European Medicines Agency
Evaluation of Medicines for Human Use

London, 25 June 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
AVASTIN

International Nonproprietary Name (INN): ***bevacizumab***

On 25 June 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[**] to recommend the variation to the terms of the marketing authorisation for the medicinal product Avastin. The Marketing Authorisation Holder for this medicinal product is Roche Registration Ltd.

The CHMP adopted a change to an indication as follows:

"Avastin in combination with paclitaxel or docetaxel is indicated for first-line treatment of patients with metastatic breast cancer. For further information as to HER2 status, please refer to section 5.1".

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indication for Avastin will be as follows[***]:

Avastin (bevacizumab) in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum.

Avastin in combination with paclitaxel **or docetaxel** is indicated for first-line treatment of patients with metastatic breast cancer. **For further information as to HER2 status, please refer to section 5.1.**

Avastin, in addition to platinum-based chemotherapy, is indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology.

Avastin in combination with interferon alfa-2a is indicated for first line treatment of patients with advanced and/or metastatic renal cell cancer.

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[*] Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

[**] Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

[***] The text in bold represents the new or the amended indication.

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