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Press Office

Press release

European Medicines Agency completes its review of Avastin used in breast cancer treatment

Avastin in combination with paclitaxel remains a treatment option for women with breast cancer, but not with other combinations

The European Medicines Agency has confirmed that the benefits of Avastin in combination with paclitaxel outweigh its risks and that this combination remains a valuable treatment option for patients suffering from metastatic breast cancer.

The Agency's Committee for Medicinal Products for Human Use (CHMP) also concluded that the balance of benefits and risks of Avastin in combination with docetaxel is negative and that this combination should no longer be used in the treatment of breast cancer. Patients who are currently being treated with this combination should discuss their ongoing treatment with their doctor.

Avastin is an anticancer medicine which contains the active substance bevacizumab. It is used in combination with other anticancer treatments to treat cancers of the colon, rectum, lung, kidney or breast. The CHMP's review was restricted to the use of Avastin in breast cancer and does not affect its use in the other indications.

The CHMP started a review of the use of Avastin in the treatment of metastatic breast cancer because new data from a study suggested that Avastin in combination with docetaxel may have a negative impact on the overall survival (how long patients lived after treatment was initiated). The study was submitted to the Agency to support an application to extend Avastin's breast cancer indication to include combination therapy with capecitabine.

Combination therapy of Avastin and docetaxel for metastatic breast cancer was approved in September 2009 on the basis of data that showed a small but significant increase in progression-free survival (how long the patients lived without their disease getting worse), and no detrimental effect on overall survival.

The new data submitted to the Agency add uncertainty about the effect on overall survival and a detrimental effect on overall survival cannot be excluded. The new data also question the size of the effect on progression-free survival, which appears to be smaller than previously observed. Because the

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increase of progression-free survival remains very small, the CHMP concluded that the benefits of Avastin in combination with docetaxel no longer outweigh its risks.

For Avastin in combination with capecitabine, the Committee found that although the data showed a modest increase in progression-free survival, no clinically relevant effects were observed on other endpoints such as overall survival or health-related quality of life. The relatively modest benefits were considered not to outweigh the high toxicity of the combination of Avastin and capecitabine, given that the new indication was aimed at patients for whom a relatively mild treatment would be appropriate. Therefore the Committee concluded that the new indication should not be approved.

For Avastin in combination with paclitaxel, the Committee concluded that the benefits continue to outweigh the risks, because the available data have convincingly shown to prolong progression-free survival of breast cancer patients without a negative effect on the overall survival.

The Committee therefore recommended that for the treatment of breast cancer Avastin should only be used in combination with paclitaxel.

The Committee's recommendations have been sent to the European Commission for the adoption of a decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The review of Avastin was carried out under Article 20 of Regulation (EC) 726/2004.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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