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Committee for Orphan Medicinal Products

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

Cyramza (ramucirumab) for the treatment of gastric cancer

During its meeting of 11-13 November 2014, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/12/1004 for Cyramza (ramucirumab) as an orphan medicinal product for the treatment of gastric cancer. 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 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 gastric cancer. 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 that Cyramza should be used as follows:

- in combination with paclitaxel for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy;
- as monotherapy for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate.

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

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2012. Gastric cancer remains a long-term debilitating and life-threatening condition with a short life expectancy.

[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 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 of gastric cancer based on data from the scientific literature.

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of gastric cancer 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 not more than 4 people in 10,000. This is equivalent to a total of not more than 204,000 people in the EU.

Existence of other methods of treatment

The COMP noted that, at the time of the review of the orphan designation, the main treatments for gastric cancer were surgery and/or chemotherapy (medicines to treat cancer), such as platinum and fluoropyrimidine–based therapy.

Significant benefit of Cyramza

The COMP concluded that the claim of a significant benefit of Cyramza in gastric cancer is justified because Cyramza, in combination with paclitaxel, improves the survival of patients whose cancer has come back despite a previous treatment with platinum and/or a fluoropyrimidine. This is based in a study which showed that patients treated with Cyramza and paclitaxel lived longer on average than patients treated with paclitaxel and placebo (a dummy treatment): 9.6 months versus 7.4 months respectively.

In addition, for patients for whom Cyramza in combination with paclitaxel is not appropriate, the COMP concluded that the claim of significant benefit of Cyramza on its own is justified because these patients tolerate this treatment better than other cancer treatments.

Therefore, although other methods for the treatment of this condition have been authorised in the EU, the COMP concluded that Cyramza is of significant benefit for patients affected by gastric cancer.

Conclusions

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

Further information on the current regulatory status of Cyramza 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.