

# Media Release



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## Roche files marketing application for Avastin with European health authorities

Roche today announced the submission of a Marketing Authorisation application to the European Union for Avastin (bevacizumab, rhuMAb-VEGF) as a treatment for first-line metastatic colorectal cancer in combination with chemotherapy. The application is based on data from a pivotal clinical study of over 900 patients on Avastin who experienced improved survival benefit compared to chemotherapy treatment alone. A safety database of more than 1,000 patients who received Avastin in clinical trials is also supporting the submission.

In 2000, colorectal cancer was the third most commonly reported cancer with 945,000 new cases worldwide. It is estimated that over 50% of people diagnosed with colorectal cancer will die, and it is the most common cancer in developed countries<sup>1</sup>.

"We are delighted to announce the submission for marketing authorisation of Avastin in the European Union," said William M. Burns, Head of Roche Pharmaceuticals Division. "Roche is dedicated to the development of safe and efficacious treatments for many types of cancers, and we will work closely with regulatory authorities to bring Avastin to patients as quickly as possible, particularly as this is the first treatment of its kind."

An application for approval of Avastin in metastatic colorectal cancer was filed with the US FDA in September and has been designated for priority review status.

Results of the pivotal study of Avastin in advanced colorectal cancer were announced earlier this year and demonstrated that Avastin plus a form of chemotherapy, the IFL regime, (5-FU/Leucovorin/CPT-11) improved median survival by approximately five months, compared to patients treated with IFL regime alone (20.3 months vs. 15.6 months).

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Avastin is the first anti-cancer agent with proven efficacy in inhibiting vascular endothelial growth factor (VEGF), which suppresses tumour growth and the spread of cancer from one part of the body to another (metastasis). As this mechanism of action could prove relevant in a number of solid tumours we are presently investigating Avastin in other forms of metastatic cancer, including non-small cell lung cancer, pancreatic and renal cell carcinoma.

### Roche in Oncology

Within the last five years Roche has become the world's leading provider of anti-cancer treatments, supportive care products and diagnostics. Its oncology business includes an unprecedented three marketed products with survival benefit; Herceptin, MabThera and Xeloda, treating a range of malignancies - breast cancer, non-Hodgkin's lymphoma and colorectal cancer. Other key products include NeoRecormon (anaemia in various cancer settings), Bondronat (prevention of skeletal events in breast cancer and bone metastases patients, hypercalcemia of malignancy), Kytril (chemotherapy and radiotherapy-induced nausea and vomiting) and Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma). Roche's cancer medicines generated sales of 4.5 billion Swiss francs in the first nine months of 2003.

Roche's products in development also promise survival benefit with Avastin. In a pivotal Phase III study Avastin increased survival duration by 30% when combined with first-line chemotherapy for patients with advanced colorectal cancer.

Roche is developing new tests which will have a significant impact on disease management for cancer patients in the future. With a broad portfolio of tumour markers for prostate, colorectal, liver, ovarian, breast, stomach, pancreas and lung cancer, as well as a range of molecular oncology tests, we will continue to be the leaders in providing cancer focused treatments and diagnostics. Roche Oncology has four research sites (two in the US, Germany and Japan) and four Headquarter Development sites (two in the US, UK and Switzerland).

### About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche employs roughly 65,000 people in 150 countries. The Group has alliances and R&D agreements with numerous partners, including majority ownership interests in

Genentech and Chugai.

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**Reference:**

1. World Health Organisation. Globocan 2000: Cancer Incidence, Mortality and Prevalence Worldwide. 2000