

Basel, 20 July 2009

Xeloda in combination with oxaliplatin shown to be effective in early colon cancer Phase III study meets primary endpoint of increasing the time patients live disease free compared with commonly used chemotherapy combination

Roche announced today results from the international phase III study NO16968 (XELOXA), investigating oral Xeloda in combination with intravenous oxaliplatin (XELOX) immediately after surgery, which show that patients with colon cancer taking XELOX live disease free for longer compared to those taking the commonly used intravenous chemotherapy combination 5-fluorouracil/leucovorin (5-FU/LV). The data prove that XELOX is superior to 5-FU/LV in terms of the time patients live without their cancer being detectable.

The trial, conducted in previously untreated patients who have undergone surgery for colon cancer, studied use of XELOX for 24 weeks. Patients in the XELOX group demonstrated significantly better disease-free survival compared to patients receiving 5-FU/LV.

“While Xeloda is already approved for the treatment of early-stage colon cancer as monotherapy, the results of this study mean that physicians will now be able to offer their patients Xeloda as a combination chemotherapy. This is an important development for patients as colon cancer, if caught early enough, can be cured, so physicians need a wide range of treatment options”, said William M. Burns, CEO of Roche’s Pharmaceuticals Division.

Data from the trial will be submitted for presentation at upcoming international scientific meetings. Roche plans to file the data with health authorities to extend the current label for Xeloda.

Xeloda is a highly effective oral chemotherapy drug that can be used alone, or in combination with other drugs, for the treatment of colorectal (including colon), stomach and breast cancer. It is already approved for the treatment of colon cancer after surgery in the US, EU, Japan and rest of the world.

Colorectal cancer is the second most common cause of death from cancer across all cancer types in men and

women in Europeⁱ and is the third most commonly reported cancer in the world, with nearly one million cases occurring annuallyⁱⁱ. Colon cancer refers to cancer of the large intestine (colon), which is the lower part of the digestive system, while rectal cancer specifies cancer of the last segment of the colon. Together, they're often referred to as colorectal cancer.

About the study

The NO16968 trial (XELOXA) is an open-label, randomised, phase III study of XELOX (oral Xeloda in combination with intravenous oxaliplatin) versus 5-fluorouracil/leucovorin (5-FU/LV) as adjuvant therapy for patients with stage III colon cancer who have undergone surgery. The study included 1886 patients and was conducted at 240 study sites across 29 countries. The primary endpoint of the study was to demonstrate the superiority of XELOX versus 5-FU/LV in terms of disease-free survival. Secondary endpoints included overall survival, safety profiles and perceived treatment convenience between the treatment arms.

About Xeloda (capecitabine)

Xeloda is a highly effective targeted oral chemotherapy offering patients a survival advantage when taken on its own or in combination with other anticancer drugs. Xeloda is converted to the active cancer-killing agent 5-FU (5-fluorouracil) directly inside the cancer cells, thus reducing damage to healthy cells. Xeloda tablets can be taken by patients in their own home, reducing the number of hospital visits.

Licensed and marketed by Roche in more than 100 countries worldwide, Xeloda has more than ten years of proven clinical experience providing an effective and flexible treatment option to over 1.8 million people with cancer. Xeloda is currently approved in:

- **Metastatic Colorectal Cancer**

- Monotherapy first-line (US & EU) – 2001
- In combination with any chemotherapy in all lines of treatment with or without Avastin (EU/RoW) - 2008

- **Metastatic Breast Cancer**

- Monotherapy first-line in patients with tumours resistant to other chemotherapy drugs such as paclitaxel and anthracyclines – (US) 1998 and (EU) 2002
- In combination with docetaxel in patients whose disease has progressed following iv chemotherapy with anthracyclines – (US) 2001 and (EU) 2002
- In patients with inoperable or recurrent breast cancer – (Japan) 2003

- **Adjuvant Colon Cancer**
 - Monotherapy (US & EU) – 2005
 - Monotherapy (Japan) - 2007
- **Advanced Gastric Cancer**
 - First-line treatment (South Korea) - 2002
 - In combination with platinum-based chemotherapy first-line (EU) – 2007
- **Metastatic Pancreatic Cancer**
 - In combination with gemcitabine first-line (South Korea) – 2006

To view and download high resolution Xeloda stills and media materials please visit www.thenewsmarket.com.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2008, Roche had over 80,000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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Further Information:

- Roche in Oncology: www.roche.com/media/media_backgroundunder/media_oncology.htm
- Cancer: www.roche.com/about_roche/business_fields/disease_areas/cancer.htm
- World Health Organization: www.who.int

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References

ⁱ Ferlay J, Autier P et al. Estimates of the cancer incidence and mortality in Europe in 2006. *Annals of Oncology* 18: 581–592, 2007

ⁱⁱ World Health Organisation, <http://www.who.int/mediacentre/news/releases/2003/pr27/en/>