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): October 1, 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 October 1, 2018, Seattle Genetics, Inc. (the "Company") issued a press release announcing top-line results from the phase 3 ECHELON-2 clinical trial evaluating ADCETRIS® (brentuximab vedotin) as part of a frontline chemotherapy regimen in patients with newly diagnosed CD30-positive peripheral T-cell lymphoma, also known as mature T-cell lymphoma. A description of these top-line results is contained in the Company's press release dated October 1, 2018, 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

Exhibit No.	Description
99.1	Press Release of Seattle Genetics, Inc. dated October 1, 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.

Date: October 1, 2018

SEATTLE GENETICS, INC.

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

Exhibit 99.1

FOR RELEASE: **Monday, October 1, 2018**
3:45 a.m. PT / 6:45 a.m. ET

Seattle Genetics and Takeda Announce Positive Results from Phase 3 ECHELON-2 Clinical Trial Evaluating ADCETRIS® (Brentuximab Vedotin) in Frontline CD30-Expressing Peripheral T-Cell Lymphoma

-ADCETRIS in Combination with Chemotherapy Achieved Primary Endpoint, Demonstrating a Statistically Significant Improvement in Progression-Free Survival Compared to a Standard of Care Chemotherapy-

-Statistically Significant Improvement Achieved in All Key Secondary Endpoints, Including Overall Survival-

-First Randomized Phase 3 Trial to Show Improvement in Overall Survival in Frontline Peripheral T-Cell Lymphoma-

-Data to be Presented at the 2018 ASH Annual Meeting; Global Regulatory Submissions Planned-

BOTHELL, Wash., CAMBRIDGE, Mass. and OSAKA, Japan, October 1, 2018 – Seattle Genetics, Inc. (Nasdaq:SGEN) and Takeda Pharmaceutical Company Limited (TSE:4502) announced today that the phase 3 ECHELON-2 clinical trial met its primary endpoint. The trial demonstrated a statistically significant improvement in progression-free survival (PFS) of ADCETRIS (brentuximab vedotin) in combination with CHP (cyclophosphamide, doxorubicin, prednisone) versus the control arm, CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone). ECHELON-2 is a global, randomized, double-blind, multicenter trial evaluating ADCETRIS as part of a frontline combination chemotherapy regimen in patients with previously untreated CD30-expressing peripheral T-cell lymphoma (PTCL), also known as mature T-cell lymphoma (MTCL). ADCETRIS is an antibody-drug conjugate (ADC) directed to CD30, which is expressed on the surface of several types of PTCL. ADCETRIS is currently not approved for the frontline treatment of PTCL.

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 the control arm for PFS as assessed by an Independent Review Facility (IRF; hazard ratio=0.71; p-value=0.0110). The ADCETRIS plus CHP arm also demonstrated superior overall survival (OS), a key secondary endpoint, compared to CHOP (hazard ratio=0.66; p-value=0.0244). All other key secondary endpoints, including PFS in patients with systemic anaplastic large cell lymphoma (sALCL), complete remission rate and objective response rate 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 chemotherapy. Additional data will be presented at the American Society of Hematology (ASH) 2018 annual meeting, December 1-4, 2018, in San Diego, California.

“Peripheral T-cell lymphoma is an aggressive type of non-Hodgkin lymphoma with approximately 4,000 CD30-expressing patients diagnosed every year in the United States,” said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. “We are excited about the groundbreaking results of the phase 3 ECHELON-2 clinical trial, which demonstrated ADCETRIS in combination with chemotherapy significantly improved treatment outcomes for adult patients with previously untreated CD30-expressing PTCL compared with the current standard of care (CHOP). We’d like to thank the many investigators and patients who participated in this study and contributed to this significant milestone for the PTCL community. We look forward to presenting results at the ASH annual meeting in December and intend to submit a supplemental Biologics License Application to the FDA for approval in this setting in the near future.”

