first cohort at multiple centers. The primary endpoint is confirmed objective response rate, per independent review. Secondary endpoints include assessments of response duration, disease control, overall survival, progression-free survival, safety and tolerability. The second cohort continues to enroll cisplatin-ineligible, platinum naïve patients with urothelial cancer who have received a PD-1/PD-L1 inhibitor but not a platinum agent.

About EV-301 Trial
EV-301 trial is a global, open label, randomized phase 3 trial designed to evaluate enfortumab vedotin versus physician's choice of chemotherapy (docetaxel, paclitaxel or vinflunine) in approximately 550 patients with locally advanced or metastatic urothelial cancer who were previously treated with a PD-1/PD-L1 inhibitor and platinum-based therapies. The primary endpoint is overall survival. Secondary endpoints include progression-free survival, overall response rate, disease control rate, duration of response and quality of life.

More information about the enfortumab vedotin clinical trials can be found at https://www.clinicaltrials.gov.

About Urothelial Cancer
According to the American Cancer Society, urothelial cancer, also known as transitional cell carcinoma (TCC), is the most common type of bladder cancer[1] (90 percent of cases). Approximately 81,000 people in the U.S. are anticipated to be diagnosed with bladder cancer during 2018. Bladder cancer is the fourth most common cancer in men, but is less common in women. Outcomes are poor for people diagnosed with metastatic disease, with a five-year survival rate of 4.8 percent.[2]

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, 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.

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.

About Seattle Genetics
Seattle Genetics, Inc. is an emerging multi-product, global biotechnology company that develops and commercializes transformative therapies targeting cancer to make a meaningful difference in people's lives. ADCETRIS® (brentuximab vedotin) utilizes the company's industry-leading antibody-drug conjugate (ADC) technology and is currently approved for the treatment of multiple CD30-expressing lymphomas. Beyond ADCETRIS, the company has established a pipeline of novel targeted therapies at various stages of clinical testing, including three in ongoing pivotal trials for solid tumors. Enfortumab vedotin for metastatic urothelial cancer and tisotumab vedotin for metastatic cervical cancer utilize our proprietary ADC technology. Tucatinib, a small molecule tyrosine kinase inhibitor, is in a pivotal trial for HER2-positive metastatic breast cancer. In addition, we are leveraging our expertise in empowered antibodies to build a portfolio of proprietary immuno-oncology agents in clinical trials targeting hematologic malignancies and solid tumors. The company is headquartered in Bothell, Washington, and has a European office in Switzerland. For more information on our robust pipeline, visit www.seattlegenetics.com and follow @SeattleGenetics on Twitter.

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. For more information, please visit our website at https://www.astellas.com/en

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 statements made in this press release are forward looking, such as those, among others, relating to the companies' expected reporting of topline efficacy and safety results from the first cohort of the EV-201 trial in the first half of 2019 and the intended use of the data to support potential registration under the U.S. Food and Drug Administration's (FDA) accelerated approval pathway, 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 possible delays in the availability of data from EV-201 and that the data from EV-201 may not be sufficient to support accelerated approval, and the inability to show sufficient activity in the clinical trials, the risk of adverse events or safety signals, and the possibility of adverse regulatory actions as enfortumab vedotin advances in clinical trials even after promising results in earlier clinical trials. 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 March 31, 2018 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.

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.

1 American Cancer Society. What is bladder cancer? https://www.cancer.org/cancer/bladder-cancer/about/what-is-bladder-cancer.html. Accessed 05-08-2018.
2 National Cancer Institute. Surveillance, Epidemiology, and End Results Program. Cancer stat facts: bladder cancer. https://seer.cancer.gov/statfacts/html/urinb.html. Accessed 05-08-2018.

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