19 September 2024
EMA/CHMP/415249/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Elahere

mirvetuximab soravtansine

On 19 September 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 Elahere[2], intended for the treatment of adults with folate receptor-alpha (FRα) positive epithelial ovarian, fallopian tube and primary peritoneal cancer.

The applicant for this medicinal product is AbbVie Deutschland GmbH & Co. KG.

Elahere will be available as 5 mg/ml concentrate for solution for infusion. The active substance of Elahere is mirvetuximab soravtansine, an antineoplastic monoclonal antibody-drug conjugate (ATC code: L01FX26). Mirvetuximab is made up of an antibody that binds to the FRα receptor expressed on the surface of ovarian cancer cells and DM4, a microtubule inhibitor attached to the antibody via a cleavable linker. Upon binding to FRα, mirvetuximab soravtansine is internalised, leading to the intracellular release of DM4 by proteolytic cleavage. Inside the cells, DM4 disrupts the microtubule network, resulting in cell cycle arrest and apoptotic cell death.

The benefits of Elahere are an improved progression-free survival (PFS) and an improved overall survival (OS) in patients with FRα positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens, when compared to chemotherapy (either paclixatel, pegylated liposomal doxorubicin or topotecan). The most common side effects of Elahere are blurred vision, nausea, diarrhoea, fatigue, abdominal pain, keratopathy, dry eye, constipation, vomiting, decreased appetite, peripheral neuropathy, headache, asthenia, increased aspartate aminotransferase and arthralgia.

The full indication is:

> ELAHERE as monotherapy is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens

[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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(see section 4.2).

Elahere should be prescribed and supervised by physicians experienced in the use of cancer treatments.

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.