Seattle Genetics and Millennium to Collaborate with Ventana on Companion Diagnostic for ADCETRIS™ in CD30-Positive Malignancies

Ventana to develop molecular companion diagnostic test to evaluate CD30 expression levels in tissue specimens-

Bothell, WA, Cambridge, MA and Tucson, AZ – April 12, 2012 – Seattle Genetics, Inc. (Nasdaq: SGEN) and Millennium: The Takeda Oncology Company, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (TSE:4502), today announced that they have formed a collaboration with Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group. Under the collaboration agreement, Ventana will seek to develop, manufacture and commercialize a molecular companion diagnostic test with the goal of identifying patients who might respond to treatment with ADCETRIS based on CD30 expression levels in their tissue specimens. As part of the ongoing clinical development of ADCETRIS, Millennium and Seattle Genetics are planning two phase III studies that will use the companion diagnostic, one in CD30-positive cutaneous T-cell lymphoma (CTCL) and the other in CD30-positive mature T-cell lymphomas (MTCL).

ADCETRIS was approved by the U.S. Food and Drug Administration in August 2011 for relapsed Hodgkin lymphoma (HL) and systemic anaplastic large cell lymphoma (sALCL). A molecular companion diagnostic is not required for the current FDA-approved indications for ADCETRIS.

“Availability of a CD30 companion diagnostic will bring us a step closer to our vision of a more personalized, target-based approach to the treatment of cancer, and supports our broad ongoing and planned clinical development of ADCETRIS for CD30-positive patients in need,” said Thomas C. Reynolds, M.D., Ph.D., Chief Medical Officer of Seattle Genetics. “Although the identification of CD30 expression and its role in the diagnosis of Hodgkin lymphoma and systemic ALCL is well-established, CD30 expression in other malignancies is more heterogeneous. The collaboration with Ventana provides an opportunity for development of a diagnostic tool to identify patients who may benefit from ADCETRIS treatment.”

“Translational medicine research is central to Millennium’s strategic focus of developing innovative, targeted therapies that provide a high benefit to patients,” said Karen Ferrante, M.D., Chief Medical Officer, Millennium. “We look forward to collaborating with Ventana and Seattle Genetics to develop this new diagnostic tool and expanding the ongoing clinical development program for ADCETRIS in patients with CD30-positive malignancies.”

CD30 is a member of the tumor necrosis factor receptor (TNFR) family and is a characteristic cell surface receptor for activated T-cells and B-cells, including the malignant cells of HL and sALCL. Published literature also reports CD30 expression in other cancers. Seattle Genetics is currently exploring the potential of ADCETRIS in two phase II clinical trials to further characterize CD30 expression and evaluate antitumor activity of ADCETRIS. One trial is evaluating patients with non-Hodgkin lymphomas, including diffuse large B-cell lymphoma, peripheral T-cell lymphoma and other less common lymphoma subtypes and the second trial is evaluating patients...
with non-lymphoma malignancies, including multiple myeloma, leukemia and solid tumors. Data from both trials are expected to be reported at upcoming medical conferences during 2012. ADCETRIS is not approved for treatment of the non-Hodgkin lymphomas and non-lymphoma malignancies studied in these trials.

“We are pleased to work with Seattle Genetics and Millennium to develop a companion diagnostic test for detecting CD30 expression levels that may assist in identifying additional patients who might benefit from ADCETRIS,” said Doug Ward, VP and General Manager, Ventana Translational Diagnostics. “We believe that a Personalized Healthcare approach is particularly relevant for targeted agents such as ADCETRIS, an antibody-drug conjugate, and this collaboration provides an opportunity to add to our growing pipeline of companion diagnostic tests.”

About ADCETRIS
ADCETRIS (brentuximab vedotin) 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.

Seattle Genetics and Millennium are jointly developing ADCETRIS. 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.

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. The U.S. Food and Drug Administration granted accelerated approval of ADCETRIS in August 2011 for two indications. ADCETRIS is being developed in collaboration with Millennium: The Takeda Oncology Company. In addition, Seattle Genetics has three other clinical-stage ADC 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.

About Millennium

About Ventana
Ventana Medical Systems, Inc. (“VMSI”) (SIX: RO, ROG; OTCQX: RHHBY), a member of the Roche Group, innovates and manufactures instruments and reagents that automate tissue processing and slide staining for cancer diagnostics. VENTANA solutions are used in clinical histology and drug development research laboratories worldwide. The company’s intuitive, integrated staining,
workflow management platforms, and digital pathology solutions optimize laboratory efficiencies to reduce errors, support diagnosis and inform treatment decisions for anatomic pathology professionals. Together with Roche, VMSI is driving Personalized Healthcare through accelerated drug discovery and the development of “companion diagnostics” to identify the patients most likely to respond favorably to specific therapies. Visit www.ventana.com to learn more.

ADCETRIS™ (brentuximab vedotin) received accelerated approval 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.

U.S. Important Safety Information

BOXED WARNING
Progressive multifocal leukoencephalopathy (PML): JC virus infection resulting in PML and death can occur in patients receiving ADCETRIS.

Contraindication:
Concomitant use of ADCETRIS and bleomycin is contraindicated due to pulmonary toxicity.

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 symptoms of neuropathy, such as hypoesthesia, hyperesthesia, paresthesia, discomfort, a burning sensation, neuropathic pain or weakness 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 immediately and permanently discontinued and appropriate medical management instituted.
• Neutropenia: Monitor complete blood counts prior to each dose of ADCETRIS and consider more frequent monitoring for patients with Grade 3 or 4 neutropenia. If Grade 3 or 4 neutropenia develops, manage by dose delays, reductions or discontinuation. Prolonged (≥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.
• Progressive multifocal leukoencephalopathy (PML): JC virus infection resulting in PML and death has been reported in ADCETRIS-treated patients. In addition to ADCETRIS therapy, other possible contributory factors include prior therapies and underlying disease that may cause immunosuppression. Consider the diagnosis of PML in any patient presenting with new-onset signs and symptoms of central nervous system abnormalities. Evaluation of PML includes, but is not limited to, consultation with a neurologist, brain MRI, and lumbar puncture or brain biopsy. Hold ADCETRIS if PML is suspected and discontinue ADCETRIS if PML is confirmed.
- Stevens-Johnson syndrome: Stevens-Johnson syndrome has been reported with ADCETRIS. If Stevens-Johnson syndrome occurs, discontinue ADCETRIS and administer appropriate medical therapy.
- 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 2 trials. Across both trials, the most common adverse reactions (≥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, including Boxed WARNING, please see the full U.S. prescribing information for ADCETRIS at www.seattlegenetics.com or www.ADCETRIS.com.

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 and initiation of future clinical trials. 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 inability to show sufficient activity in future clinical trials and the risk of adverse events as ADCETRIS advances in clinical trials. In addition, data from our clinical trials, including our pivotal trials which were the basis for FDA accelerated approval, may not necessarily be indicative of subsequent clinical trial results. More information about the risks and uncertainties faced by Seattle Genetics is contained in the company’s 10-K for the year ended December 31, 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.


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