

Astellas and Seattle Genetics Present at ASCO 2018 on Enfortumab Vedotin in Patients with Locally Advanced or Metastatic Urothelial Cancer Previously Treated with Checkpoint Inhibitor Therapy

-Updated Data from Phase 1 EV-101 Study Highlighted in ASCO 2018 Oral Presentation Support Rapid Development Program and Ongoing Pivotal Study-

TOKYO and BOTHELL, Wash. – June 3, 2018 – [Astellas Pharma Inc.](#) (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) and [Seattle Genetics, Inc.](#) (Nasdaq: SGEN) today announced the presentation of updated phase 1 data of enfortumab vedotin, an investigational antibody-drug conjugate (ADC), at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting in Chicago. In this phase 1 study (EV-101), enfortumab vedotin was evaluated as monotherapy for patients with metastatic urothelial cancer including patients who previously received a checkpoint inhibitor.¹ This phase 1 study is part of a broader program focused on investigating enfortumab vedotin in both monotherapy and in combination with a checkpoint inhibitor for locally advanced or metastatic urothelial cancer.

“Many patients with locally advanced or metastatic urothelial cancer previously treated with checkpoint inhibitors have a poor prognosis and limited subsequent treatment options,” said Jonathan E. Rosenberg, M.D., medical oncologist at Memorial Sloan Kettering Cancer Center and presenter of the updated phase 1 data at ASCO. “Data from the ongoing study support the potential of enfortumab vedotin in locally advanced or metastatic urothelial cancer, based on the objective response rate and preliminary estimates of survival.”

“We are encouraged by these updated data for enfortumab vedotin, which further support the rapid expansion of a comprehensive clinical trial program and the registrational study that is already underway in metastatic urothelial cancer,” said Steven Benner, M.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development, Astellas. “We look forward to working closely with our partner, Seattle Genetics, as we continue to evaluate enfortumab vedotin for patients with metastatic urothelial cancer.”

Robert Lechleider, M.D., Senior Vice President, Clinical Development at Seattle Genetics added, “These ASCO data from the phase 1 study of enfortumab vedotin further support its Breakthrough Therapy Designation from the FDA, and the rationale for our ongoing pivotal trial, EV-201. We look forward to completing enrollment of the EV-201 pivotal trial for patients with metastatic urothelial cancer who have received both a platinum-based therapy and a checkpoint inhibitor. Positive data in this patient subgroup may represent a potential expedited registration pathway.”

The following updated results were presented by Dr. Rosenberg:

Updated Results from the Enfortumab Vedotin Phase 1 (EV-101) Study in Patients with Metastatic Urothelial Cancer: (Abstract #4504, oral abstract session on Sunday, June 3 from 9:12-9:24 a.m. CT)¹

Study Design

- A total of 112 patients with metastatic urothelial cancer treated with 1 or more prior chemotherapy or who were ineligible for cisplatin received a 30-minute infusion of enfortumab vedotin at 1.25 mg/kg on day 1, 8 and 15 of each 28-day cycle.ⁱⁱ
- Sixty-three percent of patients had received 2 or more prior therapies in the metastatic setting.¹
- The primary objective of the study was tolerability. A secondary objective was antitumor activity, which was assessed by investigators every 8 weeks.²

Study Results

- Of 112 evaluable patients, confirmed complete responses were observed in 4 patients and confirmed partial responses were observed in 41 patients, with an overall response rate of 41 percent.¹
- The most commonly reported treatment-related adverse event was All Grade fatigue (54 percent). Anemia (8 percent), hyponatremia (7 percent), urinary tract infection (7 percent) and hyperglycemia (6 percent) were the most common \geq Grade 3 AEs.¹ Four patients experienced a fatal treatment-related adverse event (respiratory failure, urinary tract obstruction, diabetic ketoacidosis, multi-organ failure).²
- Additionally, the ORR in the 89 patients with prior checkpoint inhibitor therapy was 40 percent, 44 percent in the 23 patients who had not been treated with a checkpoint inhibitor, and 39 percent in the 33 patients with liver metastases.¹
- For all enrolled patients, the interim median overall survival was 13.6 months, the overall median duration of response was 5.75 months and the median progression-free survival was 5.4 months.¹

EV-201 Study: A Single-Arm, Open-Label, Multicenter Study of Enfortumab Vedotin for Treatment of Patients with Locally Advanced or Metastatic Urothelial Cancer Who Previously Received Immune Checkpoint Inhibitor Therapy (Abstract #TPS4590, poster session on Saturday, June 2 from 8:00-11:30 a.m. CT)ⁱⁱⁱ

In addition, the EV-201 trial in progress poster was presented at the meeting. 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 checkpoint inhibitor therapy, including those who had also been treated with a platinum chemotherapy and those who were platinum naive.³

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^{iv} (90 percent of cases^v). Approximately 81,000 people in the U.S. are anticipated to be diagnosed with bladder cancer during 2018.^{vi} Bladder cancer is the fourth most common cancer in men, but is less common in women.⁶ Outcomes are poor for people diagnosed with metastatic disease, with a five-year survival rate of 4.8 percent.^{vii}

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

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 or planned 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 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, the risk of adverse events or safety signals, and the possibility of adverse regulatory actions as enfortumab vedotin advance 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.

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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ⁱ Rosenberg J, Sridhar S, Zhang J, et al. Updated results from the enfortumab vedotin phase 1 (EV-101) study in patients with metastatic urothelial cancer [presentation]. Presented at: The 54th Annual Meeting of the American Society of Clinical Oncology. June 1-5, 2018; Chicago, IL.

ⁱⁱ Rosenberg J, Sridhar S, Zhang J, et al. Updated results from the enfortumab vedotin phase 1 (EV-101) study in patients with metastatic urothelial cancer (mUC) [Abstract #4504]. Presented at: The 54th Annual Meeting of the American Society of Clinical Oncology. June 1-5, 2018; Chicago, IL.

ⁱⁱⁱ Rosenberg JE, Heath EI, O'Donnell PH, et al. EV-201 Study: a single-arm, open-label, multicenter study of enfortumab vedotin for treatment of patients with locally advanced or metastatic urothelial cancer who previously received immune checkpoint inhibitor therapy [Abstract #TPS4590]. Presented at: The 54th Annual Meeting of the American Society of Clinical Oncology. June 1-5, 2018; Chicago, IL.

^{iv} American Cancer Society. What is bladder cancer? (05-23-2016).

<https://www.cancer.org/cancer/bladder-cancer/about/what-is-bladder-cancer.html> Accessed 06-02-2018

^v National Cancer Institute. Bladder cancer treatment (PDQ®) – health professional version (04-12-2018).

<https://www.cancer.gov/types/bladder/hp/bladder-treatment-pdq>. Accessed 05-08-2018.

^{vi} American Cancer Society. Key statistics for bladder cancer (01-04-2018).

<https://www.cancer.org/cancer/bladder-cancer/about/key-statistics.html>. Accessed 05-08-2018.

^{vii} 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.