19 July 2016
EMA/COMP/450189/2016
Committee for Orphan Medicinal Products

Recommendation for maintenance of orphan designation at the time of addition of a new indication to the marketing authorisation

Revlimid (lenalidomide) for the treatment of mantle cell lymphoma

During its meeting of 14-16 June 2016, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/11/924 for Revlimid (lenalidomide) as an orphan medicinal product for the treatment of mantle cell 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 mantle cell 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 therapeutic indication for Revlimid to include the following indication:

'Revlimid is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma'.

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

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2011. Mantle cell lymphoma remains a condition that is debilitating in the long term, particularly due to enlarged lymph node, fever and weight loss, and is life-threatening with a median survival of 3 to 5 years.

[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Prevalence of the condition

The sponsor performed a search of the scientific literature and concluded that no publications are available which suggest a change in prevalence of mantle cell lymphoma.

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of mantle cell 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 0.6 people in 10,000. This is equivalent to a total of around 31,000 people in the EU.

Existence of other methods of treatment

At the time of the review of the orphan designation, other treatments were used in the EU for the treatment of mantle cell lymphoma. The main treatments included chemotherapy (medicines to treat cancer), immunotherapy (medicines that stimulate the body's own immune system to kill the cancer cells) and radiotherapy (treatment with radiation). At the time of review, the medicines ibrutinib and temsirolimus were specifically authorised in the EU for the treatment of relapsed or refractory mantle cell lymphoma (disease that has come back after previous treatment or has not responded to other treatments). The medicine pixantrone was authorised for non-Hodgkins lymphomas (a group of diseases that includes mantle cell lymphoma) that have failed several other treatments.

Significant benefit of Revlimid

The COMP concluded that the claim of a significant benefit of Revlimid in mantle cell lymphoma over temsirolimus and pixantrone is justified on the basis of comparisons of studies of Revlimid with studies using those medicines, which suggest that response to treatment and survival may be better with Revlimid. In addition, whereas those medicines are given into a vein, Revlimid is given by mouth which is easier and more convenient for patients.

The COMP initially had some concerns that a significant benefit in mantle cell lymphoma had not been demonstrated versus ibrutinib, which is also given by mouth. However, further analyses of the studies showed that Revlimid was effective in a group of patients with disease that had not responded to other treatments and to whom ibrutinib could not be given because they were also receiving treatment that increased their risk of bleeding.

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

Conclusions

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

Further information on the current regulatory status of Revlimid 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.