23 February 2023
EMA/CHMP/76153/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tibsovo

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 Tibsovo[2], intended for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) and for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma.

The applicant for this medicinal product is Les Laboratoires Servier.

Tibsovo will be available as 250 mg film-coated tablet. The active substance of Tibsovo 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 in both hematologic and non-hematologic malignancies. The mechanism of action of ivosidenib is not fully understood beyond its ability to reduce 2-HG and restore cellular differentiation across indications.

The benefits of Tibsovo, 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 insomnia.

The benefits of Tibsovo monotherapy in locally advanced or metastatic cholangiocarcinoma are improvements in progression-free survival compared to placebo, as observed in a randomised, multicentre, double-blind, phase III clinical study. The most common side effects are fatigue, nausea, abdominal pain, diarrhoea, decreased appetite, ascites, vomiting, anaemia and rash.

The full indications are:

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- Tibsovo 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.
- Tibsovo monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1 R132 mutation who were previously treated by at least one prior line of systemic therapy.

Tibsovo 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.