17 October 2024
EMA/CHMP/444199/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Korjuny

catumaxomab

On 17 October 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Korjuny, intended for the intraperitoneal treatment of malignant ascites.

The applicant for this medicinal product is Lindis Biotech GmbH.

Korjuny will be available as 10 µg and 50 µg concentrate for solution for infusion. The active substance of Korjuny is catumaxomab, an antineoplastic agent (ATC code: L01FX03). Catumaxomab is a monoclonal antibody that targets the epithelial cell adhesion molecule (EpCAM) on tumour cells and CD3 antigen on T cells, inducing an immunoreaction against EpCAM expressing tumour cells.

The benefit of Korjuny is its ability to reduce the need for paracenteses in patients with malignant ascites. The most common side effects are pyrexia, abdominal pain, nausea and vomiting.

The full indication is:

> Korjuny is indicated for the intraperitoneal treatment of malignant ascites in adults with epithelial cellular adhesion molecule (EpCAM)-positive carcinomas, who are not eligible for further systemic anticancer therapy.

Korjuny must be administered under the supervision of a physician 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.

[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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