20 July 2023
EMA/324132/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Inaqovi

decitabine / cedazuridine

On 20 July 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 Inaqovi, intended for the treatment of acute myeloid leukaemia (AML). The applicant for this medicinal product is Otsuka Pharmaceutical Netherlands B.V.

Inaqovi will be available as a 35 mg / 100 mg film-coated tablet containing a fixed combination of the active substances decitabine and cedazuridine (ATC code: L01BC58). Decitabine is a nucleoside metabolic inhibitor that inhibits the action of DNA methyltransferases, leading to hypomethylation of DNA and subsequent cellular differentiation and/or apoptosis. Cedazuridine is a cytidine deaminase inhibitor that increases systemic exposure to decitabine.

The benefit of Inaqovi in the treatment of AML is a comparable exposure equivalent to intravenous infusion of decitabine at 20 mg/m^2, allowing for a similar efficacy as seen for IV decitabine, with a complete response rate of 21% with a median duration of response of 5.8 months and an overall response rate of 32%. The most common side effects is thrombocytopaenia. The most common serious side effects are febrile neutropaenia and pneumonia.

The full indication is:

> Inaqovi is indicated as monotherapy for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy.

Inaqovi should be prescribed by physicians experienced in the use of anticancer 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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