20 March 2014
EMA/CHMP/139146/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Folcepri

etarfolatide

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 Folcepri intended to be used, after intravenously administered folic acid, in single photon emission computed tomography (SPECT) imaging to select adult patients with ovarian cancer suitable for treatment with the anticancer medicine vintafolide.

Folcepri was designated an orphan medicinal product on 10 September 2012. The applicant for this medicinal product is Endocyte Europe, B.V.

Folcepri is to be available as a 100 microgram kit for radiopharmaceutical preparation. The active substance of Folcepri, etarfolatide, consists of folic acid and a technetium-99m chelating peptide. It binds to the folate receptor expressed on the surface of many types of cancers, including ovarian cancer. Following radiolabeling with technetium-99m, Folcepri is used in SPECT imaging to detect cancer cells with folate receptor.

The benefits with Folcepri are its ability to detect adult patients with platinum-resistant ovarian cancer that express the folate receptor on all target lesions and who are therefore suitable for treatment with vintafolide, which targets cancer cells expressing the folate receptor (see Summary of Opinion on Vynfinit). The only side effect reported with Folcepri was pruritus, which was reported uncommonly.

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

The text for the approved indication is as follows: "This medicinal product is for diagnostic use only. After radiolabelling with sodium pertechnetate (^{99m}Tc) solution, Folcepri is indicated, after intravenously administered folic acid, for single photon emission computed tomography (SPECT) imaging, in combination with Computed Tomography (CT) or Magnetic Resonance Imaging (MRI), for the selection of adult patients for treatment with vintafolide, a folate receptor (FR) targeted

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

therapeutic for use in ovarian cancer". Folcepri is to be prescribed by physicians experienced in radioisotope diagnostic imaging.

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.