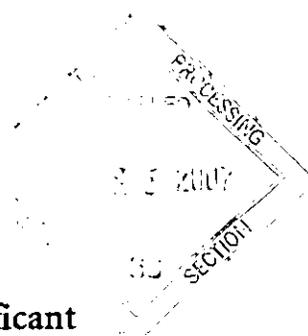




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First Actemra multinational phase III trial demonstrates significant improvement in signs and symptoms of rheumatoid arthritis

Study meets primary endpoint in rheumatoid arthritis patients who had an inadequate response to methotrexate

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Roche announced today that 'OPTION'¹, the first multinational phase III study of Actemra (tocilizumab) outside of Japan, successfully met its primary endpoint in the group of patients with moderate to severe rheumatoid arthritis (RA) who had an inadequate response to methotrexate. The study showed that a greater proportion of RA patients treated with Actemra achieved a significant improvement in disease signs and symptoms (ACR scores²) at week 24, compared to methotrexate control. Moreover, the preliminary analysis did not reveal any clinically important safety concerns with Actemra compared to control.

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"We are pleased that this study confirms the favourable efficacy and safety profile of Actemra in the treatment of RA. Actemra, through its unique blockade of the interleukin-6 receptor, will provide a new treatment option for people afflicted by rheumatoid arthritis," commented William M. Burns, CEO Division Roche Pharmaceuticals.

Data from this trial will be submitted for presentation at upcoming international scientific meetings. In addition, four other phase III trials exploring Actemra in RA are ongoing with three of them scheduled to report in 2007.

About the OPTION study

The OPTION (TOcilizumab Pivotal Trial in Methotrexate Inadequate respONDers) study was an international study which took place in 17 countries with 73 centres entering 623 patients with moderate to severe RA. In this 3 arm, randomized, double-blind study, patients received Actemra intravenously (either 4mg/kg or 8mg/kg) every 4 weeks plus methotrexate weekly or placebo

dlw
1/30

infusions plus methotrexate weekly.

The study found that patients treated with Actemra had a significant reduction in the signs and symptoms of rheumatoid arthritis over 6 months of treatment. Moreover, the preliminary analysis did not reveal any clinically important safety concerns with Actemra compared to control. The study also explored pharmacokinetics and mechanisms of the effect of IL-6 receptor blockade on the immune response in RA patients.

About Actemra

Actemra (tocilizumab) is a new humanised interleukin-6 (IL-6) receptor monoclonal antibody with a novel mechanism of action providing a unique treatment option for RA, a disease with a high unmet medical need. Roche and Chugai have initiated a collaborative phase III clinical development programme in RA running outside Japan, with more than 4000 patients enrolled in 41 countries including several European countries and the USA. In Japan, Actemra was launched in June 2005 as a therapy for Castleman's disease and in April 2006 filed for the additional indications of rheumatoid arthritis and systemic-onset juvenile idiopathic arthritis.

About rheumatoid arthritis

Rheumatoid arthritis is a progressive, systemic autoimmune disease characterized by chronic inflammation of multiple joints and fatigue as well as the possibility of osteoporosis, anaemia, and lung, skin and liver effects. This inflammation causes pain, stiffness and swelling, resulting in loss of joint function due to destruction of the bone and cartilage, often leading to progressive disability. Further, as chronic inflammation continues, there may be shortening of life expectancy as a result of effects on major organ systems. After 10 years, less than 50% of patients can continue to work or function normally on a day to day basis. RA affects more than 21 million people worldwide.

About Roche in rheumatoid arthritis

One of the most important drivers for growth at Roche over the next few years is expected to be the company's emerging franchise in autoimmune diseases with rheumatoid arthritis as the first indication. Following the launch of MabThera (rituximab) there are a number of projects in development, potentially allowing Roche to build on further opportunities. MabThera is the first and only selective B-cell therapy for RA, providing a fundamentally different treatment approach by targeting B cells, one of the key players in the pathogenesis of RA. Actemra (tocilizumab) is another 'first-in-class' medicine and is a humanised monoclonal antibody to the interleukin-6 (IL-6) receptor, blocking the activity of IL-6, a protein that plays a major role in the RA inflammation

process. Actemra is the result of research collaboration by Chugai and is being co-developed globally with Chugai. Additional projects creating a rich pipeline include compounds in Phase I, II and III clinical trials. Notably, ocrelizumab, a fully humanised anti-CD20 antibody, is just entering phase III development.