“These clinically meaningful results from ECHELON-2 represent a significant step in the development of a potential frontline treatment in this disease. This trial is the largest randomized, double-blind, phase 3 trial in PTCL,” said Jesús Gomez-Navarro, M.D., Vice President, Head of Oncology Clinical Research and Development, Takeda. “Standard of care in PTCL has not changed in several decades and there remains an unmet need for patients. These data showed a significant improvement in the primary endpoint of progression-free survival and all key secondary endpoints, including overall survival, along with a manageable safety profile. We look forward to sharing these data with regulatory authorities globally.”

Takeda and Seattle Genetics plan to submit these results to regulatory authorities for approval in their respective territories.

ECHELON-2 Phase 3 Clinical Trial Design

The 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 Independent Review Facility assessment, with events defined as progression, death, or receipt of chemotherapy for 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 multi-center 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 is being 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** 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, also known as MTCL, accounts for approximately 10 percent of non-Hodgkin lymphoma cases in the U.S. and Europe and may be as high as 24 percent in parts of Asia.

About ADCETRIS (brentuximab vedotin)

ADCETRIS is being evaluated broadly in more than 70 clinical trials, including the completed phase 3 ECHELON-2 trial in frontline peripheral T-cell lymphomas (also known as mature T-cell lymphoma), the completed phase 3 ALCANZA trial in cutaneous T-cell lymphoma (CTCL) and the completed ECHELON-1 trial in previously untreated Hodgkin lymphoma, as well as trials in many additional types of CD30-expressing malignancies.

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 five indications in adult patients with: (1) previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with chemotherapy, (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.

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 71 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.

About Takeda Pharmaceutical Company

Takeda Pharmaceutical Company Limited (TSE: 4502) is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its R&D efforts on oncology, gastroenterology and neuroscience therapeutic areas plus vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. Innovative products, especially in oncology and gastroenterology, as well as Takeda's presence in emerging markets, are currently fueling the growth of Takeda. Approximately 30,000 Takeda employees are committed to improving quality of life for patients, working with Takeda's partners in health care in more than 70 countries.

For more information, visit https://www.takeda.com/newsroom/.

Additional information about Takeda is available through its corporate website, www.takeda.com, and additional information about Takeda Oncology, the brand for the global oncology business unit of Takeda Pharmaceutical Company Limited, is available through its website, www.takedaoncology.com.

ADCETRIS (brentuximab vedotin) U.S. Select 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. Administer G-CSF primary prophylaxis starting with Cycle 1 for previously untreated patients who receive ADCETRIS in combination with chemotherapy for Stage III or IV HL. Monitor complete blood counts prior to each ADCETRIS dose. Consider more frequent monitoring 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 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%) Adverse Reactions: Neutropenia, anemia, peripheral sensory neuropathy, nausea, fatigue, constipation, diarrhea, vomiting, and pyrexia.

Drug Interactions

Concomitant use of strong CYP3A4 inhibitors or inducers, or P-gp inhibitors, 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**.**

ADCETRIS (brentuximab vedotin) Important Safety Information (European Union)

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

CONTRAINDICATIONS

ADCETRIS is contraindicated for patients with hypersensitivity to brentuximab vedotin and its excipients. In addition, combined use of ADCETRIS with bleomycin causes pulmonary toxicity.

SPECIAL WARNINGS & PRECAUTIONS

Progressive multifocal leukoencephalopathy (PML): John Cunningham virus (JCV) reactivation resulting in progressive multifocal leukoencephalopathy (PML) and death can occur in patients treated with ADCETRIS. PML has been reported in patients who received ADCETRIS after receiving multiple prior chemotherapy regimens. PML is a rare demyelinating disease of the central nervous system that results from reactivation of latent JCV and is often fatal.

Closely monitor patients for new or worsening neurological, cognitive, or behavioral signs or symptoms, which may be suggestive of PML. Suggested evaluation of PML includes neurology consultation, gadolinium-enhanced magnetic resonance imaging of the brain, and cerebrospinal fluid analysis for JCV DNA by polymerase chain reaction or a brain biopsy with evidence of JCV. A negative JCV PCR does not exclude PML. Additional follow up and evaluation may be warranted if no alternative diagnosis can be established Hold dosing for any suspected case of PML and permanently discontinue ADCETRIS if a diagnosis of PML is confirmed. Be alert to PML symptoms that the patient may not notice (e.g., cognitive, neurological, or psychiatric symptoms).

