14 November 2024
EMA/CHMP/495873/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Gohibic

vilobelimab

On 14 November 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Gohibic intended for the treatment of adults with SARS-CoV2-induced acute respiratory distress syndrome (ARDS) who are receiving systemic corticosteroids.

The applicant for this medicinal product is InflaRx GmbH.

Gohibic will be available as 200 mg concentrate for solution for infusion. The active substance of Gohibic is vilobelimab, an immunosuppressant (ATC code: L04AJ10). Vilobelimab is a monoclonal antibody which binds to, and block the activity of the human complement factor C5a.

The benefit of Gohibic in adults with ARDS receiving corticosteroids is a reduced mortality at day 28 and 60 after start of treatment compared to standard of care. The most common adverse reactions with Gohibic are pneumonia (21.7%), herpes simplex (6.3%), bronchopulmonary aspergillosis (5.7%), and sepsis (5.1%).

The full indication is:

> Gohibic is indicated for the treatment of adult patients with SARS-CoV2-induced acute respiratory distress syndrome (ARDS) who are receiving systemic corticosteroids as part of Standard of Care and receiving invasive mechanical ventilation (IMV) (with or without extracorporeal membrane oxygenation (ECMO)).

Gohibic should be initiated and monitored by a physician experienced in the management of patients treated in an intensive care unit (ICU) setting.

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

[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] In exceptional circumstances a marketing authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety to a medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical consideration involved in the collection of such data.

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.