9 November 2023
EMA/CHMP/481586/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Naveruclif

paclitaxel

On 9 November 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 Naveruclif, intended for the treatment of metastatic breast cancer, metastatic adenocarcinoma of the pancreas and non-small cell lung cancer. The applicant for this medicinal product is Accord Healthcare S.L.U.

Naveruclif will be available as a 5 mg/ml powder for dispersion for infusion. The active substance of Naveruclif is paclitaxel, a taxane antineoplastic agent (ATC code: L01CD01). Paclitaxel interferes with microtubule growth to block cell division and induces apoptosis. Naveruclif also affects non-cancer cells such as blood and nerve cells, which can cause side effects.

Naveruclif is a generic of Abraxane, another nanoparticle albumin-bound paclitaxel, which has been authorised in the EU since 2008. Studies have demonstrated the satisfactory quality of Naveruclif. A bioequivalence study versus the reference product was not required, because Naveruclif is administered intravenously and the nanoparticles dissociate rapidly, and because of the composition and behaviour of the products. A question and answer document on generic medicines can be found here.

The full indication is:

> Naveruclif monotherapy is indicated for the treatment of metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated (see section 4.4).
>
> Naveruclif in combination with gemcitabine is indicated for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.
>
> Naveruclif in combination with carboplatin is indicated for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.

Naveruclif should only be administered under the supervision of a qualified oncologist in units specialised

[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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in the administration of cytotoxic agents. It should not be substituted for or with other paclitaxel formulations.

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.