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Avastin shows impressive results for surgery with curative intent in initially unresectable first-line metastatic colorectal cancer patients

Large clinical trials investigating the use of Avastin in combination with various chemotherapy regimens in 1st line metastatic colorectal cancer reported impressive results for surgery with curative intent in patients whose metastatic lesions were assessed inoperable upon diagnosis. The data presented at the 9th World Congress on Gastrointestinal Cancer (WCGC) in Barcelona clearly demonstrate that secondary resection of metastatic disease with curative intent can be successfully achieved in a safe, well tolerated and efficacious manner with Avastin as the backbone treatment.

In the large, prospective international phase IV trial BEAT, which enrolled more than 1900 patients with inoperable metastatic colorectal cancer, impressive rates of surgery with curative intent were shown:

- Overall, 180 surgeries with curative intent (9.4%) were performed. This number compares favourably with historical data and is even more impressive as the patients included in the trial did not belong to a selected subgroup (e.g. EGFR +). The BEAT study population was unselected and reflected a standard global patient pool.
- Of interest is the number of surgeries with curative intent in the group of patients that were treated with Avastin in combination with the most widely used regimens FOLFOX and FOLFIRI:
 - In a group of 547 and 504 patients, respectively, the achieved percentage of surgeries with curative intent reached 15.4 % for Avastin + FOLFOX and 7.4% for Avastin + FOLFIRI.
 - In the subgroup of patients with metastatic lesions exclusively located in the liver the percentage increased to 26.6% for Avastin with FOLFOX and 14.2% for Avastin with FOLFIRI.

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JUL 10 2007

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In the large, international, phase III trial NO16966, which enrolled 1400 patients in the placebo-controlled part of the study, the total number of surgeries with curative intent reached 8.4% in the group treated with Avastin + oxaliplatin-based chemotherapy. The reported data for those patients with liver metastasis only (around 25% of the total study population) were even more promising. The study showed that 19.2% of patients receiving Avastin in this subgroup underwent liver surgery with curative intent compared to 12.9% in the control group.

In both trials the number of observed bleeding or wound-healing incidents following surgery did not increase, thereby demonstrating again the excellent tolerability and safety of Avastin. The safety and effectiveness of Avastin use in colorectal cancer patients with potentially resectable metastatic disease was demonstrated previously in a phase II trial (B. Gruenberger et al., abstract 4060, ASCO 2007).

All data were collected prospectively and surgery with curative intent was a preplanned assessment parameter in BEAT and NO16966.

These data provide further strong clinical evidence that Avastin is the biological agent of reference that leads not only to a significant and clinically meaningful progression-free and overall survival benefit but also to potentially curative resectability in patients with metastatic colorectal cancer.

Background on secondary resection of metastatic lesions

The concept of secondary resection of metastatic lesions is currently getting attention in a disease setting formerly seen as strictly palliative. While a small percentage of patients achieve secondary resection of metastatic lesions, the potential for cure remains limited and requires further investigation. Even though recurrence rates in resected patients are very high (80% of patients relapse within the first two years after surgery), this approach offers an increase of time without disease recurrence.

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