Media Release

Not for US media

Bowel Cancer Patients Live Longer Taking Xeloda

Analysis confirms that oral Xeloda is superior to IV 5-FU

Barcelona, Spain, 26 June 2008 –A pre-planned multivariate analysis of the five-year follow-up data shows that patients receiving chemotherapy after-surgery to treat colon cancer, are more likely to live longer when taking the chemotherapy pill Xeloda (capecitabine), compared to those receiving 5-FU/FA intravenous (IV) chemotherapy. The study compared Xeloda to the previous gold-standard IV chemotherapy for colon cancer, 5-FU/FA*, also known as the Mayo Clinic regimen. The results showed that 5 years after beginning treatment, the percentage of patients who survived was higher in the group taking Xeloda than the group receiving IV 5-FU/FA (71.4% for Xeloda versus 68.4% in the 5-FU/FA group). Results from the study, known as the X-ACT trial, will be presented on Saturday 28 June at the World Congress on Gastrointestinal Cancer.

"These data leave no doubt that Xeloda is the better treatment option for patients." said Professor Eduardo Diaz-Rubio, Chief of the Department of Medical Oncology, San Carlos Hospital Clinic, Madrid. "The Mayo Clinic Regimen has been the standard, but now that we have long-term evidence supporting Xeloda's superior efficacy it is time for that standard to change. When you combine these results with results from studies of Xeloda as an effective treatment for stomach and colorectal cancer, it is clear that Xeloda can replace IV 5-FU in all gastrointestinal cancer chemotherapy courses."

The Mayo Clinic regimen requires that patients visit the hospital on five consecutive days to receive IV 5-FU/FA, whereas the chemotherapy pill Xeloda can be taken at home and offers patients increased flexibility.

"From my perspective, I really wanted to be at work," said Andy Griffin, a colon cancer patient. "When taking Xeloda, I was able to drive myself to the hospital, have my checks and leave to go to work after only an hour. That was only once a month, which is very little time spent at the hospital and very little down time. To me that was really very good."

Results previously presented on the X-ACT study show Xeloda's superiority over IV 5-FU/FA in several other areas:

- Xeloda is more cost-effective than IV 5-FU/FA in the Mayo Clinic regimen.
- Xeloda causes less of the side-effects usually associated with chemotherapy.
- Patients taking oral Xeloda spend 85% less time visiting their doctor or hospital for treatment.

Based on the initial results of the X-ACT study, Xeloda was approved by the European Medicines Agency (EMEA) and U.S. Food and Drug Administration (FDA) for adjuvant (post-surgery) treatment of colon cancer in 2005. As part of the study design, an additional analysis was planned to provide a more precise estimate of the effect of Xeloda on patient survival, known as a Cox analysis. This analysis showed that Xeloda was superior to IV 5-FU/FA. The Xeloda European label (SPC) for colon cancer was updated in April 2008 to reflect that Xeloda's superiority against bolus 5-FU/FA has been demonstrated.

In January 2008, the EU approved Xeloda in combination with any chemotherapy in all lines of treatment with or without Avastin for advanced colorectal cancer.

This year will see 281,700 suffer with adjuvant colon cancer in the majority of the developed world (UK, Spain, Italy, France, Germany, Japan, Canada and the USA).[1]

* FA: Folinic Acid

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Notes to editors:

Highlights from the X-ACT data:

- **Overall Survival** -- With a median follow-up of 7 years, the 5-year overall survival rates were 71.4% (95% CI 68–74%) in the Xeloda group and 68.4% (95% CI 65–71%) in the 5-FU/FA group, corresponding to a HR of 0.86 (95% CI 0.74–1.01).

- **Disease-free Survival (DFS)** -- At a median follow-up of 3.8 years, DFS in the Xeloda group was at least equivalent to 5-FU/FA (intent-to-treat analysis, P<0.0001 compared with hazard ratio upper limit 1.20).

- **Relapse-free Survival (RFS)** -- Xeloda improved RFS (hazard ratio, 0.86; 95% confidence interval, 0.74 to 0.99; P=0.0407) and was associated with significantly fewer adverse events than 5-FU/FA (P<0.001).

About the X-ACT Study:

The goal of the X-ACT trial (**X**eloda in Adjuvant **C**olon Cancer **T**herapy) was to evaluate the safety and efficacy of Xeloda (capecitabine), a targeted oral chemotherapy, versus the old global standard of care, bolus intravenous 5-FU/FA (also known as the Mayo Clinic regimen), in patients who recently have had colon cancer surgery (adjuvant therapy).

The X-ACT trial randomly assigned 1987 patients with resected stage III colon cancer to oral capecitabine (n=1004) or bolus 5-FU/FA (Mayo Clinic regimen; n=983) over 24 weeks. The primary efficacy endpoint was at least equivalence in disease-free survival (DFS); other efficacy endpoints included relapse-free survival (RFS) and overall survival.

Results presented at WCGI:

Abstract Number: 316.00
Session XVIII: Adjuvant therapy for colon cancer
June 28 2008, 15:00 – 16:20

Updated 5-year efficacy data from X-ACT trial of capecitabine vs. 5-FU/LV in stage III colon cancer and preliminary analysis of relationship between hand-foot syndrome and efficacy

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

Licensed in more than 100 countries worldwide, Xeloda has over ten years proven clinical experience providing an effective and flexible treatment option to over 1.5 million people with cancer. Xeloda is currently approved in:

- ***Adjuvant Colon Cancer***
    - Monotherapy (US & EU) – 2005
    - Monotherapy (Japan) - 2007
- ***Metastatic Colorectal Cancer***
    - Monotherapy 1st line (US & EU) – 2001
    - In combination with any chemotherapy in all lines of treatment with or without Avastin

(EU) - 2008

- ***Advanced Gastric Cancer***
  - 1st line treatment (South Korea) - 2002
  - In combination with platinum-based chemotherapy 1st line (EU) – 2007
- ***Metastatic Breast Cancer***
  - Monotherapy 1st 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
- ***Metastatic Pancreatic Cancer***
  - In combination with gemcitabine 1st line (South Korea) - 2006

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. Additional information is available on the Internet at www.roche.com.

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Further information available:

- Colorectal cancer fact sheet
- Xeloda fact sheet
- Roche: www.roche.com
- Broadcast quality B-roll including doctor, caregiver and patient interviews is available for download via www.thenewsmarket.com

[1] GLOBOCAN – Cancer Incidence, Mortality and Prevalence Worldwide