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): November 16, 2018

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 November 16, 2018, Seattle Genetics, Inc. (the "Company") issued a press release announcing, among other things, that the U.S. Food and Drug Administration ("FDA") has approved ADCETRIS (brentuximab vedotin) in combination with CHP chemotherapy (cyclophosphamide, doxorubicin, and prednisone) for adults with previously untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas ("PTCL"), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified. The Company's press release 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 November 16, 2018

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: November 16, 2018

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

Exhibit 99.1

Seattle Genetics Announces FDA Approval of ADCETRIS® (Brentuximab Vedotin) in Combination with Chemotherapy for Adults with Previously Untreated Systemic Anaplastic Large Cell Lymphoma or Other CD30-Expressing Peripheral T-Cell Lymphomas

-First FDA-Approved Regimen in Frontline Peripheral T-Cell Lymphoma-

-FDA Approval Based on Results from the Phase 3 ECHELON-2 Clinical Trial; Data to be Presented at the 2018 ASH Annual Meeting-

-Application Approved Less Than Two Weeks After Submission Under FDA Real-Time Oncology Review Pilot Program-

BOTHELL, Wash., November 16, 2018 – Seattle Genetics, Inc. (Nasdaq:SGEN) today announced a new approval for ADCETRIS® (brentuximab vedotin) in combination with CHP chemotherapy (cyclophosphamide, doxorubicin, prednisone) from the U.S. Food and Drug Administration (FDA) for adults with previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified. The approval is based on the successful outcome of the phase 3 ECHELON-2 clinical trial that compared ADCETRIS plus CHP to CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone). The FDA granted Breakthrough Therapy designation and Priority Review to this supplemental Biologics License Application (BLA) and reviewed it under the Real-Time Oncology Review Pilot Program leading to approval less than two weeks after submission of the complete application.

"The current standard of care for initial treatment of peripheral T-cell lymphoma is multi-agent chemotherapy. That treatment has not significantly changed in decades and is too often unsuccessful in leading to long-term remissions, underscoring the need for new treatments," said Steven Horwitz, M.D., Department of Medicine, Lymphoma Service, Memorial Sloan Kettering Cancer Center, New York. "The ECHELON-2 clinical trial demonstrated ADCETRIS plus CHP was superior to the current standard of care, CHOP, for both progression-free survival and all other key secondary endpoints, including, most importantly, overall survival. With this approval, clinicians have the opportunity to transform the way newly diagnosed CD30-expressing PTCL patients are treated."

This is the sixth FDA-approved indication for ADCETRIS, which also has approval for adult patients with: (1) previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine (AVD), (2) cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation, (3) cHL after failure of auto-HSCT or failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates, (4) sALCL after failure of at least one prior multi-agent chemotherapy regimen, and (5) primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy.

“By participating in the FDA’s Real-Time Oncology Review process and working closely with the FDA, we are now able to make the ADCETRIS regimen available to previously untreated patients with CD30-expressing PTCL in an unprecedented less than two weeks after submission of our supplemental BLA,” said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. “The ECHELON-2 clinical trial demonstrated ADCETRIS plus CHP results in a superior outcome for patients when compared to current standard of care, CHOP. We want to thank the patients, physicians and their staff who participated in the ECHELON-2 trial, which supported this FDA approval.”

The ECHELON-2 data will be presented at the American Society of Hematology (ASH) 2018 Annual Meeting, on Monday, December 3, 2018, at 6:15 pm PT at the San Diego Convention Center in Room 6F in San Diego, Calif. Patients in ECHELON-2 were randomized to receive either a combination of ADCETRIS plus CHP or CHOP, a recognized standard of care for frontline PTCL. Results from the trial demonstrated that combination treatment with ADCETRIS plus CHP was superior to CHOP for progression free survival (PFS) as assessed by a Blinded Independent Central Review facility (BICR; hazard ratio=0.71; 95% CI, 0.54–0.93; p-value=0.011). This corresponds to a 29 percent reduction in the risk of progression, death, or receipt of subsequent anticancer chemotherapy to treat residual or progressive disease. The ADCETRIS plus CHP arm also demonstrated superior overall survival (OS), a key secondary endpoint, compared to CHOP (hazard ratio=0.66; 95% CI, 0.46-0.95; p-value=0.024). All other key secondary endpoints, including PFS in patients with sALCL (hazard ratio=0.59; 95% CI, 0.42-0.84; p-value=0.003), complete remission rate (68% vs 56%; p-value=0.007) and objective response rate (83% vs 72%; p-value=0.003) were statistically significant in favor of the ADCETRIS plus CHP arm.

