EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2016
EMA/CHMP/589981/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lartruvo

olaratumab

On 15 September 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Lartruvo, intended for the treatment of advanced soft tissue sarcoma. Lartruvo was designated as an orphan medicinal product on 12 February 2015. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Lartruvo will be available as a 10 mg/ml concentrate for solution for infusion. The active substance of Lartruvo is olaratumab, a human IgG1 monoclonal antibody (ATC code: L01XC27) and antagonist of platelet derived growth factor receptor-α (PDGFR-α) expressed on tumour and stromal cells.

Data showed that, when added to doxorubicin, Lartruvo improved survival compared with doxorubicin alone. The most common side effects are nausea, musculoskeletal pain, neutropenia and mucositis.

The full indication is: "Lartruvo is indicated 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". It is proposed that Lartruvo be prescribed and supervised by physicians experienced in oncology.

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.

[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

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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