

Basel, 22 April 2009

Phase III C-08 study of Avastin in early-stage colon cancer does not meet primary endpoint

Roche and Genentech remain committed to Avastin adjuvant programs

Roche today announced the results of the first phase III trial evaluating the use of Avastin (bevacizumab) plus chemotherapy (FOLFOX) for the treatment of colon cancer immediately following surgery (adjuvant therapy) compared to chemotherapy alone. The study, known as NSABP C-08, did not meet its primary endpoint of lowering the risk of the cancer returning (disease-free survival). This is the first trial of Avastin in early-stage cancer and results do not affect approved indications in advanced (metastatic) disease.

Safety findings were consistent with those presented from this study at the 2008 American Society of Clinical Oncology (ASCO) annual meeting (Allegra et al.)

“While we are disappointed the C-08 study did not meet its primary endpoint, our initial review of the data leads us to continue to believe Avastin may be active in patients with early-stage colon cancer and look forward to NSABP's presentation at ASCO,” said Hal Barron, M.D., senior vice president, Development and chief medical officer, Genentech. “We remain fully committed to the ongoing Avastin adjuvant programs in early-stage colon, breast and lung cancers.”

"In order to provide patients with the full potential benefit of Avastin in early-stage cancer, we believe the findings of the C-08 trial should be considered for the ongoing adjuvant trial programs," said William M. Burns, CEO of Roche's Pharmaceuticals Division. "The current studies and indications in advanced disease are not affected."

Data from the trial have been submitted for presentation at the upcoming ASCO annual meeting, May 29 – June 2, 2009.

About the NSABP C-08 Trial

This trial was initiated based on the improvement in overall survival observed in metastatic colorectal cancer patients treated with Avastin plus chemotherapy and positive results from two other adjuvant colon cancer studies (MOSAIC and NSABP C-07) with an oxaliplatin containing regimen.

C-08, a phase III randomised, multi-centre study designed to measure disease-free survival as primary endpoint in patients with resected stage II or III adenocarcinoma of the colon, is conducted by the NSABP and sponsored by the National Cancer Institute (NCI). Patients enrolled in the study were randomised to receive treatment with adjuvant Avastin [5 mg/kg intravenous every two weeks for six months] in combination with mFOLFOX6 (5-fluorouracil, leucovorin and oxaliplatin) chemotherapy, followed by Avastin alone every two weeks for an additional six months, or chemotherapy alone for six months. Overall survival is the secondary endpoint of the study.

About the Avastin Development Program

Results are expected in 2010 from a separate Roche-sponsored international Phase III study (AVANT) assessing Avastin in combination with chemotherapy for early-stage colon cancer. The three-arm trial is evaluating Avastin in combination with the chemotherapy regimens XELOX (capecitabine and oxaliplatin) or FOLFOX chemotherapy versus FOLFOX alone.

In addition to early-stage colon cancer, Avastin is being studied as an adjuvant treatment in other early-stage diseases: HER2-negative breast cancer, HER2-positive breast cancer and non-squamous, non-small cell lung cancer. Approximately 26,000 people are expected to participate in Avastin adjuvant studies.

The Avastin development program represents one of the most comprehensive undertakings in cancer research since chemotherapy and includes more than 450 clinical trials worldwide in approximately 30 different tumour types.

Avastin in Metastatic Colorectal Cancer

Avastin in combination with IV 5-FU-based chemotherapy was proven to extend overall survival by 52 percent compared to chemotherapy alone in people with advanced colorectal cancer. This is one of the largest improvements in survival ever reported in a randomized Phase III advanced colorectal cancer study (hazard ratio 0.66). In a Phase III study in second-line advanced colon cancer, Avastin in combination with FOLFOX4 chemotherapy improved overall survival by 33 percent compared to chemotherapy alone (hazard ratio 0.75).

About Avastin

Avastin is a biologic antibody designed to specifically inhibit the vascular endothelial growth factor (VEGF) protein that plays an important role in the development and maintenance of blood vessels, a process known as angiogenesis. VEGF is a potent activator of angiogenesis throughout the lifecycle of a tumor and is thought to be critical to a tumor's ability to grow and spread in the body (metastasize). Avastin is approved in EU for the treatment of the advanced stages of four common cancer types: colorectal cancer, breast cancer, lung cancer and kidney cancer. More than 500,000 patients have been treated with Avastin so far.

About Roche

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