5 August 2014
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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 Folcepri.

Withdrawal of the marketing authorisation application for Folcepri (etarfolatide)

On 16 May 2014, Endocyte 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 Folcepri as a diagnostic medicine for selecting ovarian cancer patients to be treated with the cancer medicine Vynfinit (vintafolide).

What is Folcepri?

Folcepri is a diagnostic medicine that contains the active substance etarfolatide. It was to be available as a solution for injection.

What was Folcepri expected to be used for?

Folcepri was to be used in patients with ovarian cancer as part of a scan to see if they were suitable for treatment with Vynfinit, a cancer medicine.

Folcepri was to be used with a type of scan called SPECT (single photon emission computed tomography). Folcepri was to be 'radiolabelled', which means it is mixed with a small amount of a radioactive substance (technetium-99m), which would allow the medicine to be detected during the scan.

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

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How is Folcepri expected to work?

The active substance in Folcepri, etarfolatide, attaches to proteins called folate receptors which are found in high amounts on the surface of some cancer cells. When the radiolabeled medicine is given to ovarian cancer patients, it attaches to the folate receptors on the cancer cells, from where it emits radiation that is seen on the scan.

From the images obtained from the scan, doctors can determine whether the patient's cancer cells have high levels of folate receptors and therefore whether the patient is suitable for treatment with Vynfinit, a medicine that targets these receptors.

What did the company present to support its application?

The company presented results of a study in women with ovarian cancer in which SPECT scans produced with Folcepri were analysed to see if Folcepri could accurately predict which patients would benefit from treatment with vintafolide. In total 94 images were evaluated by expert assessors and assigned a score ranging from 0 to 100% based on the percentage of cancer tumours that had folate receptors.

Another study was conducted to test the reliability of the ratings in the original study, with independent experts called in to re-evaluate the images and then asked to re-evaluate the same images after at least 4 weeks.

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 Folcepri. Since Folcepri was to be used to 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 another medicine, Neocepri, which was to be used with Folcepri.