30 January 2025
EMA/CHMP/3463/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tivdak

tisotumab vedotin

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tivdak, intended for the treatment of recurrent or metastatic cervical cancer. The applicant for this medicinal product is Pfizer Europe MA EEIG.

Tivdak will be available as a 40 mg powder for concentrate for solution for infusion. The active substance of Tivdak is tisotumab vedotin, an antineoplastic agent (L01FX23). Tisotumab vedotin is an antibody-drug conjugate that binds to tissue factor (TF)-expressing tumour cells, causing the product to enter the cells. Upon internalisation, monomethyl auristatin E is released and disrupts the microtubule network of actively dividing cells, leading to cell death.

The benefits of Tivdak are its superiority in terms of prolonging survival and survival without disease progression compared to chemotherapy, as shown in a phase 3 randomised open-label study in patients with recurrent or metastatic cervical cancer treated in second or third line of therapy. The most common side effects are peripheral neuropathy, nausea, epistaxis, conjunctivitis, alopecia, anaemia and diarrhoea.

The full indication is:

> Tivdak as monotherapy is indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy (see section 5.1).

Tivdak should be prescribed and supervised by physicians experienced in the treatment of cancer.

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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