27 November 2012
EMA/COMP/601842/2012
Committee for Orphan Medicinal Products

Recommendation for maintenance of orphan designation at the time of marketing authorisation

Adcetris (brentuximab vedotin) for the treatment of anaplastic large cell lymphoma

During its meeting of 4-5 September 2012, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/08/595 for Adcetris (brentuximab vedotin[1]) as an orphan medicinal product for the treatment of anaplastic large cell lymphoma (ALCL). The COMP assessed whether, at the time of marketing authorisation, the medicinal product still met the criteria for orphan designation. The Committee looked at the seriousness and prevalence of the condition, and the existence of other satisfactory methods of treatment. As other satisfactory methods of treatment for patients with this condition are authorised in the European Union (EU), the COMP also looked at the significant benefit of the product over existing treatments. The COMP recommended that the orphan designation of the medicine be maintained[2].

Life-threatening or long-term debilitating nature of the condition

The Committee for Medicinal Products for Human Use (CHMP) recommended the authorisation of Adcetris for the treatment of 'relapsed or refractory systemic anaplastic large cell lymphoma'.

This falls within the scope of the product's designated orphan indication(s), which is: 'anaplastic large cell lymphoma'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2009. ALCL remains a serious and life-threatening condition that is associated with a poor 5-year survival of 29-44%.

[1] Previously known as monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E.
[2] The maintenance of the orphan designation at time of marketing authorisation would, except in specific situations, give an orphan medicinal product 10 years of market exclusivity in the EU. This means that in the 10 years after its authorisation similar products with a comparable therapeutic indication cannot be placed on the market.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Prevalence of the condition

The sponsor provided updated information on the prevalence on the basis of data from the Globocan 2002 database and updated population data. On the basis of the information provided by the sponsor and the knowledge of the COMP, the Committee concluded that the prevalence of ALCL remains below the ceiling for orphan designation, which is 5 people in 10,000. At the time of the review of the orphan designation, the prevalence was estimated to be approximately 0.2 people in 10,000. This is equivalent to a total of around 10,000 people in the EU.

Existence of other satisfactory methods of treatment

At the time of the review of the orphan designation, other methods were authorised in the EU for the treatment of ALCL, including chemotherapy (medicines to treat cancer) and radiotherapy (treatment with radiations). More than one chemotherapy medicine was often used for ALCL (combination chemotherapy). Radiotherapy was commonly given after chemotherapy.

Significant benefit over existing treatments

The COMP concluded that the claim of significant benefit of Adcetris over existing treatments is justified on the basis of it being more effective at improving the survival of patients who did not respond any longer to other therapies.

This is based on data from a main study with Adcetris, showing a high response rate (proportion of patients who respond to treatment in terms of showing less/no signs of cancer) and a long progression-free survival (PFS, how long the patients lived without their disease getting worse) in patients who had no other treatment options. The data showed that for 60% of patients (35 out of 58) the PFS after Adcetris was equal or longer than the PFS after the previous treatment received by these patients. In addition, the prolonged survival seen with Adcetris could enable these patients, who generally have poor outcomes and lack suitable therapies, to undergo stem cell transplantation or other treatments that may stabilise the disease.

Therefore, although other satisfactory methods for the treatment of this condition have been authorised in the EU, the COMP concluded that Adcetris is of significant benefit for patients affected by anaplastic large cell lymphoma.

Conclusions

Based on the data submitted and the scientific discussion within the COMP, the COMP considered that Adcetris still meets the criteria for designation as an orphan medicinal product and that brentuximab vedotin should remain in the Community Register of Orphan Medicinal Products.

Further information on the current regulatory status of Adcetris can be found in the European public assessment report (EPAR) on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.