



14 September 2023
EMA/CHMP/403313/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Adcetris

brentuximab vedotin

On 14 September 2023, 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 an extension to an existing indication to include treatment of Stage III Hodgkin lymphoma (HL). For information, the full indications for Adcetris will be as follows:²

Hodgkin lymphoma

ADCETRIS is indicated for adult patients with previously untreated CD30+ Stage **III or IV** Hodgkin lymphoma (HL) in combination with doxorubicin, vinblastine and dacarbazine (AVD) (see sections 4.2 and 5.1).

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

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

1. following ASCT, or
2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option.

Systemic anaplastic large cell lymphoma

ADCETRIS in combination with cyclophosphamide, doxorubicin and prednisone (CHP) is indicated for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL) (see section 5.1).

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



ADCETRIS is indicated for the treatment of adult patients with relapsed or refractory sALCL.

Cutaneous T-cell lymphoma

ADCETRIS is indicated for the treatment of adult patients with CD30+ cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy (see section 5.1).

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.