23 November 2016
EMA/698651/2016
Committee for Orphan Medicinal Products

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

Lartruvo (olaratumab) for the treatment of soft tissue sarcoma

During its meeting of 4-6 October 2016, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/15/1447 for Lartruvo (olaratumab) as an orphan medicinal product for the treatment of soft tissue sarcoma. 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 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 soft tissue sarcoma. 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 the authorisation of Lartruvo with the following indication: 'in combination with doxorubicin for the treatment of adult patients with advanced soft tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin'.

This falls within the scope of the product's designated orphan indication, which is: 'treatment of soft tissue sarcoma'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2015. Soft tissue sarcoma remains a long-term debilitating and life-threatening disease, particularly when the cancer has spread to other parts of the body.

Prevalence of the condition

The sponsor provided updated information on the prevalence of soft tissue sarcoma based on data from cancer registries and the published scientific literature.

[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

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of soft tissue sarcoma 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 3 people in 10,000. This is equivalent to a total of around 154,000 people in the EU.

Existence of other methods of treatment

At the time of the review of the orphan designation, other treatments were authorised in the EU for the treatment of soft tissue sarcoma. These include the cancer medicines cyclophosphamide, dacarbazine, doxorubicin, epirubicin, ifosfamide and melphalan.

Significant benefit of Lartruvo

The COMP concluded that the claim of a significant benefit of Lartruvo over doxorubicin is justified, because Lartruvo plus doxorubicin was more effective than doxorubicin alone at prolonging the time patients live without their disease getting worse. Furthermore, patients treated with Lartruvo plus doxorubicin survived 26.5 months on average compared with 14.7 months in patients treated with doxorubicin only. As no other standard treatment has been shown to produce similar improvements in survival, the COMP considered that these results also demonstrated significant benefit over other authorised treatments.

Therefore, although other methods for the treatment of this condition have been authorised in the EU, the COMP concluded that Lartruvo is of significant benefit to patients affected by soft tissue sarcoma.

Conclusions

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

More information on the COMP assessment can be found in the October 2016 COMP minutes.

Further information on Lartruvo 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.