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Takeda receives EC approval to extend the marketing authorization for ADCETRIS

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In September 2018, the Japanese Ministry of Health, Labour and Welfare approved ADCETRIS in combination with AVD as a frontline treatment option for CD30-positive HL patients in Japan.

Seattle Genetics, Inc. has announced that its collaborator, Takeda Pharmaceutical Company Limited, received approval from the European Commission (EC) to extend the marketing authorization for ADCETRIS (brentuximab vedotin) to include ADCETRIS in combination with AVD (Adriamycin, vinblastine and dacarbazine) in adults patients with previously untreated CD30+ stage IV classical Hodgkin lymphoma (HL). The decision follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) on December 13, 2018. As a result, Seattle Genetics will receive a milestone payment from Takeda of $30 million. ADCETRIS is an antibody-drug conjugate (ADC) directed to CD30, a defining marker of classical HL that plays a role in tumor growth and survival.

“Receipt of this milestone payment reflects continued progress by our partner Takeda to expand ADCETRIS approved indications globally,” said Clay Siegall, Ph.D., President and Chief Executive Officer at Seattle Genetics. “We look forward to continuing our work with Takeda to establish ADCETRIS as the global foundation of care for CD30-expressing lymphomas, including Hodgkin lymphoma.”

The marketing authorization for ADCETRIS is based on positive results from the ECHELON-1 phase 3 clinical trial that were presented in the Plenary Scientific Session at the 59thAmerican Society of Hematology (ASH) annual meeting in December 2017 with simultaneous publication in the New England Journal of Medicine.

In September 2018, the Japanese Ministry of Health, Labour and Welfare approved ADCETRIS in combination with AVD as a frontline treatment option for CD30-positive HL patients in Japan. In March 2018, the U.S. Food and Drug Administration (FDA) approved ADCETRIS in combination with AVD for the treatment of adult patients with previously untreated stage III or IV classical HL based on the positive results of the ECHELON-1 phase 3 clinical trial.

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

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.

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.