5 August 2014
EMA/303644/2014
EMEA/H/C/002773

Questions and answers

Update of 5 August 2014:

Following the withdrawal of the application by the company, the European Commission issued a decision formally refusing marketing authorisation for Neocepri.

Withdrawal of the marketing authorisation application for Neocepri (folic acid)

On 16 May 2014, Europe B.V. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it has decided to withdraw its application for a marketing authorisation for Neocepri as a diagnostic medicine to help select ovarian cancer patients to be treated with the cancer medicine Vynfinit (vintafolide).

What is Neocepri?

Neocepri is a diagnostic medicine that contains the active substance folic acid. It was to be available as a solution for injection.

What was Neocepri expected to be used for?

Neocepri was to be given to patients with ovarian cancer as part of a scan to see if they were suitable for treatment with Vynfinit, a cancer medicine. Neocepri would help doctors obtain a clearer image from the scan.

It was to be given into a vein before the patient would receive an injection of another medicine called Folcepri. The patient would then undergo a type of scan called a SPECT scan or single photon emission computed tomography.

Neocepri was designated an 'orphan medicine' (a medicine to be used in rare diseases) on 10 September 2012 for ovarian cancer.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

How is Neocepri expected to work?

The images from the SPECT scan come from Folcepri that has been radiolabelled (mixed with a radioactive substance) beforehand. The radiolabelled Folcepri attaches to proteins called folate receptors which are present in high amounts on the surface of some cancer cells, from where it emits radiation that is seen on the scan. This allows doctors to determine whether the patient's cancer has high levels of folate receptors and so is suitable for treatment with Vynfinit, a medicine that targets these receptors. However, because these folate receptors are also found in much lower amounts in some normal cells, Folcepri will also attach to normal tissues and the image on the scan will not show the tumours clearly.

The active substance in Neocepri, folic acid, readily attaches to the folate receptors in normal tissue. By injecting Neocepri before Folcepri, doctors reduce the binding of Folcepri to normal cells allowing the scan to show a clearer image that can be read more easily.

What did the company present to support its application?

The company presented data from small studies involving 28 participants in which Neocepri was given before Folcepri to see if it led to clearer images on SPECT scans.

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the CHMP had recommended a conditional marketing authorisation for Neocepri. Since Neocepri was to be used to help identify patients suitable for treatment with the cancer medicine Vynfinit, the authorisation was conditional upon the company providing confirmatory data from an ongoing study with Vynfinit. However, before the authorisation process could be completed by the European Commission, preliminary data from this study became available which showed that the study could not confirm the benefit of Vynfinit in ovarian cancer patients. Therefore the company had to terminate the study and decided to withdraw the application.

What was the recommendation of the CHMP at that time?

Following the termination of the study, the European Commission had requested the CHMP to revise its recommendation but the application was withdrawn before the CHMP had started the revision. However, although no formal review has been carried out, the CHMP informed the European Commission that, as confirmatory data on the benefits of Vynfinit will not be forthcoming, the grounds for the previous CHMP recommendation for a conditional marketing authorisation are no longer valid.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that the condition of the marketing authorisation to provide confirmatory data will not be met since the study had been terminated. The preliminary data from the study could not confirm the benefit of Vynfinit in ovarian cancer patients. The withdrawal letter is available here.

In addition, the company notified the Agency of the withdrawal of the applications for Vynfinit and Folcepri.