

# Large International Phase III Trial in Metastatic Colorectal Cancer Meets Primary Endpoints for Xelox (Xeloda + Oxaliplatin) and for Avastin

## Results Further Support Replacing IV Chemotherapy with Oral Xeloda for Colorectal Cancer

JULY 31, 2006—NUTLEY N.J. Roche announced today that a large, international Phase III study (N016966) enrolling 2,035 previously untreated metastatic colorectal cancer patients met both primary endpoints. Results of the study showed that:

- > The chemotherapy combination Xeloda plus oxaliplatin, called XELOX, is as effective in terms of progression-free survival (PFS) – a measure of the time patients live without their disease progressing – as infused 5-FU/LV (5-fluorouracil/leucovorin) plus oxaliplatin, called FOLFOX;
- > The addition of Avastin to chemotherapy (FOLFOX and XELOX) significantly improved progression-free survival compared to chemotherapy alone.

Some variability in subgroup analyses for efficacy was observed. No new safety signals related to Avastin were observed in the trial.

“This is the first time we have significant data showing that oral Xeloda in combination with oxaliplatin is as effective as FOLFOX,” said Lars E. Birgerson, Vice President, Medical Affairs, Roche. “This study demonstrates that oral Xeloda plus oxaliplatin (XELOX) provides a new treatment option for colorectal patients. These data again show the benefits of adding Avastin to chemotherapy. In this trial, Avastin combined with XELOX and FOLFOX improved the chance of delaying progression of the disease by 20% in patients with advanced colorectal cancer. Furthermore, the results of this study underscore the tremendous potential of combinations using cornerstone therapies such as Xeloda.”



Results from the study will be submitted for presentation at a future international medical meeting.

In 2004, colorectal cancer was one of the leading cancers and accounted for 13 percent of all cancers; it is estimated that more than 394,000 people die worldwide from colorectal cancer each year. Colorectal cancer is the third most common cancer in the United States. The American Cancer Society estimates that in 2006, more than 148,000 people in the U.S. will be diagnosed and about 55,000 people will die from the disease.

### About the Study

The N016966 trial is a large, international phase III trial which randomized 2,035 patients and compared as first line colorectal cancer treatment initially:

- > XELOX (Xeloda plus oxaliplatin) vs

FOLFOX (intravenous bolus and infusional 5-FU/LV plus oxaliplatin) After release of the pivotal Avastin data in colorectal cancer in 2003, the protocol was amended to investigate in a 2 by 2 factorial design:

- > XELOX + placebo vs XELOX + Avastin (7.5 mg/kg q3w) vs FOLFOX + placebo vs FOLFOX + Avastin (5.0 mg/kg q2w).

The primary objectives were to answer two questions: first, whether the XELOX regimen is non-inferior to FOLFOX and, second, whether the addition of Avastin to chemotherapy is superior to chemotherapy alone. The secondary endpoints included overall survival, overall response rates, and safety profile.

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