ENDOCYTE

16-May-2014

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

Subject: Withdrawal of Neocepri, folic acid, 0.5 mg, solution for injection
EMEA/H/0002773

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 Neocepri, folic acid, 0.5 mg, solution for injection, which was intended to be used for the enhancement of 99mTc-etarfolatide single photon emission computed tomography (SPECT) image quality.

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 Neocepri no longer meets this specific obligation.

The future clinical development of Neocepri is being evaluated. The Sponsor does not intend to initiate new compassionate use programs for Neocepri; the Sponsor will continue to provide Neocepri 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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