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. 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 (www.roche.com).

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Further information

- Roche & Autoimmune diseases: www.roche.com/med_events_mb1106

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References:

¹OPTION refers to the TOcilizumab Pivotal Trial in Methotrexate Inadequate respONDers

²The ACR response is a standard assessment used to measure patients' responses to anti-rheumatic therapies, devised by the American College of Rheumatology (ACR). It requires a patient to have a defined percentage reduction in a number of symptoms and measures of their disease. For example, a 20 or 50% level of reduction (the percentage of reduction of RA symptoms) is represented as ACR20, ACR50 or ACR70. An ACR70 response is exceptional for existing treatments and represents a significant improvement in a patient's condition.

Basel, 22 January 2007



New phase III data highlights excellent efficacy of Roche's cancer drugs Xeloda and Avastin for treatment of advanced colorectal cancer

New phase III data presented at the American Society of Clinical Oncology Gastrointestinal Symposium (ASCO GI) continue to demonstrate the excellent efficacy of two of Roche's innovative cancer drugs Xeloda and Avastin, which offers improved survival for patients with advanced colorectal cancer. The NO16966 study showed that:

- XELOX (oral Xeloda plus oxaliplatin) is at least as effective as FOLFOX-4 in terms of overall survival
- the addition of Avastin to either XELOX or FOLFOX leads to a statistically significant improvement in progression-free survival, as determined by an independent review committee (IRC)

"Overall, these results confirm the role of XELOX as the most convenient and patient-friendly treatment option in this disease area, which is very encouraging for colorectal cancer patients and healthcare providers," said Professor Jim Cassidy, co-lead investigator for study NO16966 and Cancer Research UK Professor of Oncology and Chair of Medical Oncology, Beatson Oncology Centre, at the University of Glasgow, Scotland. "In addition, the independent review confirms that by adding Avastin to any oxaliplatin-based regimen we can improve progression-free survival times even further, which we knew all along based on the second line data with FOLFOX plus Avastin."

In the treatment of advanced (metastatic) colorectal cancer, these data showed that XELOX reached its primary endpoint:

- The chemotherapy combination XELOX is as effective in terms of time patients live without their disease progressing (PFS) as FOLFOX-4.
- Overall-survival data of the first 634 patients enrolled prior to the introduction of Avastin indicate that XELOX is at least comparable to FOLFOX-4.

These data add to the results of previous studies, further endorsing that Xeloda should replace infused 5-FU/leucovorin (FOLFOX) in colorectal cancer regimens.

The IRC which conducted a blinded analysis of the scans confirmed that Avastin reached its primary endpoint:

- The benefit provided by Avastin when added to chemotherapy (FOLFOX or XELOX) significantly improved progression-free survival by 43% compared to chemotherapy alone, as assessed by the IRC. A previous analysis presented in October 2006 showed an advantage of 20%.
- Specifically there was also a statistically significant improvement in PFS when assessing the addition of Avastin to either the XELOX or FOLFOX subgroup ($p < 0.007$)

No new safety findings related to Avastin or Xeloda were observed in the trial.

Further analyses are ongoing and updated results will be presented at future scientific meetings. Based on findings from this study and the NO16967 and E3200 studies, Roche will be approaching worldwide regulatory authorities for new file submissions with Xeloda and Avastin respectively in advanced colorectal cancer.

