Seattle Genetics and Astellas Announce US FDA Grants Priority Review for Enfortumab Vedotin Biologics License Application in Locally Advanced or Metastatic Urothelial Cancer

- Food & Drug Administration Sets Prescription Drug User Fee Action Date for March 15, 2020 -

BOTHELL, Wash. and TOKYO, September 16, 2019 – Seattle Genetics, Inc. (Nasdaq:SGEN) and Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) for the investigational agent enfortumab vedotin and granted Priority Review 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 filing 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 oral presentation at the annual meeting of the American Society of Clinical Oncology (ASCO) in June 2019. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of March 15, 2020. Enfortumab vedotin is a novel investigational antibody-drug conjugate (ADC) that targets Nectin-4, a protein that is highly expressed in urothelial cancers.[1]

The FDA granted enfortumab vedotin Breakthrough Therapy designation in March 2018, for patients with locally advanced or metastatic urothelial cancer whose disease has progressed during or following checkpoint inhibitor therapy.

"The FDA's filing of the application for enfortumab vedotin and granting of Priority Review is a significant milestone toward offering a new treatment to patients with advanced urothelial cancer who have a clear unmet need," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics.

"If approved, enfortumab vedotin will likely play an important role in the treatment of advanced urothelial cancer, and we look forward to working with the FDA as the review process advances," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Oncology Therapeutic Area Head at Astellas.

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, including those who have also been treated with a platinum-containing chemotherapy (cohort 1) and those who have not received a platinum-containing chemotherapy and who are ineligible for cisplatin (cohort 2). In cohort 1, 128 patients were enrolled at multiple centers internationally.[2] 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). In 2018, more than 82,000 people were diagnosed with bladder cancer in the United States.[3] Globally, approximately 549,000 people were diagnosed with bladder cancer last year, and there were approximately 200,000 deaths worldwide.[4]

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 Zug, 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, 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 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 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 June 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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2. Data on file at Seattle Genetics.
3. American Society of Clinical Oncology. Bladder Cancer: Statistics (05-2019). https://www.cancer.net/cancer-types/bladder-cancer/statistics
4. Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin 2018;68(6):394-424.