

Avastin label updated reflecting confidence in safety profile

Contraindication for patients with untreated brain metastases removed

Basel, 31st March 2009: The European Medicines Agency (EMA) has removed a restriction in the product label which prevented the use of Avastin[®] (bevacizumab) in some patients whose primary cancer has spread to their brain (brain metastases). The label change is based on safety data which show that the risk of bleeding in patients with untreated brain metastases is similar for patients who receive Avastin and those who do not. The updated label supports Avastin's well established safety profile across various tumour types.

Brain metastases can bleed and potentially cause severe problems for patients, regardless of any treatment given. These metastases develop when cancer cells break away from primary tumours in other organs in the body and travel through the bloodstream to the brain. This occurs most often with lung cancer but can also occur in breast, skin (malignant melanoma), kidney, and colon cancers.

Avastin is approved for the treatment of the advanced stages of four of the most common cancers: colorectal cancer, breast cancer, lung cancer and renal cell cancer and has already helped more than 500,000 patients with cancer worldwide.

Commenting on the updated label, Professor Jean-Charles Soria from Institut Gustave Roussy, Villejuif, France, said: "The fact that the change to the label is based on a comprehensive safety database gives added confidence in use of this major cancer treatment for patients with many different types of cancer."

The EMA made their decision following review of a number of analyses from clinical trials, as well as a safety database generated through use of Avastin for more than a decade. Data were reviewed from randomised, controlled and open label clinical studies and the company's safety database. This includes data from the USA where Avastin has never been contraindicated for use in patients with brain metastases.

About Avastin

Avastin is an innovative medicine that limits the growth of blood vessels feeding cancerous tissues with oxygen and nutrients. It works by blocking angiogenesis; an important and unique therapeutic target common to most cancers and which is crucial to cancer growth. There are more than 450 clinical trials

underway to investigate the use of Avastin in over 30 tumour types.

About Roche

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