

## **Astellas and Seattle Genetics Receive FDA Breakthrough Therapy Designation for Enfortumab Vedotin in Locally Advanced or Metastatic Urothelial Cancer**

**TOKYO and BOTHELL, Wash., – March 26, 2018** – Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, “Astellas”) and Seattle Genetics, Inc. (NASDAQ: SGEN) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to enfortumab vedotin, an antibody-drug conjugate (ADC), for patients with locally advanced or metastatic urothelial cancer who were previously treated with checkpoint inhibitors (CPI).

Breakthrough Therapy Designation is a process designed to expedite the development and review of drugs that are intended to treat a serious or life-threatening condition. It is based upon preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

“The FDA Breakthrough Therapy Designation underscores the potential of enfortumab vedotin as a meaningful treatment for patients with locally advanced or metastatic urothelial cancer. Further, it supports our rapid development plans for this ADC, including the ongoing pivotal study in this patient population,” said Robert Lechleider, M.D., Vice President, Clinical Development at Seattle Genetics. “Seattle Genetics is an emerging multi-product oncology company, advancing a robust pipeline with the goal of improving outcomes for cancer patients. Enfortumab vedotin is at the forefront of our late-stage clinical pipeline, and we are working closely with our partner and the FDA to bring this potential new treatment to patients as quickly as possible.”

“Achieving Breakthrough Therapy Designation for enfortumab vedotin is another step forward in our goal to bring an additional treatment option to patients who need it most,” said Steven Benner, M.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development at Astellas. “With the enfortumab vedotin registrational phase 2 trial and CPI-combination trial actively underway, Astellas looks forward to expanding development of enfortumab vedotin and its oncology pipeline, including treatments that would target some of the hardest-to-treat cancers.”

The Breakthrough Therapy Designation was granted based on interim results from the phase 1 study examining enfortumab vedotin as monotherapy treatment for patients with metastatic urothelial cancer who were previously treated with CPIs. Enfortumab vedotin is being studied in a pivotal clinical trial, EV-201 (NCT03219333), as monotherapy in this patient setting and in an early-phase clinical trial in combination with CPI therapy, EV-103 (NCT03288545). The companies are also evaluating enfortumab vedotin in other solid tumors, including ovarian and non-small cell lung carcinoma.

More information about the ongoing trials can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **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.

### **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 targeted 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](http://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 Annual Report on Form 10-K for the year ended December 31, 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.

### **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.

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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