

Xeloda Combination Meets Primary Endpoint in International Phase III Advanced Colorectal Cancer Study

XELOX (Xeloda plus oxaliplatin) Delays Disease Progression in Patients with Recurring Cancer



NUTLEY, DECEMBER 11, 2006 — Roche announced today that a large,

international Phase III study (N016967) of 627 previously treated patients with advanced colorectal cancer met its primary endpoint of progression-free survival. Study results showed that the chemotherapy combination XELOX (oral Xeloda plus oxaliplatin) is as effective in delaying disease progression as the chemotherapy combination FOLFOX-4 (infused 5-FU/leucovorin plus oxaliplatin).

"Our data complement the findings of the N016966 study, suggesting that XELOX is a very reasonable treatment option for patients with recurrent colorectal cancer," said Mace Rothenberg, MD, lead investigator and Professor of Medicine at Vanderbilt University Medical Center and Ingram Professor of Cancer Research at Vanderbilt-Ingram Cancer Center. "By demonstrating that Xeloda in combination with oxaliplatin was as effective as FOLFOX-4, these two studies provide the strongest evidence yet that Xeloda may be used in place of IV 5-FU in the treatment of patients with advanced colorectal cancer."

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.

"Roche is committed to advancing treatment for patients with colorectal cancer," said Lars E. Birgerson, Vice President, Medical Affairs, Roche. "Based on the data from the N016966 and N016967 studies, we are pleased to report that our filings with worldwide regulatory authorities will continue as planned."

Results from the N016967 study will be submitted for presentation at future major medical meetings.

About the Study

The N016967 trial is a large, international phase III trial that randomized 627 patients who had previously received chemotherapy and whose disease had returned or continued to progress. The trial compared XELOX (oral Xeloda plus oxaliplatin) vs. FOLFOX-4 (intravenous bolus and infusional 5-fluorouracil/leucovorin plus oxaliplatin) as first line colorectal treatment. The primary objective was to determine whether the XELOX regimen was as effective as FOLFOX-4 in terms of progression-free survival (a measure of time to disease progression or death). The secondary outcomes included overall survival, overall response rates and safety profile. There were no unexpected safety findings in the study.

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