



## Seattle Genetics Announces FDA Accelerated Approval of ADCETRIS™ (Brentuximab Vedotin) for Two Indications

*-First in a new class of ADCs to be FDA-approved-*

*-Seattle Genetics to implement comprehensive reimbursement support and patient assistance program-*

*-Conference call Monday, August 22, 2011, at 8:30 a.m. ET to provide further information on the launch and commercialization of ADCETRIS-*



Bothell, WA – August 19, 2011 – Seattle Genetics, Inc. (Nasdaq: SGEN) today announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval of ADCETRIS™ (brentuximab vedotin) for two indications: (1) the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and (2) the treatment of patients with systemic anaplastic large cell lymphoma (ALCL) after failure of at least one prior multi-agent chemotherapy regimen. The indications for ADCETRIS are based on response rate. There are no data available demonstrating improvement in patient-reported outcomes or survival with ADCETRIS. ADCETRIS is the first drug approved by the FDA for Hodgkin lymphoma in more than 30 years, and provides a new therapeutic alternative for Hodgkin lymphoma and systemic ALCL in these settings. Seattle Genetics expects to make ADCETRIS available to patients next week. ADCETRIS is an antibody-drug conjugate (ADC) directed to CD30.

“Bringing a new product to the market is a significant milestone for Seattle Genetics in fulfilling its mission to improve the lives of people with cancer,” said Clay B. Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. “The approval of ADCETRIS is a result of more than a decade of research and development by talented scientists and physicians. The company has deep appreciation for the hundreds of patients who participated in ADCETRIS trials, and the passion and determination of the clinicians at sites around the world in investigating this first in a new class of targeted anticancer agents. We are committed to continued clinical investigation of ADCETRIS through a broad development program for CD30-positive malignancies, including confirmatory trials in front-line Hodgkin and T-cell lymphomas that we have planned in consultation with the FDA.”

“The marked single agent activity seen with ADCETRIS, including a high durable complete remission rate, offers an opportunity to improve the treatment paradigm of patients for whom the treatment is indicated,” said Owen A. O'Connor, M.D., Ph.D., Professor, and Director, Division of Hematology and Medical Oncology at NYU Cancer Institute. “This approval represents a major advancement in the care of these patients.”

Seattle Genetics also announced that it has established a patient assistance program named SeaGen Secure™ that offers patients and providers access to ADCETRIS reimbursement support, benefit investigations and patient assistance programs. More information about SeaGen Secure is available at (855)-4SEAGEN (855-473-2436) Monday through Friday from 9:00 a.m. to 8:00 p.m. Eastern Time.

## **About ADCETRIS**

ADCETRIS (brentuximab vedotin) is an antibody-drug conjugate (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.

The ADCETRIS approvals were based on data from two open-label, single-arm clinical trials: a pivotal trial in Hodgkin lymphoma patients who relapsed after ASCT and a pivotal trial in relapsed systemic ALCL patients. The primary endpoint of both trials was overall response rate as assessed by an independent review facility.

In the pivotal Hodgkin lymphoma clinical trial, 102 patients were enrolled who had relapsed after ASCT. Data demonstrated that 73 percent (95 percent CI 65, 83) of patients achieved an objective response following treatment with ADCETRIS, including 32 percent (95 percent CI 23, 42) with complete remissions and 40 percent with partial remissions (95 percent CI 32, 49). The median duration of objective response was 6.7 months (95 percent CI 4.0, 14.8; range 1.3 to 21.9+ months).

In the pivotal systemic ALCL clinical trial, 58 patients with relapsed disease were enrolled. These data demonstrated that 86 percent (95 percent CI 77, 95) of patients achieved an objective response following treatment with ADCETRIS, including 57 percent with complete remissions (95 percent CI 44, 70) and 29 percent with partial remissions (95 percent CI 18, 41). The median duration of objective response was 12.6 months (95 percent CI 5.7, not estimable; range 0.1 to 15.9+ months).

**Please see important safety information below, and the full prescribing information for ADCETRIS at [www.seattlegenetics.com](http://www.seattlegenetics.com) or [www.ADCETRIS.com](http://www.ADCETRIS.com).**

## **Indications and Usage**

ADCETRIS is a CD30-directed antibody-drug conjugate indicated for the treatment of patients with Hodgkin lymphoma after failure of ASCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and for the treatment of patients with systemic ALCL after failure of at least one prior multi-agent chemotherapy regimen. The indications for ADCETRIS are based on response rate. There are no data available demonstrating improvement in patient-reported outcomes or survival with ADCETRIS.

The recommended dose of ADCETRIS is 1.8 milligrams per kilogram administered only as an intravenous infusion over 30 minutes every three weeks. Treatment should be continued until a maximum of 16 cycles, disease progression or unacceptable toxicity.

## **Important Safety Information**

### **Warnings and Precautions:**

- **Peripheral neuropathy:** ADCETRIS treatment causes a peripheral neuropathy that is predominantly sensory. Cases of peripheral motor neuropathy have also been reported. ADCETRIS-induced peripheral neuropathy is cumulative. Treating physicians should monitor patients for neuropathy and institute dose modifications accordingly.
- **Infusion reactions:** Infusion-related reactions, including anaphylaxis, have occurred with ADCETRIS. Monitor patients during infusion. If an infusion reaction occurs, the infusion should be interrupted and

appropriate medical management instituted. If anaphylaxis occurs, the infusion should be discontinued immediately and appropriate medical management instituted.

