



## **Astellas and Seattle Genetics Initiate Pivotal Trial of Enfortumab Vedotin for Patients with Locally Advanced or Metastatic Urothelial Cancer**

*Solid Tumor Antibody-Drug Conjugate (ADC) Enfortumab Vedotin to be Evaluated as a Monotherapy in Patients Previously Treated with a Checkpoint Inhibitor*

**TOKYO and BOTHELL, Wash., October 10, 2017** - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") and Seattle Genetics Inc., Inc., (NASDAQ: SGEN) today announced dosing of the first patient in EV-201, a registrational phase 2 clinical trial of enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who have been previously treated with checkpoint inhibitor (CPI) therapy. The EV-201 study will assess the antitumor activity and safety of enfortumab vedotin to support potential registration under the U.S. Food and Drug Administration's (FDA) accelerated approval regulations.

"Locally advanced or metastatic urothelial cancers are often aggressive and treatment-resistant. Treatment options are limited for those many patients who do not respond to chemotherapy and checkpoint inhibitors, or CPIs. In addition, there are no FDA-approved therapies for patients who progress following CPI treatment," said Jonathan Drachman, M.D., Chief Medical Officer and Executive Vice President, Research and Development at Seattle Genetics. "Initiation of this pivotal phase 2 trial of enfortumab vedotin is a significant advance toward our goal of providing a new treatment option for patients with locally advanced or metastatic urothelial cancer."

The primary endpoint of the single-arm, open-label trial is confirmed objective response rate (ORR), per independent review. Secondary endpoints include assessments of overall survival, progression free-survival, safety and tolerability. The study will enroll approximately 120 patients at multiple centers globally, and enfortumab vedotin will be administered three of every four weeks for the duration of treatment.

"The initiation of the EV-201 clinical trial demonstrates our continued commitment to patients living with locally advanced or metastatic urothelial cancer," said Steven Benner, M.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development at Astellas. "Our decision to move forward with this registrational trial is based on the results of our ongoing Phase 1 study, and we look forward to future clinical development milestones for enfortumab vedotin."

The companies also plan to initiate a combination trial of enfortumab vedotin with CPI therapy in late 2017.

For more information about the phase 2 pivotal trial, including enrolling centers, please visit [www.clinicaltrials.gov](http://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 Agensys (an affiliate of Astellas), which is expressed on many solid tumors. Nectin-4 is highly expressed in urothelial cancers, particularly in bladder cancer. Preclinical data demonstrate that enfortumab vedotin binds to Nectin-4 on cancer cells and releases the cell-killing agent into these target cells upon internalization.

### **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 that develops and commercializes novel antibody-based therapies for the treatment of cancer. 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. ADCETRIS<sup>®</sup> (brentuximab vedotin), the company's lead product, in collaboration with Takeda Pharmaceutical Company Limited, is the first in a new class of ADCs commercially available globally in 67 countries for relapsed classical Hodgkin lymphoma (HL) and relapsed systemic anaplastic large cell lymphoma (sALCL). Seattle Genetics is also advancing enfortumab vedotin, an ADC in a pivotal trial for metastatic urothelial cancer, in collaboration with Astellas and tisotumab vedotin, an ADC in a phase 1/2 trial for solid tumors, in collaboration with Genmab. Headquartered in Bothell, Washington and with European and international operations in Zug, Switzerland, Seattle Genetics has a robust pipeline of innovative therapies for blood-related cancers and solid tumors designed to address significant unmet medical needs and improve treatment outcomes for patients. The company has collaborations for its proprietary ADC technology with a number of companies including AbbVie, Astellas, Bayer, Celldex, Genentech, GlaxoSmithKline and Pfizer. More information can be found at [www.seattlegenetics.com](http://www.seattlegenetics.com).

### **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 possibility that EV-201 will generate data that

would be sufficient to support potential registration of enfortumab vedotin, under the U.S. Food and Drug Administration's (FDA) accelerated approval regulations, 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 August 1, 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. 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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