The safety profile of ADCETRIS plus CHP in the ECHELON-2 trial was comparable to CHOP and consistent with the established safety profile of ADCETRIS in combination with AVD. The most common adverse events of any grade that occurred in at least 20 percent of patients in the ADCETRIS plus CHP arm were peripheral neuropathy, nausea, diarrhea, neutropenia, lymphopenia, fatigue, mucositis, constipation, alopecia, pyrexia, vomiting and anemia. Serious adverse reactions occurring in at least two percent of ADCETRIS plus CHP-treated patients included febrile neutropenia, pneumonia, pyrexia and sepsis. Based on ECHELON-2 clinical trial results, prophylactic growth factors (G-CSF) should be administered starting at cycle one for patients receiving ADCETRIS plus CHP for previously untreated PTCL.

ECHELON-2 Phase 3 Clinical Trial Design

The multi-center, randomized, double-blind, placebo-controlled phase 3 trial is investigating ADCETRIS plus CHP (cyclophosphamide, doxorubicin, prednisone) versus CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) as frontline therapy in patients with CD30-expressing peripheral T-cell lymphoma, also known as mature T-cell lymphoma. The primary endpoint is progression-free survival (PFS) per BICR facility assessment, with events defined as progression, death due to any cause, or receipt of subsequent anticancer chemotherapy to treat residual or progressive disease. Secondary endpoints include PFS in patients with systemic anaplastic large cell lymphoma (sALCL), complete remission rate, overall survival and objective response rate, in addition to safety. The trial was conducted at sites across North America, Europe and Asia and was designed to enroll 450 patients, approximately 75 percent of whom were to be diagnosed with sALCL. The ECHELON-2 trial was conducted under a Special Protocol Assessment (SPA) agreement from the U.S. Food and Drug Administration (FDA) and the trial also received European Medicines Agency (EMA) scientific advice.

Please see **Important Safety Information, including Boxed Warning,** at the end of this press release.

About T-Cell Lymphomas

Lymphoma is a general term for a group of cancers that originate in the lymphatic system. There are two major categories of lymphoma: Hodgkin lymphoma and non-Hodgkin lymphoma. There are more than 60 subtypes of non-Hodgkin lymphomas which are broadly divided into two major groups: B-cell lymphomas, which develop from abnormal B-lymphocytes, and T-cell lymphomas, which develop from abnormal T-lymphocytes. There are many different forms of T-cell lymphomas, some of which are extremely rare. T-cell lymphomas can be aggressive (fast-growing) or indolent (slow-growing). PTCL accounts for approximately 10 percent of the estimated 74,680 people diagnosed with non-Hodgkin lymphoma in the U.S. in 2018 .[1]

About ADCETRIS (brentuximab vedotin)

ADCETRIS is being evaluated broadly in more than 70 clinical trials in CD30-expressing lymphomas. These include the recently completed phase 3 ECHELON-2 trial in frontline peripheral T-cell lymphomas (also known as mature T-cell lymphoma), the completed phase 3 ECHELON-1 trial in previously untreated Hodgkin lymphoma, the completed phase 3 ALCANZA trial in cutaneous T-cell lymphoma, and the ongoing CHECKMATE 812 trial of ADCETRIS in combination with *Opdivo* (nivolumab) for relapsed/refractory Hodgkin lymphoma.

ADCETRIS is an ADC comprising an anti-CD30 monoclonal antibody attached by a protease-cleavable linker to a microtubule disrupting agent, monomethyl auristatin E (MMAE), utilizing Seattle Genetics' proprietary technology. The ADC employs a linker system that is designed to be stable in the bloodstream but to release MMAE upon internalization into CD30-expressing tumor cells.

