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Full results from first Phase III study of Avastin in adjuvant colon cancer announced Results suggest future trials may hold promise for Avastin as early-stage colon cancer treatment even though C-08 study does not meet primary endpoint

Full results from the first phase III trial of Avastin (bevacizumab) in early-stage colon cancer, known as NSABP C-08, were announced today. The study evaluated the use of Avastin plus chemotherapy (FOLFOX) for the treatment of colon cancer immediately following surgery (adjuvant therapy) compared to chemotherapy alone. The study showed the addition of one year of Avastin to chemotherapy did not result in a statistically significant improvement in overall disease-free survival (DFS). However, during the year of Avastin treatment there was an early and significant improvement in disease-free survival that diminished over the course of the study. These data were featured at a press briefing during the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO) and will be presented on Sunday (May 31).

“During the year that patients received Avastin treatment there was a 40 percent lower risk of cancer returning; however, this initial improvement over chemotherapy alone gradually diminished over time,” said Norman Wolmark, M.D., Chairman, NSABP (National Surgical Adjuvant Breast and Bowel Project). “These results suggest longer durations of Avastin treatment should be considered for future studies in early-stage colon cancer to further reduce the risk of the cancer coming back.”

No new safety signals for Avastin were observed in the study and careful review of the data did not provide evidence that cancer returns faster or more aggressively after Avastin therapy was stopped.

“These results are encouraging and suggest that Avastin may have an important role in early cancer treatment. We are committed to the ongoing programme of Avastin in early-stage cancers and believe that these results could help us optimise the use of Avastin for the benefit of patients,” said William M. Burns, CEO of Roche’s Pharmaceutical Division.

Avastin based therapy is the standard of care in advanced colon cancer treatment which will be further confirmed throughout ASCO with 53 efficacy and safety data presentations including more than 6,000 patients.

NSABP C-08 Study Results

Overall in the study, there was 12 percent improvement in DFS that was not statistically significant (hazard ratio=0.89, p=0.15; risk reduction 11 percent). In the first year of the study, while patients received Avastin in addition to a standard six-months of adjuvant chemotherapy, disease-free survival improved by 67 percent compared to chemotherapy alone (hazard ratio=0.60; risk reduction of 40 percent). However, this early improvement in DFS began to diminish after the first year, and overall DFS was not improved.

Efficacy Results	Treatment Phase	Observational Phase				Overall Results
		1 Year	1.5 Years	2 Years	2.5 Years	
Disease-Free Survival (DFS)						
Risk Reduction (%)	40	26	19	15	13	11
Percent Improvement (%)	67	35	23	18	15	12
Hazard Ratio	0.60	0.74	0.81	0.85	0.87	0.89
p-value	0.0004	0.004	0.02	0.05	0.08	0.15

NSABP C-08 included a comprehensive safety analysis that showed no new or unexpected safety events related to Avastin in the study. Specific severe (Grade 3 or greater) adverse events (AEs) that occurred with increased frequency in patients who received Avastin versus chemotherapy alone were: hypertension (12 percent vs. 1.8 percent), pain (11.1 percent vs. 6.3 percent), proteinuria (2.7 percent vs. 0.8 percent) and wound-healing complications (1.7 percent vs. 0.3 percent).

About the NSABP C-08 Trial

The C-08 study was conducted by the NSABP and sponsored by the National Cancer Institute (NCI) under a Cooperative Research and Development Agreement between Genentech and NCI. NSABP C-08 was a randomised multi-center Phase III study designed to evaluate the effect of FOLFOX (5-fluorouracil, leucovorin and oxaliplatin) chemotherapy with or without Avastin on DFS in patients with surgically-resected Stage II or III adenocarcinoma of the colon. DFS was measured from the date of randomization to the date of any type of cancer recurrence or death from any cause. Patients enrolled in the study were randomized after surgery to receive either FOLFOX chemotherapy alone for six months or FOLFOX in combination with Avastin (intravenously every two weeks) for six months, followed by an additional six months of Avastin monotherapy. Patients continue to be followed for overall survival, a secondary endpoint

of the study.

About the Avastin Development Programme

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.

About Avastin

Avastin is an antibody that specifically binds and blocks VEGF (vascular endothelial growth factor). VEGF is the key driver of tumour angiogenesis – an essential process of development and maintenance of blood vessels which is required for a tumour to grow and to spread (metastasize) to other parts of the body. Avastin's precise mode of action helps control tumour growth and metastases with only a limited impact on side effects of chemotherapy.

Avastin has proven survival benefits across multiple tumour types. Avastin is approved in Europe for the treatment of the advanced stages of four common types of cancer: colorectal cancer, breast cancer, lung cancer and kidney cancer. These types of cancer collectively cause nearly 3 million deaths each year. In the US, Avastin was the first anti-angiogenesis therapy approved by the FDA and is now approved for the treatment of four tumour types: breast, colorectal, glioblastoma, and non-small cell lung cancer (NSCLC).

More than 500,000 patients have been treated with Avastin so far. A comprehensive clinical programme with more than 450 clinical trials is investigating the use of Avastin in various tumour types (including colorectal, breast, lung, brain, gastric, ovarian, prostate and others) and different settings (advanced or early stage disease).

About Roche

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