23 February 2023
EMA/180261/2023 Rev.1
Committee for Medicinal Products for Human Use (CHMP)

**Update as of 26 April 2023:**

The applicant withdrew the marketing authorisation application for Tidhesco on 27 March 2023. This application was a duplicate of the application for the medicine Tibsovo, for which the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion on 23 February 2023.

The application was withdrawn after CHMP had adopted a positive opinion recommending the granting of a marketing authorisation. At the time of withdrawal, the European Commission had not yet granted marketing authorisation for this product.

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

# Tidhesco

ivosidenib

On 23 February 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 Tidhesco[2], intended for the treatment of adult patients with for newly diagnosed acute myeloid leukaemia (AML).

The applicant for this medicinal product is Les Laboratoires Servier.

Tidhesco will be available as 250 mg film-coated tablet. The active substance of Tidhesco is ivosidenib, an antineoplastic agent (ATC code: L01XX62). Ivosidenib inhibits the mutant IDH1 enzyme, which converts alpha- ketoglutarate (α-KG) to 2-hydroxyglutarate (2-HG). This blocks cellular differentiation and promotes tumorigenesis. The mechanism of action of ivosidenib beyond its ability to reduce 2-HG and restore cellular differentiation is not fully understood across indications.

The benefits of Tidhesco, in combination with azacitidine, in newly diagnosed acute myeloid leukaemia are improvements in event-free survival compared to placebo in combination with azacitidine, as observed in a randomised, multicentre, double-blind, phase III clinical study. The most common side effects of combination treatment are vomiting, neutropenia, thrombocytopenia, electrocardiogram QT prolonged and

[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 an 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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insomnia.

The full indication is:

> Tidhesco in combination with azacitidine is indicated for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive standard induction chemotherapy.

Tidhesco should be prescribed by physicians experienced in the use of anti-cancer medicinal products.

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.