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## **Avastin achieves impressive rate of curative surgery in patients with advanced colorectal cancer**

*Largest series of patients with successful surgery reported in large, prospective clinical trial*

**BARCELONA, SPAIN -- 24 September 2007** – New data from the large international *First BEAT* trial unveiled today at the European Cancer Conference (ECCO) demonstrate that a high number of patients treated with Avastin plus standard chemotherapy for their colorectal cancer underwent complete surgical removal of their metastatic lesions. Complete removal of metastatic lesions was achieved in almost 80% of these patients, all of whom had been considered inoperable prior to the start of treatment. This outcome with Avastin is higher than has been previously seen in trials with other biologics/chemotherapy combinations.

The *First BEAT* trial included 1,965 patients with advanced colorectal cancer with primarily inoperable metastatic disease. Patients received Avastin in combination with the commonly used fluoropyrimidine based chemotherapy regimens\* as first line treatment and were assessed for their suitability for potentially curative surgery during the course of the treatment.

“The complete resection of metastatic lesions is the only option for cure in patients with metastatic colorectal cancer. Therefore these results represent a major step forward for the patient,” said Dr Mondher Mahjoubi, Global Head Medical Affairs Oncology, Roche. “The high rates of successful, curative surgery achieved with Avastin plus standard chemotherapy are impressive, especially because First BEAT is a trial looking at a general, real life patient population”.

First BEAT results presented at ECCO demonstrated that 215 (11.5%) of all patients included in the current data analysis (1,914) became eligible for and underwent surgery with curative intent during the course of treatment. Successful, complete removal of the metastatic lesions (R0 resection) was achieved in 170 patients, an impressive success rate of 79%. The best outcomes as expected were achieved in the subgroup of patients with metastatic disease confined to the liver only (n=704). In this subgroup, 102

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\* The chemotherapy regimens selected were at the treating physician's discretion. The most commonly used were FOLFOX, XELOX, FOLFIRI and Xeloda (capecitabine) which is a reflection of current clinical practice.

(14.5%) patients underwent surgical removal of their liver metastases in curative intent with successful complete (R0) resection achieved in 81 patients.

No increase in wound-healing complications or bleeding incidents was observed compared with historical controls underlining the favourable safety profile of Avastin in this setting.

Colorectal cancer is the third most common cancer with approximately one million new cases worldwide every year. It is estimated that over 50% of people diagnosed with colorectal cancer will die of the disease<sup>1</sup>.

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### **About First BEAT**

First BEAT is an international phase IV trial which has enrolled 1965, community based patients from 41 countries worldwide. Patients diagnosed with unresectable metastatic disease received Avastin in combination with standard first line chemotherapy; the most common regimens were FOLFOX, XELOX, FOLFIRI and Xeloda (capecitabine). The dose of Avastin used was equivalent to 2.5 mg/kg/week (5 mg/kg every 2 weeks with 5-FU-based regimens and 7.5 mg/kg every 3 weeks with capecitabine-based regimens).

First BEAT completed recruitment in February 2006. The primary endpoint was safety,. General efficacy and surgery with curative intent were preplanned secondary endpoints and data were collected in a prospective fashion. Efficacy data from the BEAT trial are continuing to be evaluated with further data presentations expected at upcoming oncology conferences.

### **About Colorectal Cancer**

Colorectal cancer, also known as bowel cancer, can occur anywhere in the colon or rectum. Cancer develops when the normal process of renewal among the cells lining the bowel is interrupted. A tumour may form which, if detected at an early stage, can be removed. However, there are often no initial symptoms and the cancer may have spread to other parts of the body before it is detected.

It is estimated that over half the people diagnosed with colorectal cancer will die of the disease<sup>1</sup>. Nearly 945,000 new cases are diagnosed worldwide each year and the disease accounts for 492,000 deaths<sup>2</sup>. Colorectal cancer is the second most common cause of death from cancer across all cancer types in men and women in Europe<sup>3</sup>.

Treatment options are limited and vary in accordance with the stage of the cancer – its size, position and whether it has spread. Surgery is the main treatment option and may be used in combination with

radiotherapy and chemotherapy. Chemotherapy is often given after surgery to try and reduce the chances of the cancer reoccurring. It is also given when the cancer is advanced and has spread to other parts of the body. In spite of these options the five-year survival rate following detection and treatment of colorectal cancer remains at only 50%<sup>1</sup>.

### **About Avastin**

Avastin is the first treatment that inhibits angiogenesis – the growth of a network of blood vessels that supply nutrients and oxygen to cancerous tissues. Avastin targets a naturally occurring protein called VEGF (Vascular Endothelial Growth Factor), a key mediator of angiogenesis, thus choking off the blood supply that is essential for the growth of the tumour and its spread throughout the body (metastasis).

Avastin has now demonstrated a progression-free and/or overall survival benefit for patients in four cancer types, namely: colorectal, breast, lung and renal cell cancer.

Roche and Genentech are pursuing a comprehensive clinical programme investigating the use of Avastin in various tumour types (including colorectal, breast, lung, pancreatic cancer, ovarian cancer, renal cell carcinoma and others) and different settings (advanced and adjuvant i.e. post-operation). The total development programme is expected to include over 40,000 patients worldwide.

### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolic disorders and diseases of the central nervous system. In 2006 sales by the Pharmaceuticals Division totalled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invests approximately 7 billion Swiss francs a year in R&D. Worldwide, the Group employs about 75,000 people. Additional information is available on the Internet at [www.roche.com](http://www.roche.com).

### **Additional information**

- Roche in Oncology: [www.roche.com/pages/downloads/company/pdf/mboncology05e\\_b.pdf](http://www.roche.com/pages/downloads/company/pdf/mboncology05e_b.pdf)
- Roche Health Kiosk, Cancer: [www.health-kiosk.ch/start\\_krebs](http://www.health-kiosk.ch/start_krebs)

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3. Ferlay J, et al. Estimates of the cancer incidence and mortality in Europe in 2006. *Annals of Oncology*. 2007; 18: 581-92