25 September 2014
EMA/CHMP/552028/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cyramza

ramucirumab

On 25 September 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cyramza, 10 mg/ml, concentrate for solution for infusion intended for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy. Cyramza was designated as an orphan medicinal product on 4 July 2012. The applicant for this medicinal product is Eli Lilly Nederland B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Cyramza is ramucirumab, a human receptor-targeted antibody that specifically binds VEGF Receptor 2 and blocks angiogenesis by binding of VEGF-A, VEGF-C, and VEGF-D.

The benefits with Cyramza are its ability to improve the survival in patients compared to chemotherapy alone (when used in combination with chemotherapy) and compared to placebo (when used alone). The most common side effects are fatigue/asthenia, neutropenia, leukopenia, diarrhoea, epistaxis, and hypertension.

A pharmacovigilance plan for Cyramza will be implemented as part of the marketing authorisation.

The approved indication is:

Cyramza in combination with paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy.

Cyramza monotherapy is indicated 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.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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It is proposed that Cyramza be prescribed by physicians experienced in the administration of anticancer therapy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Cyramza and therefore recommends the granting of the marketing authorisation.