

# Media Release



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## Oral chemotherapy Xeloda shown to be effective in stomach cancer

New treatment option for patients with this debilitating disease

Roche today announced that the first-ever phase III study investigating Xeloda (capecitabine) in the first-line treatment in advanced gastric (stomach) cancer successfully met its primary endpoint. The data show that Xeloda, added to another chemotherapy called cisplatin, is at least as effective as the current standard treatment (intravenous 5-fluorouracil plus cisplatin) in terms of time to disease progression. Full results from the study have been submitted to the American Society of Clinical Oncology (ASCO) for presentation at their Annual Meeting taking place from 2nd-6th June 2006, in Atlanta, GA, USA.

"These new data are encouraging. For many patients the prognosis has been poor, despite recent advances in managing this common, yet often fatal, disease." said Ed Holdener, Head of Global Development at Roche. "Compared to the current standard, where patients spend five days every three weeks in hospital receiving treatment, Xeloda has the additional benefit of reducing that amount of time to only one day, which helps patients to live as normal life as possible."

Gastric cancer is the fourth most commonly diagnosed cancer and the second leading cause of cancer-related deaths worldwide.<sup>1</sup> In Europe alone, nearly 140,000 people die from gastric cancer each year.<sup>2</sup> Gastric cancer affects twice as many men as women and occurs more frequently in people aged over 55 years.<sup>3</sup>

Based on the results of this study, Roche plans to file for an indication in advanced gastric cancer with worldwide regulatory authorities.

### About the study

This international study is a randomised, open-label study of the effect of first-line chemotherapy

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with Xeloda plus cisplatin versus intravenous 5-fluorouracil plus cisplatin on time to disease progression in patients with advanced or metastatic gastric cancer. The secondary endpoints included overall response rate, overall survival, duration of response, time to response and the safety results between the treatment arms.

#### About Xeloda

Xeloda is licensed in more than 90 countries worldwide including the EU, USA, Japan, Australia and Canada and has been shown to be effective, safe, simple and convenient oral chemotherapy.

Roche received marketing authorisation for Xeloda as a first-line monotherapy (by itself) in the treatment of metastatic colorectal cancer (colorectal cancer that has spread to other parts of the body) in most countries (including the EU and USA) in 2001. Xeloda has also been approved by the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) for adjuvant (post-surgery) treatment of colon cancer in March and June 2005, respectively.

Xeloda is licensed in combination with Taxotere (docetaxel) in women with metastatic breast cancer (breast cancer that has spread to other parts of the body) and whose disease has progressed following intravenous (i.v.) chemotherapy with anthracyclines. Xeloda monotherapy is also indicated for treatment of patients with metastatic breast cancer that is resistant to other chemotherapy drugs such as paclitaxel and anthracyclines. Xeloda is licensed for the first-line treatment of stomach cancer that has spread, in South Korea.

The most commonly reported adverse events with Xeloda include diarrhoea, abdominal pain, nausea, stomatitis and hand-foot syndrome.

#### About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet

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