14 September 2023
EMA/CHMP/378674/2023
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Vanflyta

quizartinib

On 14 September 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vanflyta, intended for the treatment of acute myeloid leukaemia (AML) that is FLT3-ITD positive. The applicant for this medicinal product is Daiichi Sankyo Europe GmbH.

Vanflyta will be available as 17.7 mg and 26.5 mg film-coated tablets. The active substance of Vanflyta is quizartinib, a protein kinase inhibitor (ATC code: L01EX11). Quizartinib, together with its major metabolite AC886, inhibits the receptor tyrosine kinase FLT3 by preventing autophosphorylation of the receptor, thereby inhibiting further downstream FLT3 receptor signalling and blocking FLT3-ITD-dependent cell proliferation.

The benefit of Vanflyta is an increased survival rate (median OS of 31.9 months and 15.1 months respectively for quizartinib and placebo) when used in the approved indication, as shown in a randomised, double-blind, placebo-controlled, phase 3 study in adult patients with FLT3-ITD-positive AML. The most common side effects are increased alanine aminotransferase, decreased platelet count, decreased haemoglobin, diarrhoea, nausea, abdominal pain, headache, vomiting and decreased neutrophil count.

The full indication is:

> VANFLYTA is indicated in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, followed by VANFLYTA single-agent maintenance therapy for adult patients with newly diagnosed acute myeloid leukaemia (AML) that is FLT3-ITD positive.

Vanflyta should 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

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