

Basel, 30 March 2010

Xeloda in combination with oxaliplatin approved in Europe for the adjuvant treatment of patients with early colon cancer

More patients will be able to benefit from treatment with Xeloda

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that Xeloda (capecitabine) in combination with oxaliplatin (a combination known as XELOX) has been approved by the European Commission for the adjuvant (post-surgery) treatment of patients with early colon cancer. The approval was based on results from the pivotal NO16968 (XELOXA) study, one of the largest studies of patients with stage III (early) colon cancer, which showed that patients taking XELOX immediately after surgery lived disease-free for longer compared to those treated with chemotherapy regimen 5-fluorouracil/leucovorin (5-FU/LV).ⁱ The 3 year disease-free survival (DFS) for patients receiving XELOX was superior to the 5-FU/LV arm (71.0% versus 67.0%, HR 0.80, p=0.0045).

"The approval of XELOX for the adjuvant treatment of early colon cancer is great news for patients, who now have the added benefits and convenience of oral Xeloda in combination therapy for this disease, which is potentially curable if diagnosed and treated promptly," said Pascal Soriot, Chief Operating Officer (COO), Roche Pharmaceutical Division.

Following approval in the European Union, label extensions for XELOX in other regions of the world are expected. Xeloda monotherapy is already approved for use immediately after surgery in patients with colon cancer throughout the world including Europe, the US and Japan.

"I am delighted that XELOX will now be made available to patients with early colon cancer, particularly as it is at this stage of the disease that we have the best chance of curing them," said Professor Hans-Joachim Schmoll, Martin Luther University Clinic for Internal Medicine IV, Halle, Germany and one of the lead investigators. "Having a range of treatment options means more patients are given the chance to live without their disease returning, potentially enabling them to be cured," he added.

Colorectal cancer is the second most common cause of death from cancer across all tumour types in Europeⁱⁱ and is the third most commonly reported cancer in the world.ⁱⁱⁱ

About the NO16968 study

The NO16968 trial (XELOXA) is a randomised, phase III study of XELOX (oral Xeloda in combination with intravenous oxaliplatin) versus 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 226 study sites across 29 countries. The primary objective of the study was to assess the superiority of XELOX versus 5-FU/LV in terms of 3 year disease-free survival (DFS). The trial demonstrated that XELOX offered significantly superior DFS at 3, 4 and 5 years.

About Xeloda (capecitabine)

Xeloda (capecitabine) 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 uniquely activates the cancer-killing agent 5-FU (5-fluorouracil) directly inside the cancer cells. Xeloda tablets can be taken by patients in their own home, reducing the number of hospital or clinic visits.

Licensed and marketed by Roche in more than 100 countries worldwide, Xeloda has over 11 years 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 and ROW) – 2001
- In combination with any chemotherapy in all lines of treatment with or without Avastin (EU/ROW) – 2008
- In combination with oxaliplatin for the treatment of patients with advanced or refractory colorectal cancer who are not candidates for curative surgery (Japan) – 2009

Adjuvant Colon Cancer

- Monotherapy (US & EU) – 2005
- Monotherapy (Japan) – 2007
- In combination with oxaliplatin as XELOX (EU) – 2010

Advanced Gastric Cancer

- First-line treatment (South Korea) – 2002
- In combination with platinum-based chemotherapy first-line (EU and ROW) – 2007

Metastatic Breast Cancer

- Monotherapy first-line in patients with tumours resistant to taxanes 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

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 2009, Roche had over 80'000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 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.

All trademarks used or mentioned in this release are protected by law.

Additional information

- About cancer: www.roche.com/cancer.htm
- B-Roll and visuals can be found at: www.thenewsmarket.com

Roche Group Media Relations

Phone: +41 -61 688 8888 / e-mail: basel.mediaoffice@roche.com

- Alexander Klauser
- Martina Rupp
- Claudia Schmitt
- Nina Schwab-Hautzinger

References:

-
- ⁱ Haller D et al. European Journal of Cancer Supplements, Vol. 7, No 3, September 2009, Page 4 (abstract 5LBA)
ⁱⁱ Ferlay J et al. Ann Oncol 2007; 18:581-92
ⁱⁱⁱ Parkin DM et al. CA cancer J Clin 2005; 55:74-108