EMA Recommends Granting a Conditional Marketing Authorisation for Lorlatinib

It is intended for treatment of patients with ALK-positive advanced NSCLC previously treated with other ALK tyrosine kinase inhibitors

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On 28 February 2019, **the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion**, recommending the granting of a conditional marketing authorisation for the medicinal product lorlatinib (Lorviqua), intended for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).

The applicant for this medicinal product is Pfizer Europe MA EEIG.

Lorviqua will be available as 25 mg and 100 mg film-coated tablets. The active substance of Lorviqua is lorlatinib, a protein kinase inhibitor (L01XE36) that inhibits autophosphorylation of ALK, ALK-mediated phosphorylation of downstream signalling proteins and proliferation of ALK-dependent cancer cells.

Treatment with Lorviqua was shown to result in clinically relevant response rates and durations of response in patients previously treated with other ALK tyrosine kinase inhibitors.

The most common side effects are hypercholesterolaemia, hypertriglyceridaemia, oedema, peripheral neuropathy, cognitive effects, fatigue, weight increased and mood effects.

The full indication is:

Lorlatinib as monotherapy is indicated for the treatment of adult patients with ALK-positive advanced NSCLC whose disease has progressed after:

- alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or
- crizotinib and at least one other ALK TKI.

It is proposed that Lorviqua be prescribed by physicians experienced in the use of anticancer medicinal products.

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

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

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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