19 July 2012
EMA/CHMP/471107/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Adcetris

Brentuximab vedotin

On 19 July 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Adcetris, 50 mg, powder for concentrate for solution for infusion, intended for the treatment of of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): (1) following autologous stem cell transplant (ASCT) or (2) following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option as well as for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).

Adcetris was designated as an orphan medicinal product on 15 January 2009. The applicant for this medicinal product is Takeda Global Research and Development Centre (Europe) Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Adcetris is brentuximab vedotin, a monoclonal antibody (L01XC12) drug conjugate that delivers an antineoplastic agent that results in apoptotic cell death selectively in CD30-expressing tumour cells. The anti-tumour activity of brentuximab-vedotin has been established in the HL and sALCL study populations as well as in the relapsed or refractory HL patients ineligible for ASCT/multidrug chemotherapy. The different clinical endpoints demonstrated clinical benefit in terms of disease control, resolution of B-symptoms and in terms of enabling further potentially curative treatment options.

The most common side effects are peripheral sensory neuropathy, fatigue, nausea, diarrhoea, neutropenia, vomiting, pyrexia, and upper respiratory tract infection.

A pharmacovigilance plan for Adcetris will be implemented as part of the marketing authorisation.

The approved indication is:

" Adcetris is indicated for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL):

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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1. following autologous stem cell transplant (ASCT) or
2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option.

Adcetris is indicated for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL)."

It is proposed that Adcetris be prescribed by physicians experienced in the use of anti-cancer agents.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Adcetris and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[2].

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.