19 May 2017
EMA/310037/2017
EMEA/H/C/004388

Questions and answers

Refusal of the marketing authorisation for Human IgG1 monoclonal antibody specific for human interleukin-1 alpha XBiotech

On 18 May 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for Human IgG1 monoclonal antibody specific for human interleukin-1 alpha XBiotech, intended for treating debilitating symptoms of advanced colorectal cancer.

The company that applied for authorisation is XBiotech Germany GmbH. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

What is Human IgG1 monoclonal antibody specific for human interleukin-1 alpha XBiotech?

This is a medicine containing the active substance human IgG1 monoclonal antibody specific for human interleukin-1 alpha.

It was to be available as a concentrate to be made up into a solution for infusion.

What was the medicine expected to be used for?

The medicine was expected to be used for treating debilitating symptoms of advanced colorectal cancer (cancer of the large intestine). Such symptoms include cachexia, a form of muscle wasting with significant weight loss.

How does the medicine work?

The active substance is a protein that attaches to and blocks another protein called human interleukin-1 alpha, which is involved in many activities in the body including some that aid the growth and spread

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of cancer cells. By blocking the actions of human interleukin-1 alpha, the medicine is expected to slow down the growth of the cancer, thus relieving patients' symptoms.

What did the company present to support its application?

The company presented results of a main study in 333 patients looking at the effects of this medicine on lean body mass (body weight excluding fat) and quality of life. The medicine was compared with placebo (a dummy treatment).

What were the CHMP's main concerns that led to the refusal?

The CHMP had a number of concerns. First, the committee noted that the study did not show clear improvements in either lean body mass or quality of life. Secondly, there was an increased risk of infection in patients taking the medicine, which was not considered acceptable in vulnerable patients who will be receiving palliative care. Lastly, there were inadequate controls of the manufacturing process to ensure the medicine would have the same quality as the product used in clinical trials.

Therefore, the CHMP was of the opinion that the benefits of this medicine did not outweigh its risks and recommended that it be refused marketing authorisation.

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

The company informed the CHMP that it will continue to provide the medicine to all patients currently enrolled in clinical trials or compassionate use programmes.

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