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Millennium and Takeda get EU approval for cancer drug

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Singapore: Millennium, The Takeda Oncology Company and Takeda Pharmaceutical announced that the European Commission (EC) has granted conditional marketing authorization for ADCETRIS (brentuximab vedotin) for two indications.

These include, the treatment of adult patients with relapsed or refractory CD30 positive Hodgkin lymphoma (HL) following autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option; and for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).

On July 19, 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for conditional marketing authorization for ADCETRIS, based on a positive benefit-risk assessment in the above indications. Granting of conditional marketing authorization by the EC means that there are specific obligations to provide additional clinical data at a later stage to confirm the positive benefit-risk balance.

Takeda intends to launch ADCETRIS across Europe, with the first launches planned in the coming weeks. ADCETRIS is an antibody-drug conjugate (ADC) directed to CD30, a defining marker of classical HL and sALCL. The marketing authorisation, which will be held by Takeda Global Research & Development Centre (Europe) Ltd, is valid in all EU member states as well as Iceland, Liechtenstein and Norway, and is based on data from clinical trials and other supportive data in relapsed or refractory HL and relapsed or refractory sALCL.