14 December 2023
EMA/CHMP/543409/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Mevlyq

eribulin

On 14 December 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 Mevlyq, intended for the treatment of adult patients with locally advanced or metastatic breast cancer, or adult patients with unresectable advanced or metastatic liposarcoma.

The applicant for this medicinal product is YES Pharmaceutical Development Services GmbH.

Mevlyq will be available as a solution for injection (0.44 mg/ml). The active substance of Mevlyq is eribulin, an antineoplastic agent (ATC code: L01XX41). Eribulin inhibits the growth phase of microtubules without affecting the shortening phase and sequesters tubulin into nonproductive aggregates. Eribulin exerts its effects via a tubulin-based antimitotic mechanism leading to G_2/M cell-cycle block, disruption of mitotic spindles, and, ultimately, apoptotic cell death after prolonged mitotic blockage.

Mevlyq is a generic of Halaven, which has been authorised in the EU since 17 March 2011. Since Mevlyq is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Halaven was not required. A question and answer document on generic medicines can be found here.

The full indication is:

> Mevlyq is indicated for the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease (see section 5.1). Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.
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> Mevlyq is indicated for the treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease (see section 5.1).

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 67 days from adoption of the opinion

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Mevlyq should be prescribed by physicians experienced in the appropriate use of cytotoxic 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.