26 May 2016
EMA/CHMP/207100/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Adcetris

brentuximab vedotin

On 26 May 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Adcetris. The marketing authorisation holder for this medicinal product is Takeda Pharma A/S.

The CHMP adopted a new indication as follows:

"Adcetris is indicated for the treatment of adult patients with CD30+ HL at increased risk of relapse or progression following ASCT (see section 5.1)".

For information, the full indications for Adcetris will be as follows[2]:

"Adcetris is indicated for the treatment 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.

Adcetris is indicated for the treatment of adult patients with CD30+ HL at increased risk of relapse or progression following ASCT (see section 5.1).

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

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

[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

[2] New text in bold

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact