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Questions and answers

Withdrawal of the marketing authorisation application for Kyomarc (bevacizumab)

On 17 October 2017, Amgen Europe BV officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Kyomarc, for the treatment of cancer of the colon or rectum, breast cancer, non-small cell lung cancer (NSCLC), kidney cancer, cervical cancer, and cancer of the ovary, the fallopian tube, or the peritoneum.

What is Kyomarc?

Kyomarc is a cancer medicine that contains the active substance bevacizumab. It was to be available as a concentrate to be made up into a solution for infusion (drip) into a vein.

Kyomarc was developed as a 'biosimilar' medicine. This means that Kyomarc was intended to be highly similar to another biological medicine (the 'reference medicine') already authorised in the EU. The reference medicine for Kyomarc is Avastin. For more information on biosimilar medicines, see here.

What was Kyomarc expected to be used for?

Kyomarc was to be used to treat cancer of the colon or rectum, breast cancer, NSCLC, kidney cancer, cervical cancer, and cancer of the ovary, the fallopian tube, or the peritoneum.

How does Kyomarc work?

Kyomarc was expected to work in the same way as the reference medicine, Avastin. The active substance in Kyomarc and Avastin, bevacizumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to vascular endothelial growth factor (VEGF), a protein that circulates in the blood and makes blood vessels grow. By attaching to VEGF, bevacizumab stops it

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having an effect. As a result, the cancer cells cannot develop their own blood supply and are starved of oxygen and nutrients, helping to slow down the growth of tumours.

What did the company present to support its application?

The company presented laboratory studies comparing Kyomarc to its reference medicine Avastin in terms of its structure, purity and biological activity. A study in 202 healthy volunteers compared Kyomarc with Avastin to determine whether the two medicines produce similar levels of the active substance in the body. In addition, a study in 642 patients with advanced NSCLC compared the effectiveness and safety of Kyomarc and Avastin.

How far into the evaluation was the application when it was withdrawn?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 CHMP was assessing the company's responses 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 no major concerns and was of the provisional opinion that Kyomarc could have been approved for the treatment of the cancers listed above.

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 for marketing reasons. The company said it will continue with its marketing authorisation application for another medicine, Mvasi, which is also a biosimilar medicine containing bevacizumab.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there are no ongoing clinical trials or compassionate-use programmes for this medicine.