Seattle Genetics and Astellas Announce Clinical Trial Collaboration with Merck to Evaluate Enfortumab Vedotin in Combination with KEYTRUDA® (pembrolizumab) in Patients with Metastatic Urothelial Cancer

- Companies to Initiate Phase 3 Trial to Support Global Registrations -

BOTHELL, Wash., and TOKYO, December 2, 2019 – Seattle Genetics, Inc. (Nasdaq:SGEN) and Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas"), today announced a clinical collaboration agreement with Merck, known as MSD outside the United States and Canada through a subsidiary, to evaluate the combination of Seattle Genetics' and Astellas' antibody-drug conjugate (ADC) enfortumab vedotin and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with previously untreated metastatic urothelial cancer.

Under the terms of the agreement, the three companies will conduct and fund a global, registrational phase 3 clinical trial to be led by Seattle Genetics. The trial will be designed to evaluate the efficacy of the combination of enfortumab vedotin and pembrolizumab in patients with previously untreated locally advanced or metastatic urothelial cancer. The companies are working in consultation with regulatory authorities to finalize the trial design and currently plan to initiate the trial in the first half of 2020.

"We look forward to initiating a randomized phase 3 trial in patients with previously untreated locally advanced or metastatic urothelial cancer," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics. "Recent data from a phase 1b trial of enfortumab vedotin in combination with pembrolizumab showed evidence of clinical activity leading to the development of this phase 3 trial."

"An unmet medical need exists for previously untreated patients with metastatic urothelial cancer, and we are committed to studying enfortumab vedotin in combination with other agents in different stages of urothelial cancer," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Oncology Therapeutic Area Head at Astellas. "We look forward to further evaluating enfortumab vedotin and pembrolizumab in this high unmet need patient population."

Enfortumab vedotin is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of adult 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 PDUFA action date is March 15, 2020.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

About Urothelial Cancer

Urothelial cancer is the most common type of bladder cancer (90 percent of cases).[1] In 2019, more than 80,000 people will be 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.[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 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 clinical development plans including the proposed phase 3 trial of enfortumab vedotin in combination with pembrolizumab as a potential treatment option for previously untreated metastatic urothelial cancer; the therapeutic potential of enfortumab vedotin including its possible safety, efficacy, and therapeutic uses, including in previously untreated metastatic urothelial cancer, and 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. 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 ongoing and subsequent clinical trials of enfortumab vedotin, including the proposed phase 3 trial of enfortumab vedotin in combination with pembrolizumab, may fail to establish sufficient efficacy; that adverse events or safety signals may occur; that adverse regulatory actions or other setbacks could occur as enfortumab vedotin advances in clinical trials even after promising results in earlier clinical trials; and that the Biologics License Application submission and any future potential supplemental Biologics License Application submissions for enfortumab vedotin may not be approved by the FDA in a timely manner or at all or with the requested label(s). 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 September 30, 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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[1] American Society of Clinical Oncology. Bladder Cancer: Introduction (05-2019). https://www.cancer.net/cancer-types/bladder-cancer/introduction.
[2] International Agency for Research on Cancer. Cancer tomorrow: bladder. http://gco.iarc.fr/tomorrow.