Pancreatitis: Acute pancreatitis has been observed in patients treated with ADCETRIS. Fatal outcomes have been reported. Closely monitor patients for new or worsening abdominal pain, which may be suggestive of acute pancreatitis. Patient evaluation may include physical examination, laboratory evaluation for serum amylase and serum lipase, and abdominal imaging, such as ultrasound and other appropriate diagnostic measures. Hold ADCETRIS for any suspected case of acute pancreatitis. ADCETRIS should be discontinued if a diagnosis of acute pancreatitis is confirmed.

Pulmonary Toxicity: Cases of pulmonary toxicity, some with fatal outcomes, including pneumonitis, interstitial lung disease, and acute respiratory distress syndrome (ARDS), have been reported in patients receiving ADCETRIS. Although a causal association with ADCETRIS has not been established, the risk of pulmonary toxicity cannot be ruled out. Promptly evaluate and treat new or worsening pulmonary symptoms appropriately. Consider holding dosing during evaluation and until symptomatic improvement.

Serious infections and opportunistic infections: Serious infections such as pneumonia, staphylococcal bacteremia, sepsis/septic shock (including fatal outcomes), and herpes zoster, and opportunistic infections such as *Pneumocystis jiroveci* pneumonia and oral candidiasis have been reported in patients treated with ADCETRIS. Carefully monitor patients during treatment for emergence of possible serious and opportunistic infections.

Infusion-related reactions (IRR): Immediate and delayed IRR, as well as anaphylaxis, have occurred with ADCETRIS. Carefully monitor patients during and after an infusion. If anaphylaxis occurs, immediately and permanently discontinue administration of ADCETRIS Appropriate medical therapy should be administered. If an IRR occurs, interrupt the infusion and institute appropriate medical management. The infusion may be restarted at a slower rate after symptom resolution. Patients who have experienced a prior IRR should be premedicated for subsequent infusions. IRRs are more frequent and more severe in patients with antibodies to ADCETRIS.

Tumor lysis syndrome (TLS): TLS has been reported with ADCETRIS. Patients with rapidly proliferating tumor and high tumor burden are at risk of TLS. Monitor these patients closely and managed according to best medical practice.

Peripheral neuropathy (PN): ADCETRIS treatment may cause PN, both sensory and motor. ADCETRIS-induced PN is typically cumulative and reversible in most cases. Monitor patients for symptoms of PN, such as hypoesthesia, hyperesthesia, paresthesia, discomfort, a burning sensation, neuropathic pain, or weakness. Patients experiencing new or worsening PN may require a delay and a dose reduction or discontinuation of ADCETRIS.

Hematological toxicities: Grade 3 or Grade 4 anemia, thrombocytopenia, and prolonged (equal to or greater than one week) Grade 3 or Grade 4 neutropenia can occur with ADCETRIS. Monitor complete blood counts prior to administration of each dose.

Febrile neutropenia: Febrile neutropenia has been reported. Closely monitor patients for fever and manage according to best medical practice if febrile neutropenia develops.

Stevens-Johnson syndrome (SJS): SJS and toxic epidermal necrolysis (TEN) have been reported with ADCETRIS. Fatal outcomes have been reported. Discontinue treatment with ADCETRIS if SJS or TEN occurs and administer appropriate medical therapy.

Gastrointestinal (GI) Complications: GI complications, some with fatal outcomes, including intestinal obstruction, ileus, enterocolitis, neutropenic colitis, erosion, ulcer, perforation and haemorraghe, have been reported. Promptly evaluate and treat patients if new or worsening GI symptoms occur.

Hepatotoxicity: Elevations in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) have been reported. Serious cases of hepatotoxicity, including fatal outcomes, have also occurred. Test liver function prior to treatment initiation and routinely monitor patients receiving ADCETRIS for liver elevations. Patients experiencing hepatotoxicity may require a delay, dose modification, or discontinuation of ADCETRIS.

Hyperglycemia: Hyperglycemia has been reported during trials in patients with an elevated body mass index (BMI) with or without a history of diabetes mellitus. Closely monitor serum glucose for patients who experiences an event of hyperglycemia. Administer anti-diabetic treatment as appropriate.