- Neutropenia: Monitor complete blood counts prior to each dose of ADCETRIS. If Grade 3 or 4 neutropenia develops, manage by dose delays, reductions or discontinuation. Prolonged ( $\geq 1$  week) severe neutropenia can occur with ADCETRIS.
- Tumor Lysis Syndrome: Patients with rapidly proliferating tumor and high tumor burden are at risk of tumor lysis syndrome and these patients should be monitored closely and appropriate measures taken.
- Stevens-Johnson syndrome: Stevens-Johnson syndrome has been reported with ADCETRIS. If Stevens-Johnson syndrome occurs, discontinue ADCETRIS and administer appropriate medical therapy.
- Progressive Multifocal Leukoencephalopathy (PML): A fatal case of PML has been reported in a patient who received four chemotherapy regimens prior to receiving ADCETRIS.
- Use in pregnancy: Fetal harm can occur. Pregnant women should be advised of the potential hazard to the fetus.

#### **Adverse Reactions:**

ADCETRIS was studied as monotherapy in 160 patients in two phase II trials. Across both trials, the most common adverse reactions ( $\geq 20\%$ ), regardless of causality, were neutropenia, peripheral sensory neuropathy, fatigue, nausea, anemia, upper respiratory tract infection, diarrhea, pyrexia, rash, thrombocytopenia, cough and vomiting.

#### **Drug Interactions:**

Patients who are receiving strong CYP3A4 inhibitors concomitantly with ADCETRIS should be closely monitored for adverse reactions.

**For additional important safety information, please see the full prescribing information for ADCETRIS at [www.seattlegenetics.com](http://www.seattlegenetics.com) or [www.ADCETRIS.com](http://www.ADCETRIS.com).**

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

#### **Conference Call Details**

Seattle Genetics' management will host a conference call and webcast to discuss the approval, the price of ADCETRIS, and the company's reimbursement and patient assistance program. The call will be held Monday, August 22, 2011 at 5:30 a.m. Pacific Time (PT); 8:30 a.m. Eastern Time (ET). The live event will be available from Seattle Genetics' website at [www.seattlegenetics.com](http://www.seattlegenetics.com), under the Investors and News section, or by calling (877) 941-8609 (domestic) or (480) 629-9818 (international). The access code is 4466950. A replay of the discussion will be available beginning at approximately 7:30 a.m. PT on August 22, 2011 from Seattle Genetics' website or by calling (800) 406-7325 (domestic) or (303) 590-3030 (international), using access code 4466950. The telephone replay will be available until 5:00 p.m. PT on August 24, 2011.

**More information about ADCETRIS is available at (855)-4SEAGEN (855-473-2436) Monday through Friday from 9:00 a.m. to 8:00 p.m. Eastern Time.**

## **About Hodgkin Lymphoma and Systemic ALCL**

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. Hodgkin lymphoma is distinguished from other types of lymphoma by the presence of one characteristic type of cell, known as the Reed-Sternberg cell<sup>(1)</sup>. The Reed-Sternberg cell generally expresses CD30<sup>(2)</sup>. Systemic ALCL is an aggressive type of T-cell non-Hodgkin lymphoma that also expresses CD30<sup>(2)</sup>.

## **About Seattle Genetics**

Seattle Genetics is a biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for the treatment of cancer. Seattle Genetics' first product, ADCETRIS™, was approved by the FDA on August 19, 2011 for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and for the treatment of patients with systemic anaplastic large cell lymphoma (ALCL) after failure of at least one prior multi-agent chemotherapy regimen. In addition to ADCETRIS, Seattle Genetics has three other clinical-stage programs: SGN-75, ASG-5ME and ASG-22ME. Seattle Genetics has collaborations for its ADC technology with a number of leading biotechnology and pharmaceutical companies, including Abbott, Bayer, Celldex Therapeutics, Daiichi Sankyo, Genentech, GlaxoSmithKline, Millennium, Pfizer and Progenics, as well as ADC co-development agreements with Agensys, an affiliate of Astellas, and Genmab. More information can be found at [www.seattlegenetics.com](http://www.seattlegenetics.com).

Certain of the statements made in this press release are forward looking, such as those, among others, relating to the company's statements regarding the potential for ADCETRIS to offer an improved treatment paradigm of patients for whom the treatment is indicated, and other statements that are other than statements of historical facts. 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 risks and uncertainties associated with fulfilling sales, marketing and distribution requirements; the acceptance of ADCETRIS in the marketplace; the status of reimbursement from third-party payors; the company's dependence on third-party manufacturers; and the company's compliance with applicable regulatory requirements, including the healthcare fraud and abuse laws and the company's post-marketing requirements. More information about the risks and uncertainties faced by Seattle Genetics is contained in the company's 10-Q for the quarter ended June 30, 2011, 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.

<sup>1</sup>National Cancer Institute. Hodgkin lymphoma. Available at <http://www.cancer.gov/cancertopics/types/hodgkin>. Accessed August 15, 2011.

<sup>2</sup>Haluska FG, et al. The Cellular Biology of the Reed-Sternberg Cell. *Blood*. 1994; 84:1005-1019.

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