ENDOCYTE

16-May-2014

Tomas Salmonson
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of Folcepri, etarfolatide, 0.1 mg, kit for radiopharmaceutical preparation
EMEA/H/0002570

Dear Tomas Salmonson,

I would like to inform you that, at this point of time, Endocyte B.V. has taken the decision to withdraw the application for Marketing Authorisation of Folcepri, etarfolatide, 0.1 mg, kit for radiopharmaceutical preparation which was intended to be used, 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 therapeutic for use in ovarian cancer.

This withdrawal is based on the following reason: the Conditional Marketing Authorisation (CMA) includes the requirement for an ongoing confirmatory study to provide comprehensive data. However, the phase 3 trial (Study EC-FV-06) which was included in the application for CMA has been terminated. Therefore, the CMA for Folcepri no longer meets this specific obligation.

The future clinical development of Folcepri is being evaluated. The Sponsor does not intend to initiate new compassionate use programs for Folcepri; the Sponsor will continue to provide Folcepri to patients who are currently receiving treatment through a compassionate use program pending further discussion with local regulatory authorities which have granted approval for compassionate use.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMEA website.

Kind regards

[redacted]

Vice President of Regulatory Affairs
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