ADCETRIS injection for intravenous infusion has received FDA approval for six indications in adult patients with: (1) previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone, (2) previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine, (3) cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation, (4) cHL after failure of auto-HSCT or failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates, (5) sALCL after failure of at least one prior multi-agent chemotherapy regimen, and (6) primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy.

Health Canada granted ADCETRIS approval with conditions for relapsed or refractory Hodgkin lymphoma and sALCL in 2013, and non-conditional approval for post-autologous stem cell transplantation (ASCT) consolidation treatment of Hodgkin lymphoma patients at increased risk of relapse or progression.

ADCETRIS received conditional marketing authorization from the European Commission in October 2012. The approved indications in Europe are: (1) for the treatment of adult patients with relapsed or refractory CD30-positive Hodgkin lymphoma following ASCT, or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option, (2) the treatment of adult patients with relapsed or refractory sALCL, (3) for the treatment of adult patients with CD30-positive Hodgkin lymphoma at increased risk of relapse or progression following ASCT, and (4) for the treatment of adult patients with CD30-positive cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy.

ADCETRIS has received marketing authorization by regulatory authorities in 72 countries for relapsed or refractory Hodgkin lymphoma and sALCL. See select important safety information, including Boxed Warning, below.

Seattle Genetics and Takeda are jointly developing ADCETRIS. Under the terms of the collaboration agreement, Seattle Genetics has U.S. and Canadian commercialization rights and Takeda has rights to commercialize ADCETRIS in the rest of the world. Seattle Genetics and Takeda are funding joint development costs for ADCETRIS on a 50:50 basis, except in Japan where Takeda is solely responsible for development costs.

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 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.

ADCETRIS (brentuximab vedotin) Important Safety Information

BOXED WARNING: PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML):

JC virus infection resulting in PML and death can occur in ADCETRIS-treated patients.

Contraindication

ADCETRIS concomitant with bleomycin due to pulmonary toxicity (e.g., interstitial infiltration and/or inflammation).

Warnings and Precautions

- **Peripheral neuropathy (PN):** ADCETRIS causes PN that is predominantly sensory. Cases of motor PN have also been reported. ADCETRIS-induced PN is cumulative. Monitor for symptoms such as hypoesthesia, hyperesthesia, paresthesia, discomfort, a burning sensation, neuropathic pain, or weakness. Institute dose modifications accordingly.
- **Anaphylaxis and infusion reactions:** Infusion-related reactions (IRR), including anaphylaxis, have occurred with ADCETRIS. Monitor patients during infusion. If an IRR occurs, interrupt the infusion and institute appropriate medical management. If anaphylaxis occurs, immediately and permanently discontinue the infusion and administer appropriate medical therapy. Premedicate patients with a prior IRR before subsequent infusions. Premedication may include acetaminophen, an antihistamine, and a corticosteroid.
- **Hematologic toxicities:** Fatal and serious cases of febrile neutropenia have been reported with ADCETRIS. Prolonged (□1 week) severe neutropenia and Grade 3 or 4 thrombocytopenia or anemia can occur with ADCETRIS. Start primary prophylaxis with G-CSF beginning with Cycle 1 for patients who receive ADCETRIS in combination with chemotherapy for previously untreated Stage III or IV classical HL or previously untreated PTCL. Monitor complete blood counts prior to each ADCETRIS dose. Monitor more frequently for patients with Grade 3 or 4 neutropenia. Monitor patients for fever. If Grade 3 or 4 neutropenia develops, consider dose delays, reductions, discontinuation, or G-CSF prophylaxis with subsequent ADCETRIS doses.
- **Serious infections and opportunistic infections:** Infections such as pneumonia, bacteremia, and sepsis or septic shock (including fatal outcomes) have been reported in ADCETRIS-treated patients. Closely monitor patients during treatment for bacterial, fungal, or viral infections.

