15 September 2017
EMA/564631/2017
EMEA/H/C/004346

Questions and answers

Withdrawal of the marketing authorisation application for Ogivri (trastuzumab)

On 3 August 2017, Mylan S.A.S. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Ogivri, for the treatment of breast cancer and gastric cancer.

What is Ogivri?

Ogivri is a medicine that contains the active substance trastuzumab. It was to be available as a powder to be made up into a solution for infusion (drip) into a vein.

Ogivri was developed as a 'biosimilar' medicine. This means that it was intended to be highly similar to a biological medicine (the 'reference medicine') already authorised in the European Union called Herceptin. For more information on biosimilar medicines, see here.

What was Ogivri expected to be used for?

Ogivri was expected to be used to treat early and metastatic breast cancer and metastatic gastric (stomach) cancer.

Ogivri was to be used only when the cancer has been shown to 'overexpress HER2': this means that the cancer produces a protein called HER2 in large quantities on the surface of the tumour cells, which makes the tumour cells grow more quickly. HER2 is overexpressed in about a quarter of breast cancers and a fifth of gastric cancers.

How does Ogivri work?

The active substance in Ogivri and Herceptin, trastuzumab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific

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

structure (called an antigen) that is found on certain cells in the body. Trastuzumab has been designed to attach to HER2. By attaching to HER2, trastuzumab activates cells of the immune system, which then kill the tumour cells. Trastuzumab also stops HER2 producing signals that cause the tumour cells to grow.

What did the company present to support its application?

The company presented results of studies on the quality, safety and effectiveness of the medicine.

Two studies were carried out in healthy volunteers to investigate whether Ogivri produces the same levels of the active substance in the body as the reference medicine Herceptin and therefore has the same effect.

In a third study, Ogivri in combination with a taxane was compared with Herceptin used in combination with a taxane in 500 patients with metastatic breast cancer whose tumour cells overexpressed HER2. The study measured the number of patients who responded to treatment.

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

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions. The company had not responded to the last round of questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Ogivri could not have been approved for the treatment of breast cancer and gastric cancer.

The CHMP's main concern was the lack of a valid certificate confirming that the manufacturing facility of the product complies with good manufacturing practice (GMP) requirements.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the company had not provided enough documentation to support the application for Ogivri.

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

In its letter notifying the Agency of the withdrawal of the application, the company stated that it was withdrawing the application because a GMP certificate for the manufacturing site of the product could not be obtained in the time available.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that the withdrawal does not impact ongoing clinical trials with Ogivri.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.