EMA/CHMP/655859/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Celdoxome pegylated liposomal

doxorubicin hydrochloride

On 21 July 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Celdoxome pegylated liposomal, intended for the treatment of metastatic breast cancer, advanced ovarian cancer, progressive multiple myeloma and AIDS-related Kaposi's sarcoma.

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

Celdoxome pegylated liposomal will be available as a 2 mg/ml concentrate for dispersion for infusion. The active substance of Celdoxome pegylated liposomal is doxorubicin hydrochloride, a cytotoxic agent (ATC code: L01DB01) that inhibits DNA, RNA and protein synthesis.

Celdoxome pegylated liposomal is a hybrid medicine[2] of Adriamycin which has been authorised in the EU since 24 October 1979. Celdoxome pegylated liposomal contains the same active substance as Adriamycin, but is available in a pegylated liposomal formulation.

Studies have demonstrated the satisfactory quality of Celdoxome, and its bioequivalence to the reference product Caelyx, which contains doxorubicin hydrochloride in a pegylated liposomal formulation and was chosen as comparator.

The full indication is:

> Celdoxome pegylated liposomal is indicated in adults:

[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] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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- As monotherapy for patients with metastatic breast cancer, where there is an increased cardiac risk.

- For treatment of advanced ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.

- In combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.

- For treatment of AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (< 200 CD4 lymphocytes/mm3) and extensive mucocutaneous or visceral disease.

Celdoxome pegylated liposomal may be used as first-line systemic chemotherapy, or as second line chemotherapy in AIDS-KS patients with disease that has progressed with, or in patients intolerant to, prior combination systemic chemotherapy comprising at least two of the following agents: a vinca alkaloid, bleomycin and standard doxorubicin (or other anthracycline).

Celdoxome pegylated liposomal should only be administered under the supervision of a qualified oncologist specialised in the administration of cytotoxic agents.

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.