27 November 2012
EMA/COMP/601841/2012
Committee for Orphan Medicinal Products

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

Adcetris (brentuximab vedotin) for the treatment of Hodgkin lymphoma

During its meeting of 4-5 September 2012, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/08/596 for Adcetris (brentuximab vedotin[1]) as an orphan medicinal product for the treatment of Hodgkin lymphoma. 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 CD30+ Hodgkin lymphoma (HL): following autologous stem cell transplant or following at least two prior therapies when autologous stem cell transplantation or multi-agent chemotherapy is not a treatment option'.

This falls within the scope of the product's designated orphan indication, which is: 'Hodgkin lymphoma'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2009. Hodgkin lymphoma remains a serious and life threatening condition that is associated with poor long-term prognosis in patients whose disease has come back after previous treatment.

[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.

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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 Hodgkin lymphoma 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 1 in 10,000 people. This is equivalent to a total of around 51,000 people in the EU.

Existence of other satisfactory methods of treatment

At the time of the review of the orphan designation, several medicines were authorised for the treatment of Hodgkin lymphoma in the EU. The main treatments for Hodgkin lymphoma included chemotherapy (medicines to treat cancer) and radiotherapy (treatment with radiation). Autologous haematopoietic (blood) stem cell transplantation was also used when the disease had not responded or had come back after treatment. This is a complex procedure where patients receive their own stem cells to help them restore the bone marrow.

Significant benefit over existing treatments

The COMP concluded that the claim of a significant benefit of Adcetris over existing treatments is justified on the basis of it being more effective at improving the survival of patients who previously received other treatments and who no longer responded to them.

This is based on study data in patients who had previously received other treatments such as chemotherapy and/or stem cell transplantation. These data showed that progression-free survival (PFS, how long the patients lived without their disease getting worse) after Adcetris was longer than the actual or predicted PFS after other treatments. In addition, the prolonged survival seen with Adcetris could enable some patients to undergo further stem cell transplantation.

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 Hodgkin 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.