27 February 2025
EMA/CHMP/559896/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Trabectedin Accord

trabectedin

On 27 February 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 Trabectedin Accord, intended for the treatment of advanced soft tissue sarcoma and of relapsed platinum-sensitive ovarian cancer.

The applicant for this medicinal product is Accord Healthcare S.L.U.

Trabectedin Accord will be available as 0.25 mg and 1 mg powder for concentrate for solution for infusion. The active substance of Trabectedin Accord is trabectedin, an anti-neoplastic agent (ATC code: L01CX01). Trabectedin binds to the minor groove of DNA, interfering with transcription, DNA repair and cell division. By doing so, trabectedin prevents cancer cells from growing and causes them to die.

Trabectedin Accord is a generic of Yondelis, which has been authorised in the EU since 17 September 2007. Studies have demonstrated the satisfactory quality of Trabectedin Accord. Since Trabectedin Accord is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Yondelis was not required. A question and answer document on generic medicines can be found on the EMA website.

The full indication is:

> Trabectedin Accord is indicated for the treatment of adult patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients.
>
> Trabectedin Accord in combination with pegylated liposomal doxorubicin (PLD) is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer.

Trabectedin Accord must be administered under the supervision of a physician experienced in the use of chemotherapy. Its use should be confined to qualified oncologists or other health professionals specialised in the administration of cytotoxic agents.

[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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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.