EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2019
EMA/CHMP/501445/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xospata

gilteritinib

On 19 September 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xospata,[2] intended for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation. Xospata was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Astellas Pharma Europe B.V.

Xospata will be available as 40-mg film-coated tablets. The active substance of Xospata is gilteritinib, a protein kinase inhibitor (ATC code: L01XE54) which inhibits FLT3 receptor signalling and proliferation in cells and subsequently induces apoptosis in leukaemic cells expressing FLT3 ITD.

The benefit with Xospata is its ability to improve overall survival compared to salvage chemotherapy. The most common side effects are increased blood creatine phosphokinase, increased alanine aminotransferase, increased aspartate aminotransferase, increased blood alkaline phosphatase, diarrhoea, fatigue, nausea, constipation, cough, peripheral oedema, dyspnoea, dizziness, hypotension, pain in the extremities, asthenia, arthralgia and myalgia.

The full indication is: "Xospata is indicated as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation (see sections 4.2 and 5.1)."

It is proposed that Xospata be prescribed by physicians experienced in the use of anti-cancer therapies.

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] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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