- **Tumor lysis syndrome:** Closely monitor patients with rapidly proliferating tumor and high tumor burden.
- **Increased toxicity in the presence of severe renal impairment:** The frequency of ≥Grade 3 adverse reactions and deaths was greater in patients with severe renal impairment compared to patients with normal renal function. Avoid use in patients with severe renal impairment.
- **Increased toxicity in the presence of moderate or severe hepatic impairment:** The frequency of ≥Grade 3 adverse reactions and deaths was greater in patients with moderate or severe hepatic impairment compared to patients with normal hepatic function. Avoid use in patients with moderate or severe hepatic impairment.
- **Hepatotoxicity**: Fatal and serious cases have occurred in ADCETRIS-treated patients. Cases were consistent with hepatocellular injury, including elevations of transaminases and/or bilirubin, and occurred after the first ADCETRIS dose or rechallenge. Preexisting liver disease, elevated baseline liver enzymes, and concomitant medications may increase the risk. Monitor liver enzymes and bilirubin. Patients with new, worsening, or recurrent hepatotoxicity may require a delay, change in dose, or discontinuation of ADCETRIS.
- **PML:** Fatal cases of JC virus infection resulting in PML and death have been reported in ADCETRIS-treated patients. First onset of symptoms occurred at various times from initiation of ADCETRIS therapy, with some cases occurring within 3 months of initial exposure. Other possible contributory factors other than ADCETRIS include prior therapies and underlying disease that may cause immunosuppression. Consider PML diagnosis in patients with new-onset signs and symptoms of central nervous system abnormalities. Hold ADCETRIS if PML is suspected and discontinue ADCETRIS if PML is confirmed.
- **Pulmonary toxicity:** Fatal and serious events of noninfectious pulmonary toxicity including pneumonitis, interstitial lung disease, and acute respiratory distress syndrome have been reported. Monitor patients for signs and symptoms, including cough and dyspnea. In the event of new or worsening pulmonary symptoms, hold ADCETRIS dosing during evaluation and until symptomatic improvement.
- **Serious dermatologic reactions:** Fatal and serious cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with ADCETRIS. If SJS or TEN occurs, discontinue ADCETRIS and administer appropriate medical therapy.
- **Gastrointestinal (GI) complications:** Fatal and serious cases of acute pancreatitis have been reported. Other fatal and serious GI complications include perforation, hemorrhage, erosion, ulcer, intestinal obstruction, enterocolitis, neutropenic colitis, and ileus. Lymphoma with preexisting GI involvement may increase the risk of perforation. In the event of new or worsening GI symptoms, perform a prompt diagnostic evaluation and treat appropriately.
- **Embryo-fetal toxicity:** Based on the mechanism of action and animal studies, ADCETRIS can cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus, and to avoid pregnancy during ADCETRIS treatment and for at least 6 months after the final dose of ADCETRIS.

Most Common (≥20% in any study) Adverse Reactions: Peripheral neuropathy, fatigue, nausea, diarrhea, neutropenia, upper respiratory tract infection, pyrexia, constipation, vomiting, alopecia, decreased weight, abdominal pain, anemia, stomatitis, lymphopenia and mucositis

Drug Interactions

Concomitant use of strong CYP3A4 inhibitors or inducers has the potential to affect the exposure to monomethyl auristatin E (MMAE).

Use in Specific Populations

Moderate or severe hepatic impairment or severe renal impairment: MMAE exposure and adverse reactions are increased. Avoid use.

Advise males with female sexual partners of reproductive potential to use effective contraception during ADCETRIS treatment and for at least 6 months after the final dose of ADCETRIS.

Advise patients to report pregnancy immediately and avoid breastfeeding while receiving ADCETRIS.

For additional Important Safety Information, including BOXED WARNING, please see the full Prescribing Information for ADCETRIS at www.seattlegenetics.com or http://www.ADCETRIS.com.

Forward-Looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, relating to the utilization of and therapeutic potential of ADCETRIS (brentuximab vedotin) as a treatment for adults with previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, the possibility that the approved regimen could transform the way newly diagnosed CD30-expressing PTCL patients are treated, and the anticipated presentation of data from the ECHELON-2 clinical trial at ASH in 2018. Actual results or developments may differ materially from those projected or implied in these forward-looking statements due to factors such as utilization and adoption of the approved treatment regimen by prescribing physicians, the availability and extent of reimbursement, the risk of adverse events and adverse regulatory action. 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 September 30, 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 except as required by law.

References:

1 American Cancer Society, Key Statistics for Non-Hodgkin Lymphoma. Available at https://www.cancer.org/cancer/non-hodgkin-lymphoma.html. Accessed November 2018.

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