Astellas and Seattle Genetics Announce Submission of Biologics License Application to FDA for Enfortumab Vedotin for Patients with Locally Advanced or Metastatic Urothelial Cancer

-Submission Based on Pivotal Phase 2 Trial Results Recently Presented at Annual Meeting of American Society of Clinical Oncology-

TOKYO and BOTHELL, Wash., July 16, 2019 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and Seattle Genetics, Inc. (Nasdaq:SGEN) today announced submission of a Biologics License Application for accelerated approval to the U.S. Food and Drug Administration for the investigational agent enfortumab vedotin for the treatment of patients with locally advanced or metastatic urothelial cancer who have received a PD-1/L1 inhibitor and who have received a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting.

The submission is based on results from the first cohort of patients in the EV-201 pivotal phase 2 clinical trial that were presented as a late-breaking abstract at the annual meeting of the American Society of Clinical Oncology (ASCO) in June. Enfortumab vedotin is an investigational antibody-drug conjugate (ADC) that targets Nectin-4, a protein that is highly expressed in urothelial cancers.[i]

"There are limited treatment options for patients with advanced urothelial cancer, and we are encouraged by the results observed in the pivotal trial for enfortumab vedotin," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Oncology Therapeutic Area Head at Astellas.

"There is an urgent need for new therapies for patients with advanced urothelial cancer, and we look forward to working with our partner Astellas and the FDA on the review of this application," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics.

Based on preliminary results from a phase 1 trial (EV-101), the FDA granted enfortumab vedotin Breakthrough Therapy designation for patients with locally advanced or metastatic urothelial cancer whose disease has progressed during or following checkpoint inhibitor therapy.

A global, randomized phase 3 confirmatory clinical trial (EV-301) is ongoing and is intended to support global registrations. Another ongoing trial, EV-103, is evaluating enfortumab vedotin in earlier lines of treatment for patients with locally advanced or metastatic urothelial cancer, including in combination with pembrolizumab and/or platinum chemotherapy in newly diagnosed patients as well as patients whose cancer progressed from earlier-stage disease.

About the EV-201 Trial

EV-201 is an ongoing single-arm, pivotal phase 2 clinical trial of enfortumab vedotin in patients with locally advanced or metastatic urothelial cancer who have been previously treated with a PD-1/L1 inhibitor and a platinum-containing chemotherapy (cohort 1) and those who have not received a platinum-containing chemotherapy or who are ineligible for cisplatin (cohort 2). In cohort 1, 128 patients were enrolled at multiple centers internationally.[ii] The primary endpoint is confirmed objective response rate per blinded independent central review. Secondary endpoints include assessments of duration of response,

disease control rate, progression-free survival, overall survival, safety and tolerability. EV-201 continues to enroll patients in cohort 2.

More information about enfortumab vedotin clinical trials can be found at clinical trials.gov.

About Urothelial Cancer

Urothelial cancer is the most common type of bladder cancer (90 percent of cases).[iii] In 2018, more than 82,000 people were diagnosed with bladder cancer in the United States. Globally, approximately 549,000 people were diagnosed with bladder cancer last year, and there were approximately 200,000 deaths worldwide.[iv]

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 that is expressed on many solid tumors, and that has been identified as an ADC target by Astellas.

The safety and efficacy of enfortumab vedotin are under investigation and have not been established. There is no guarantee that the agent will receive regulatory approval or become commercially available for the uses being investigated.

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. 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

Seattle Genetics and Astellas are co-developing enfortumab vedotin under a collaboration that was entered into in 2007 and expanded in 2009. Under the collaboration, the companies are sharing costs and profits on a 50:50 basis worldwide.

Seattle Genetics Forward Looking Statements

Certain statements made in this press release are forward looking, such as those, among others, relating to the potential FDA approval of enfortumab vedotin for the treatment of patients with locally advanced or metastatic urothelial cancer who have received a PD-1/L1 inhibitor and who have received a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting; the conduct of an ongoing randomized phase 3 confirmatory clinical trial (EV-301) intended to support global registrations, and of a trial (EV-103) evaluating enfortumab vedotin in earlier lines of treatment for patients with locally advanced or metastatic urothelial cancer, including in combination with pembrolizumab and/or platinum chemotherapy in newly diagnosed patients as well as patients whose

cancer progressed from earlier-stage disease; and the therapeutic potential of enfortumab vedotin including its possible safety, efficacy, and therapeutic uses. 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 possibility that the Biologics License Application submission based on the EV-201 trial may not be accepted for filing by, or ultimately approved by, the FDA in a timely manner or at all or with the requested label; that the data from EV-201 may not be sufficient to support accelerated approval; that EV-301 and EV-103 and subsequent clinical trials may fail to establish sufficient efficacy; that adverse events or safety signals may occur; and that adverse regulatory actions could occur 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, 2019 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, except as required by law.

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.

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[i] Vlachostergios P, Jakubowski C, Niaz J, et al. (2018). Antibody-Drug Conjugates in Bladder Cancer. Bladder Cancer (Version 4.2018). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6087439/pdf/blc-4-blc180169.pdf
[ii] Data on file at Seattle Genetics
[iii] American Society of Clinical Oncology. Bladder Cancer: Introduction (05-2019). https://www.cancer.net/cancer-types/bladder-cancer/introduction.
[iv] International Agency for Research on Cancer. Cancer tomorrow: bladder. http://gco.iarc.fr/tomorrow.