19 August 2016
EMA/COMP/370418/2016
Committee for Orphan Medicinal Products

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

Gazyvaro (obinutuzumab) for the treatment of follicular lymphoma

During its meeting of 17 to 19 May 2016, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/15/1504 for Gazyvaro (obinutuzumab) as an orphan medicinal product for the treatment of follicular lymphoma. The COMP assessed whether, at the time of addition of a new indication to the 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 methods of treatment. As other methods of treatment are authorised in the European Union (EU), the COMP also considered whether the medicine is of significant benefit to patients with follicular lymphoma. The COMP recommended that the orphan designation of the medicine be maintained[1].

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

The Committee for Medicinal Products for Human Use (CHMP) recommended extending the approved use of Gazyvaro to include the following indication:

'Gazyvaro in combination with bendamustine followed by Gazyvaro maintenance is indicated for the treatment of patients with follicular lymphoma who did not respond or who progressed during or up to 6 months after treatment with rituximab or rituximab-containing regimen'.

This falls within the scope of one of the product's designated orphan indications, which is: 'treatment of follicular lymphoma'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2015. Follicular lymphoma remains a condition that is debilitating in the long term and life-threatening, particularly due to organ damage and the cancer coming back.

[1] 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 the same therapeutic indication cannot be placed on the market.

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Prevalence of the condition

The sponsor provided updated information on the prevalence of follicular lymphoma based on data from the GLOBOCAN 2012 database, as well as data from US National Cancer Institute's SEER cancer registry.

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of follicular 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 less than 4 people in 10,000. This is equivalent to a total of fewer than 205,000 people in the EU.

Existence of other methods of treatment

At the time of designation, the main treatments for follicular lymphoma available in the EU included chemotherapy (medicines to treat cancer) combined with immunotherapy (medicines that stimulate the body's immune system to kill the cancer cells). The chemotherapy medicines bendamustine and idelalisib and the immunotherapy rituximab and ibritumomab tiuxetan were specifically authorised for the treatment of follicular lymphoma.

Significant benefit of Gazyvaro

The COMP concluded that the claim of a significant benefit of Gazyvaro over bendamustine and rituximab is justified on the basis of study data on patients with follicular lymphoma in whom treatment with rituximab had either not worked or had stopped working. Patients treated with Gazyvaro and bendamustine lived significantly longer on average without their disease getting worse than patients treated with bendamustine alone (29.2 months versus 13.7 months).

Idelalisib is approved for use on its own in follicular lymphoma patients whose disease has not responded to two previous treatments. The significant benefit of Gazyvaro over idelalisib is justified because whereas idelalisib is only used after two previous treatments have failed, Gazyvaro in combination with bendamustine can be used earlier after one previous treatment with rituximab (either alone or in combination with other cancer medicines) has failed.

Unlike Gazyvaro, ibritumomab tiuxetan must be radiolabelled (tagged with a radioactive compound) before use. The significant benefit of Gazyvaro over ibritumomab tiuxetan is justified because it spares patients the side effects linked to radioactive treatment.

Therefore, although other methods for the treatment of this condition have been authorised in the EU, the COMP concluded that Gazyvaro is of significant benefit to patients affected by follicular lymphoma.

Conclusions

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

Further information on the current regulatory status of Gazyvaro 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.