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ASIA EDITION

Takeda receives Japanese nod for Adcetris

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Singapore: Japanese pharma major Takeda Pharma has announced that it has received approval of Adcetris (brentuximab vedotin) from the Japanese Ministry of Health, Labour and Welfare (MHLW). The drug is used for the treatment of patients with CD30-positive relapsed or refractory Hodgkin lymphoma (HL) and anaplastic large cell lymphoma (ALCL).

Adcetris is an antibody-drug conjugate (ADC) directed to CD30, a defining marker of classical HL and known to be expressed in some types of non-Hodgkin lymphoma, including ALCL.

The approval of the new drug application was based on two global pivotal phase 2 clinical trials of Adcetris, as well as a phase 1/2 clinical trial conducted in Japan, for patients with relapsed or refractory CD30-positive HL and ALCL. In March 2012, the Japanese MHLW granted Adcetris orphan drug designation for the treatment of patients with HL and ALCL, which triggered priority review in Japan.

"Until now, patients in Japan with relapsed or refractory Hodgkin lymphoma or ALCL had few therapeutic treatment options, and the approval of Adcetris represents a significant milestone in making this innovative targeted therapy available to these patients in need," said Clay B Siegall, president and chief executive officer of Seattle Genetics.

He added, "Adcetris is now approved in 39 countries, and we continue to work with our collaborator, Takeda, to expand regulatory approvals globally. Through both our regulatory activities and robust clinical development program, our goal is to establish Adcetris as the foundation of therapy worldwide for patients with CD30-positive malignancies."

Seattle Genetics and Takeda are jointly developing Adcetris. Under the terms of the collaboration agreement, Seattle Genetics has US 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 will be solely responsible for development costs. Seattle Genetics is entitled to royalties based on a percentage of Takeda's net sales in its territory at rates that range from the mid-teens to the mid-twenties based on sales volume, subject to

offsets for royalties paid by Takeda to third parties.