20 March 2014
EMA/CHMP/138539/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vynfinit

vintafolide

On 20 March 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation[2] for the medicinal product Vynfinit, intended for the treatment of adult patients with platinum-resistant ovarian cancer who express the folate receptor on all target lesions. Folate receptor status should be assessed by a diagnostic medicinal product approved for the selection of adult patients for treatment with vintafolide, such as Folcepri (see Summary of Opinion on Folcepri).

Vynfinit was designated an orphan medicinal product on 9 February 2012. The applicant for this medicinal product is Endocyte Europe, B.V.

Vynfinit is to be available as a 2.5 mg powder for solution for injection. The active substance of Vynfinit is vintafolide, which belongs to the therapeutic group 'vinca alkaloid and analogues' (L01CA06). Vintafolide consists of folic acid and the cytotoxic agent desacetylvinblastine hydrazide (DAVLBH). The folic acid component enables DAVLBH to be delivered preferentially to cancer cells expressing folate receptors. Once delivered inside cancer cells, DAVLBH is released from vintafolide and acts by inhibiting microtubule assembly and arresting cells in mitosis.

The benefits with Vynfinit are its ability, in combination with pegylated liposomal doxorubicin (PLD), to improve progression-free survival in patients with platinum-resistant ovarian cancer when compared with treatment with PLD alone. The most common side effects are fatigue, stomatitis, neutropenia, anaemia, nausea, palmar-plantar erythrodysaesthesia, constipation, rash and peripheral sensory neuropathy.

A pharmacovigilance plan for Vynfinit will be implemented as part of the marketing authorisation.

The text for the approved indication is as follows: "Vynfinit in combination with pegylated liposomal doxorubicin (PLD) is indicated for the treatment of adult patients with platinum resistant ovarian

[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] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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cancer (PROC) who express the folate receptor (FR) on all target lesions. Folate receptor status should be assessed by a diagnostic medicinal product approved for the selection of adult patients for treatment with vintafolide, using single photon emission computed tomography (SPECT) imaging, in combination with Computed Tomography (CT) or Magnetic Resonance Imaging (MRI)". Vynfinit is to be prescribed by physicians experienced in chemotherapy treatment.

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.