Renal and Hepatic Impairment: There is limited experience in patients with renal and hepatic impairment. Available data indicate that MMAE clearance might be affected by severe renal impairment, hepatic impairment, and by low serum albumin concentrations.

CD30+ CTCL: The size of the treatment effect in CD30 + CTCL subtypes other than mycosis fungoides (MF) and primary cutaneous anaplastic large cell lymphoma (pcALCL) is not clear due to lack of high level evidence. In two single arm phase II studies of ADCETRIS, disease activity has been shown in the subtypes Sézary syndrome (SS), lymphomatoid papulosis (LyP) and mixed CTCL histology. These data suggest that efficacy and safety can be extrapolated to other CTCL CD30+ subtypes. Carefully consider the benefit-risk per patient and use caution in other CD30+ CTCL patient types.

Sodium content in excipients: ADCETRIS contains a maximum of 2.1 mmol (or 47 mg) of sodium per dose. Take this into consideration for patients on a controlled sodium diet.

INTERACTIONS

Patients who are receiving a strong CYP3A4 and P-gp inhibitor, concomitantly with ADCETRIS may have an increased risk of neutropenia and should be closely monitored. Co-administration of ADCETRIS with a CYP3A4 inducer did not alter the plasma exposure of ADCETRIS but it appeared to reduce plasma concentrations of MMAE metabolites that could be assayed. ADCETRIS is not expected to alter the exposure to drugs that are metabolized by CYP3A4 enzymes.

PREGNANCY: Advise women of childbearing potential to use two methods of effective contraception during treatment with ADCETRIS and until 6 months after treatment. There are no data from the use of ADCETRIS in pregnant women, although studies in animals have shown reproductive toxicity. Do not use ADCETRIS during pregnancy unless the benefit to the mother outweighs the potential risks to the fetus.

LACTATION (breast-feeding): There are no data as to whether ADCETRIS or its metabolites are excreted in human milk, therefore a risk to the newborn/infant cannot be excluded. With the potential risk, a decision should be made whether to discontinue breast-feeding or discontinue/abstain from therapy with ADCETRIS.

FERTILITY: In nonclinical studies, ADCETRIS treatment has resulted in testicular toxicity, and may alter male fertility. Advise men being treated with ADCETRIS not to father a child during treatment and for up to 6 months following the last dose.

Effects on ability to drive and use machines: ADCETRIS may have a minor influence on the ability to drive and use machines.

UNDESIRABLE EFFECTS

The most frequent adverse reactions (□10%) were infections, peripheral sensory neuropathy, nausea, fatigue, diarrhoea, pyrexia, upper respiratory tract infection, neutropenia, rash, cough, vomiting, arthralgia, peripheral motor neuropathy, infusion-related reactions, pruritus, constipation, dyspnoea, weight decreased, myalgia and abdominal pain.

Serious adverse drug reactions were: pneumonia, acute respiratory distress syndrome, headache, neutropenia, thrombocytopenia, constipation, diarrhea, vomiting, nausea, pyrexia, peripheral motor neuropathy, peripheral sensory neuropathy, hyperglycemia, demyelinating polyneuropathy, tumor lysis syndrome, and Stevens-Johnson syndrome. Serious adverse drug reactions occurred in 12% of patients. The frequency of unique serious adverse drug reactions was ≤1%.

Forward-Looking Statements for Seattle Genetics

Certain of the statements made in this press release are forward looking, such as those, among others, relating to the therapeutic potential of ADCETRIS (brentuximab vedotin) as a potential treatment in frontline peripheral T-cell lymphoma, anticipated presentation of data from ECHELON-2 at ASH in 2018 and plans and timing for submission for supplemental regulatory approval to and obtaining regulatory approval from the FDA and other regulatory authorities. 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 safety and/or efficacy results of the ECHELON-2 trial in peripheral T-cell lymphoma will not be presented as anticipated or sufficient to gain marketing approval in the United States or any other country, that we will be required to amend our submission for marketing approval or that such submission will be refused or delayed. In addition, our regulatory plans may change as a result of consultation with the FDA or other regulatory authorities. 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, 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.

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