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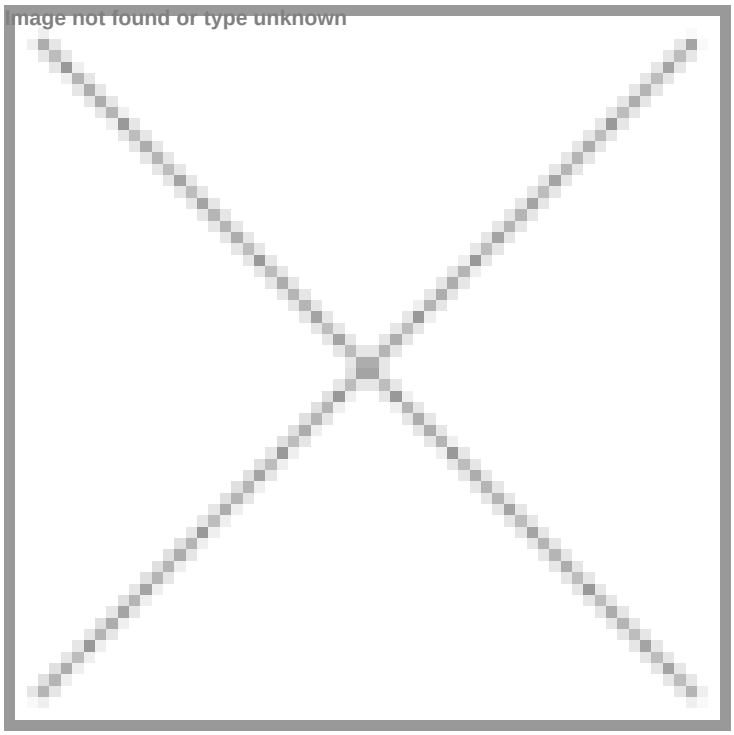

Singapore: The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for conditional approval of brentuximab vedotin by Takeda Pharmaceutical and Millennium: The Takeda Oncology Company for two indications. One of them if for the treatment 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 the other is for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).

Brentuximab vedotin is an antibody-drug conjugate (ADC) directed to CD30, a defining marker of classical HL and sALCL. The CHMP opinion is based on data from clinical trials and other supportive data in relapsed or refractory HL and relapsed or refractory sALCL.

"We are very pleased with the CHMP positive recommendation for brentuximab vedotin," said Mr Trevor Smith, head of Commercial Operations, Europe & Canada, Takeda Pharmaceuticals. "Takeda is dedicated to developing innovative and novel therapeutics that make a real difference to patients' lives. If approved, brentuximab vedotin will be the third product in the Takeda oncology franchise to be launched in Europe. Brentuximab vedotin has the potential to make a significant difference to patients with relapsed or refractory Hodgkin lymphoma or relapsed or refractory systemic anaplastic large cell lymphoma."

The CHMP positive opinion for brentuximab vedotin will now be reviewed by the European Commission (EC). If the CHMP recommendation is formally adopted by the EC, brentuximab vedotin would be approved for marketing in the 27 member states of the European Union.

"CHMP's positive opinion and recognition of the clinical benefit of brentuximab vedotin takes us a step closer to providing a targeted treatment option for patients with relapsed or refractory Hodgkin lymphoma or relapsed or refractory systemic anaplastic large cell lymphoma," said Dr Karen Ferrante, chief medical officer, Millennium. "With no new treatments approved for relapsed or refractory Hodgkin lymphoma in over thirty years, this patient population represents an area of high unmet medical need."

In January 2009, brentuximab vedotin received orphan product designations for the treatment of patients with HL or ALCL in the European Union from the Committee for Orphan Medicinal Products (COMP). Orphan medicinal product designation is conferred upon products for diseases that affect no more than 5 in 10,000 people in the European Union at the time of the submission.