In 2004, colorectal cancer was one of the leading cancers and accounted for 13 percent of all cancers in Europe.¹ A World Health Organization report suggested that in 2005, 655,000 people worldwide died from colorectal cancer.²

About the study

NO16966 is a large, international Phase III trial which finally recruited 2,034 patients. It was originally planned to compare XELOX vs FOLFOX as first-line treatment in metastatic colorectal cancer:

- XELOX (Xeloda plus oxaliplatin) vs FOLFOX-4 (intravenous bolus and infusional 5-fluorouracil plus oxaliplatin)

The two-arm study recruited 634 patients.

After release of the pivotal Avastin data in colorectal cancer in 2003, the protocol was amended to investigate using a 2 by 2 factorial design:

- XELOX + placebo vs XELOX + Avastin (7.5 mg/kg q3w) vs FOLFOX + placebo vs FOLFOX + Avastin (5.0 mg/kg q2w).

The primary objective was to answer two questions: 1) whether the XELOX regimen is non-inferior to FOLFOX; 2) whether the addition of Avastin to chemotherapy improved results compared to chemotherapy alone. The secondary endpoints included overall survival, overall response rates, time to, and duration of, response and safety profile.

Results presented previously at the European Society of Medical Oncology (ESMO) meeting in October 2006 of the entire study population (N=2,034) show that:

- XELOX is as effective as FOLFOX in terms of PFS (hazard ratio: 1.05; upper limit of the 97.5

percent confidence interval was below the non-inferiority margin of 1.23).

- Adding Avastin to chemotherapy (FOLFOX and XELOX) significantly improved PFS compared to chemotherapy alone (hazard ratio: 0.83). This means that adding Avastin to either chemotherapy combination improves the chances of delaying progression of the disease by 20 percent.
- No unexpected safety findings were identified for either XELOX or Avastin:
 - Adverse events which occurred at a rate greater than 10 percent in any of the treatment arms were: diarrhoea (FOLFOX, 11.2 percent of patients; XELOX, 20.2 percent of patients), neutropenia (FOLFOX, 43.8 percent of patients, XELOX, 7.0 percent of patients) and neurosensory toxicity (FOLFOX, 16.5 percent of patients; XELOX, 17.4 percent of patients).
 - The percentage of gastrointestinal perforations was 0.6 percent in the Avastin arms compared to 0.3 percent in the placebo group. Grade 3/4 arterial thromboembolic events occurred in 1.7 percent vs 1.0 percent respectively. Grade 3/4 proteinuria was reported for 0.6 percent of all patients receiving Avastin. Wound healing complications were not observed in a higher frequency than in the placebo group (0.1 vs 0.3 percent).

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 an effective, safe, simple and convenient oral chemotherapy in treating over 1 million patients to date.

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 recently received approval in South Korea for the first-line treatment of patients with locally advanced (metastatic) pancreatic cancer, in combination with gemcitabine. Xeloda is licensed in South Korea for the first-line treatment of stomach cancer.

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

About Avastin

Avastin is the first treatment that inhibits angiogenesis – the growth of a network of blood vessels that supply nutrients and oxygen to cancerous tissues. Avastin targets a naturally occurring protein called Vascular Endothelial Growth Factor (VEGF), a key mediator of angiogenesis, thus choking off the blood supply that is essential for the growth of the tumour and its spread throughout the body (metastasis).

In Europe, Avastin was approved in early 2005 and in the US in February 2004 for first-line treatment of patients with advanced colorectal cancer. It received another approval in the US in June 2006 as a second-line treatment for patients with advanced colorectal cancer. The first filing for Avastin in Japan occurred in April 2006 for the treatment of advanced colorectal cancer. Most recently following priority review, the world's first angiogenesis inhibitor was approved by the FDA in October for the treatment of non-small cell lung cancer (NSCLC); a filing for the same indication was submitted to EU authorities in August.

Roche and Genentech are pursuing a comprehensive clinical programme investigating the use of Avastin in various tumour types (including colorectal, breast, lung, pancreatic cancer, ovarian cancer, renal cell carcinoma and others) and different settings (advanced and adjuvant ie post-operation). The total development programme is expected to include over 40,000 patients worldwide.

For more information, please visit www.avastin-info.com

About Roche

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