UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 28, 2019

Seattle Genetics, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	0-32405	91-1874389
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S Employer Identification No.)

21823 30th Drive SE
Bothell, Washington 98021
(Address of principal executive offices, including zip code)

(425) 527-4000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events

On March 28, 2019, Seattle Genetics, Inc. (the "Company") issued a press release announcing top-line results from cohort 1 of the pivotal phase 2 trial evaluating enfortumab vedotin in patients with locally advanced or metastatic urothelial cancer who previously received both platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor. A description of these top-line results is contained in the Company's press release dated March 28, 2019, which is attached as Exhibit 99.1 to this current report and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release of Seattle Genetics, Inc. dated March 28, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SEATTLE GENETICS, INC.

Date: March 28, 2019

By: /s/ Clay B. Siegall
Clay B. Siegall
President and Chief Executive Officer

Seattle Genetics and Astellas Announce Positive Topline Results from Pivotal Trial of Enfortumab Vedotin in Locally Advanced or Metastatic Urothelial Cancer

– Companies Plan to Submit Biologics License Application Later This Year –

– Seattle Genetics to Hold Conference Call Today at 9:00 a.m. EDT –

BOTHELL, Wash. and TOKYO, March 28, 2019 – Seattle Genetics, Inc. (Nasdaq:SGEN) and Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced positive topline results from the first cohort of patients in a pivotal phase 2 single-arm clinical trial known as EV-201. The cohort is evaluating enfortumab vedotin for the treatment of patients with locally advanced or metastatic urothelial cancer who have received previous treatment with both platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor. Results showed a 44 percent objective response rate (ORR) per blinded independent central review. The duration of response was consistent with that recently reported in the previous phase 1 study (EV-101). The most common treatment-related adverse events included fatigue, alopecia, decreased appetite, rash and peripheral neuropathy. The data will be presented at an upcoming medical meeting.

Enfortumab vedotin is an investigational antibody-drug conjugate (ADC) that targets Nectin-4, a therapeutic target that is highly expressed in multiple solid tumors including urothelial cancers. Based on preliminary results from a phase 1 trial (EV-101), enfortumab vedotin was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) for patients with locally advanced or metastatic urothelial cancer whose disease has progressed during or following treatment with a PD-1 or PD-L1 inhibitor.

The companies plan to submit a Biologics License Application (BLA) to the FDA later this year based on the results from the EV-201 trial (cohort 1). A global, randomized phase 3 clinical trial (EV-301) is ongoing and intended to support global registration as well as to serve as the confirmatory randomized trial for enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who have been previously treated with a platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor.

"Despite recent approvals of multiple checkpoint inhibitors for previously treated locally advanced or metastatic urothelial cancer, there remains a high unmet need for effective treatments upon progression after initial chemotherapy and immunotherapy," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics. "These results for enfortumab vedotin indicate it may be able to help patients whose urothelial cancer progresses following treatment with standard chemotherapy and a PD-1 or PD-L1 inhibitor."

"After progression on platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor, patients with locally advanced or metastatic urothelial cancer are left with no approved standard of care treatment options," said Steven Benner, M.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development at Astellas. "These data are very encouraging, and we look forward to discussing the data with relevant health authorities."

Urothelial cancer is the most common type of bladder cancer (90 percent of cases).[1] In 2018, more than 82,000 people were diagnosed with bladder cancer in the United States.[2] Globally, approximately 549,000 people were diagnosed with bladder cancer last year, and there were approximately 200,000 deaths worldwide.[3] Approximately 80 percent of people do not respond to PD-1 or PD-L1 inhibitors after a platinum-containing therapy has failed as an initial treatment for advanced disease.[4] There are currently no approved therapies for metastatic urothelial cancer once it has progressed after chemotherapy and a PD-1 or PD-L1 inhibitor.[5]

In addition to the ongoing confirmatory phase 3 study intended to also support global registration, development of enfortumab vedotin is underway in earlier lines of treatment for locally advanced or metastatic urothelial cancer, including in newly diagnosed patients in combination with pembrolizumab and/or platinum chemotherapy.

About EV-201 Trial

EV-201 is an ongoing single-arm, pivotal phase 2 clinical trial of enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who have been previously treated with a PD-1 or PD-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). The EV-201 phase 2 trial continues to enroll patients in cohort 2. In cohort 1, 128 patients were enrolled at multiple centers internationally.[6] 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. More information about enfortumab vedotin clinical trials can be found at clinical trials.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.

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 and become commercially available for the uses being investigated.

Seattle Genetics Conference Call Details Seattle Genetics' management will host a conference call and webcast to discuss the announcement of enfortumab vedotin topline data. The event will be held today at 6:00 a.m. Pacific Time (PT); 9:00 a.m. Eastern Time (ET). The live event will be available from the Seattle Genetics website at www.seattlegenetics.com, under the Investors section, or by calling 866-288-0540 (domestic) or 786-460-7199 (international). The conference ID is 3807860. A replay of the live event will be available starting on March 28, 2019 on the Seattle Genetics website or by calling 888-203-1112 (domestic) or 719-457-0820 (international), using conference ID 3807860. The telephone replay will be available until 5:00 p.m. PT on April 1, 2019.

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 Statement

Certain statements made in this press release are forward looking, such as those, among others, relating to the companies' expected reporting of data from cohort 1 of the EV-201 trial in upcoming medical conferences, and plan to submit a Biologics License Application (BLA) to the FDA in the near term under FDA's Accelerated Approval program based on the results of the pivotal EV-201 trial; conduct of a comprehensive clinical development program for enfortumab vedotin, which includes an ongoing randomized phase 3 confirmatory trial (EV-301) intended to support global registration in locally advanced or metastatic urothelial cancer; and 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 that the data from EV-201 may not be selected for publication at medical conferences; the possibility of delays in the submission of a BLA to the FDA; that the data from EV-201 may not be sufficient to support accelerated approval; and the inability to show sufficient activity in EV-301 and subsequent clinical trials; the risk of adverse events or safety signals; and the possibility of adverse regulatory actions 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 Annual Report on Form 10-K for the year ended December 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.

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 (10-2017). https://www.cancer.net/cancer-types/bladder-cancer/introduction.
2 https://gco.iarc.fr/today/data/factsheets/populations/840-united-states-of-america-fact-sheets.pdf
3 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.
4 Alhalabi O, Shah AY, Lemke EA, Gao J (2019). Immune checkpoint inhibitors in urothelial cancer. Oncology (Williston Park) 33(1): 1108.
5 National Comprehensive Cancer Network. Bladder Cancer (Version 1.2019). http://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf.
6 Data on file at Seattle Genetics