EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers

Refusal of a change to the marketing authorisation for Avastin (bevacizumab)

On 22 May 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of a change to the marketing authorisation for the medicinal product Avastin. The change concerned an extension of indication to add treatment of glioblastoma (an aggressive type of brain cancer).

The company that applied for the change to the authorisation is Roche Registration Ltd. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

What is Avastin?

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

Avastin has been authorised in the EU since 12 January 2005. It is used, in combination with other chemotherapy medicines (medicines to treat cancer), to treat certain types of the following cancers: cancer of the colon or rectum (large intestine); breast cancer; lung cancer; kidney cancer; cancer of the ovary; cancer of the fallopian tube or the peritoneum (the membrane lining the abdomen).

What was Avastin expected to be used for?

Avastin was also expected to be used to treat adult patients with newly diagnosed glioblastoma in combination with radiotherapy (treatment with radiation) and temozolomide (another cancer medicine).

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How is Avastin expected to work?

In glioblastoma, Avastin is expected to work in the same way as it does in its existing indications. The active substance in 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, Avastin stops cancer cells from developing their own blood supply and starves them of oxygen and nutrients, helping to slow down the growth of the cancer.

What did the company present to support its application?

The company presented the results from one main study with Avastin involving 921 patients with newly diagnosed glioblastoma. In the study, patients received Avastin or placebo (a dummy treatment) in addition to treatment with radiotherapy and temozolomide. The main measures of effectiveness were overall survival (how long the patients lived) and progression-free survival (how long the patients lived without their disease getting worse).

What were the CHMP's main concerns that led to the refusal of the change to the marketing authorisation?

The CHMP noted that the effectiveness of Avastin in combination with radiotherapy and temozolomide had not been sufficiently demonstrated. Although there was an improvement in progression-free survival, it could not be considered clinically relevant because of limitations in the methods available to measure the size of brain tumours. In addition, there was no benefit in terms of overall survival. Therefore, at that point in time, the CHMP was of the opinion that the benefits of Avastin in the treatment of glioblastoma did not outweigh its risks. Hence, the CHMP recommended that the change to the marketing authorisation be refused.

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

The company informed the CHMP that there are no consequences for patients with glioblastoma receiving Avastin in clinical trials: patients will continue to receive Avastin in the on-going and future clinical trials.

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

What is happening with Avastin for treatment of other cancers?

There are no consequences on the use of Avastin in its authorised indications.

The full European Public Assessment Report for Avastin can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.