20 September 2018
EMA/CHMP/583486/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Alunbrig

brigatinib

On 20 September 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Alunbrig, intended for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib. The applicant for this medicinal product is Takeda Pharma A/S.

Alunbrig will be available as film-coated tablets (30 mg, 90 mg and 180 mg). The active substance of Alunbrig is brigatinib, a protein kinase inhibitor (ATC code: L01XE43) that inhibits autophosphorylation of ALK, ALK-mediated phosphorylation of downstream signalling proteins and proliferation of ALK-dependent cancer cells.

The benefits with Alunbrig are its ability to produce a response in patients with ALK-positive NSCLC previously treated with crizotinib, with an objective response rate of 56% (ITT population) in a phase II study.

The most common side effects are hyperglycaemia, hyperinsulinaemia, anaemia, increased CPK, nausea, increased lipase, decreased lymphocyte count, increased ALT and AST, diarrhoea, increased amylase, fatigue, cough, headache, increased alkaline phosphatase, hypophosphataemia, increased APTT, rash, vomiting, dyspnoea, hypertension, decreased white blood cell count, myalgia, and peripheral neuropathy.

The full indication is:

“Alunbrig is indicated as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib”.

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

[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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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.