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EPAR summary for the public

Avastin

bevacizumab

This is a summary of the European public assessment report (EPAR) for Avastin. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Avastin.

For practical information about using Avastin, patients should read the package leaflet or contact their doctor or pharmacist.

What is Avastin and what is it used for?

Avastin is a cancer medicine used to treat adults with the following types of cancer, in combination with other cancer medicines:

- cancer of the colon (large intestine) or rectum that is metastatic (has spread to other parts of the body), in combination with chemotherapy medicines that include a 'fluoropyrimidine';
- metastatic breast cancer, in combination with paclitaxel or capecitabine;
- advanced non-small cell lung cancer in patients whose cancer cells are not mainly of the squamous type, where it is given with platinum-based chemotherapy;
- advanced non-small cell lung cancer in patients whose cancer cells have a certain change ('activating mutations') in the gene for a protein called EGFR, where it is given in combination with erlotinib;
- advanced or metastatic kidney cancer, in combination with interferon alfa-2a;
- epithelial cancer of the ovary, cancer of the fallopian tube (that connect the ovaries to the womb) or the peritoneum (the membrane lining the abdomen). Avastin is used in combination with certain chemotherapy medicines in newly diagnosed patients when the cancer is advanced, or in previously treated patients whose cancer has come back (recurrent).

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- cancer of the cervix (the neck of the womb) that is persistent, recurrent or metastatic. Avastin is given in combination with paclitaxel and either the platinum-based medicine cisplatin or, if this cannot be used, another chemotherapy medicine, topotecan.

Avastin contains the active substance bevacizumab.

How is Avastin used?

Avastin can only be obtained with a prescription and treatment should be supervised by a doctor who has experience in the use of cancer treatments.

Avastin is available as a concentrate that is made up into a solution for infusion (drip) into a vein. The first infusion of Avastin should last 90 minutes, but subsequent infusions may be given more quickly if the first infusion is tolerated well. The dose is between 5 and 15 mg per kilogram body weight every two or three weeks, depending on the type of cancer being treated. The treatment is continued until the patient no longer benefits from it. The doctor may decide to interrupt or stop treatment if the patient develops certain side effects.

How does Avastin work?

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 it 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 benefits of Avastin have been shown in studies?

Several studies have shown that Avastin is effective at treating the types of cancers for which it is approved. In all of the studies, the main measure of effectiveness was either overall survival (how long the patients lived) or progression-free survival (how long the patients lived without their disease getting worse).

Cancer of the colon or rectum

In metastatic cancer of the colon or rectum, Avastin used with chemotherapy including a fluoropyrimidine has been shown to increase overall and progression-free survival in three main studies. The first two studies involved patients whose metastatic disease was being treated for the first time (‘first-line’ treatment): in the first study (923 patients),the average overall survival was 20.3 months in patients adding Avastin and 15.6 months in those receiving chemotherapy alone; in the second study in 1,401 patients, progression-free survival was 9.4 months in patients adding Avastin and 8.0 months in those receiving chemotherapy alone. The third study involved 829 patients who had failed previous treatment including a fluoropyrimidine and irinotecan. Overall survival was 12.9 months in patients adding Avastin and 10.8 months in those receiving chemotherapy alone.

Breast cancer

In metastatic breast cancer, Avastin has been shown to increase progression-free survival in two main studies. In the first study (722 patients), progression-free survival was 11.4 months in patients receiving Avastin with paclitaxel, compared with 5.8 months in those receiving paclitaxel alone. In the second study (1,237 patients), when Avastin was added to capecitabine, the average progression-free survival was 8.6 months, compared with 5.7 months in those receiving capecitabine with placebo.

Non-small cell lung cancer

- In advanced, metastatic or recurrent lung cancer, Avastin plus platinum-based chemotherapy has been shown to increase overall survival in one study in 878 patients: the average overall survival was 12.3 months in the patients taking Avastin with platinum-based chemotherapy, and 10.3 months for those taking chemotherapy alone.
- In patients with a certain subtype of non-small cell lung cancer with activating mutations in the EGFR gene, Avastin plus erlotinib has been shown to increase progression-free survival in one study in 152 patients: patients on Avastin plus erlotinib had progression-free survival of 16.0 months on average compared with 9.7 months in patients given erlotinib alone.

Kidney cancer

In advanced or metastatic kidney cancer, Avastin plus interferon alfa-2a has been shown to increase progression-free survival in one study in 649 patients: the average progression-free survival was 10.2 months in the patients receiving Avastin plus interferon alfa-2a and 5.4 months in those receiving interferon alfa-2a.

Ovarian, fallopian tube and peritoneal cancer

- Newly diagnosed disease (including advanced disease, first-line treatment): in newly diagnosed ovarian, fallopian tube and peritoneal cancer, Avastin, in combination with carboplatin and paclitaxel, has been shown to increase progression-free survival in two main studies involving 3,401 patients: the average progression-free survival was 19.3 months in patients adding Avastin versus 16.9 months with carboplatin and paclitaxel alone in one study, and 14.7 months versus 10.6 months in the second study.
- Recurrent disease: three studies with Avastin in recurrent ovarian, fallopian tube and peritoneal cancers were performed in a total of 1,518 patients. The first two studies included patients whose cancer came back 6 months or more after previous treatment (‘platinum-sensitive disease’), while the third study was in patients with more aggressive cancer that had come back within 6 months of previous treatment (‘platinum-resistant disease’). In the first study, average progression-free survival was 12.4 months when Avastin was added to carboplatin and gemcitabine, compared with 8.4 months when placebo was added. In the second study, overall survival in patients given Avastin in combination with carboplatin and paclitaxel was 42.6 months, compared with 37.3 months in patients treated with carboplatin and paclitaxel only. In the third study in patients with more aggressive cancer, progression-free survival was 6.7 months when Avastin was added to paclitaxel, topotecan, or pegylated liposomal doxorubicin, compared with 3.4 months when these chemotherapies were used on their own.

Cervical cancer

In cancer of the cervix, Avastin has been shown to increase overall survival in one main study involving 452 patients with advanced persistent, recurrent or metastatic cancer of the cervix. The study compared the effect of adding Avastin to chemotherapy using paclitaxel plus cisplatin or topotecan to results in patients given chemotherapy alone.

Results showed that the average overall survival was 16.8 months with chemotherapy including Avastin compared with 12.9 months on chemotherapy alone. When the type of chemotherapy was taken into account, there was a tendency for patients given cisplatin-based treatment to live on average about 2 months longer than those given topotecan-based treatment, independently of giving Avastin as part of the treatment regimens.

What is the risk associated with Avastin?

The most common side effects with Avastin are hypertension (high blood pressure), tiredness or asthenia (weakness), diarrhoea and abdominal (belly) pain. The most serious side effects are gastrointestinal perforation (hole in the gut wall), haemorrhage (bleeding) and arterial thromboembolism (blood clots in the arteries). For the full list of all side effects reported with Avastin, see the package leaflet.

Avastin must not be used in people who are hypersensitive (allergic) to bevacizumab or any of the other ingredients, to Chinese hamster ovary cell products or other recombinant antibodies. It must not be given to pregnant women.

Why has Avastin been approved?

The CHMP decided that Avastin's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Avastin?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Avastin have been included in the summary of product characteristics and the package leaflet.

Other information about Avastin

The European Commission granted a marketing authorisation valid throughout the European Union for Avastin on 12 January 2005.

The full EPAR for Avastin can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Avastin, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2017.