

Investor Update



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Basel and Amsterdam, 22 June 2006

New evidence shows MabThera inhibits joint damage in patients with rheumatoid arthritis

First RA drug to achieve these results in patients with an inadequate response to currently available treatments

Conference call for investors and analysts to present and discuss EULAR data tomorrow Friday, 23. June 2006

New data presented at the EULAR meeting (European League Against Rheumatism) show for the first time that MabThera (rituximab), a unique B cell targeted therapy, is able to significantly inhibit structural damage of joints caused by rheumatoid arthritis (RA). The study was conducted in patients who had an inadequate response to one or more TNF inhibitors and they received either MabThera plus methotrexate (MTX) or MTX alone.

X-ray evidence at 56 weeks showed that patients receiving MabThera plus MTX saw further inhibition of joint damage, compared to patients receiving MTX alone, based on several measurements:

- the mean change in the Genant-modified Sharp score, which assesses progression of both joint space narrowing and joint erosion, was substantially lower among MabThera-treated patients than placebo-treated patients (1.00 versus 2.31, respectively; $p=0.0046$)
 - in more details, the mean changes in the joint space narrowing score and the erosion score were more than 50% reduced for patients receiving MabThera over placebo (0.41 versus 0.99; $p=0.0006$ and 0.59 versus 1.32; $p=0.0114$, respectively) and finally
- a significantly higher proportion of MabThera-treated patients showed no erosive progression at 56 weeks, compared to patients receiving MTX only (61% versus 52%, respectively; $p=0.0494$)

Consistent with previous findings, analysis of the REFLEX 56-week data did not reveal any unexpected safety signals. The companies involved in the clinical development continue to monitor the long-term safety of rituximab in all clinical trials.

Damage to the structure of the joints ultimately causes destruction of the joints and contributes to joint deformity and loss of mobility. Patients' ability to work and perform every day tasks such as getting dressed, walking and eating can be severely hampered.

Presenting the results, Professor Keystone, Rheumatology Department at the University of Toronto, Canada, said: "This is the first evidence demonstrating that MabThera can inhibit structural joint damage in patients with an inadequate response to one or more TNF inhibitors. Preventing structural damage is a critical outcome in treating rheumatoid arthritis. These X-ray data confirm MabThera as an effective and innovative therapy for patients with rheumatoid arthritis and highlight the value of targeting B cells."

Repeat treatment courses

Additional new data presented at EULAR demonstrate that repeat courses of MabThera in RA patients 6 to 12 months after the initial course, provide continued improvement of symptoms, across all clinical measures. Each treatment course consists of two infusions of 1000mg given two weeks apart. The challenging goal of treatment in RA is remission and following a second course of MabThera in patients with an inadequate response to one or more TNF inhibitors, the number of patients achieving remission doubled from 6 % following an initial course to 13 % following a second course. A similar trend was seen for those achieving the hard-to-reach goal of a 70 % improvement in symptoms (ACR70), with responses increasing from 12 % following an initial course to 21 % following a second course.

Long term safety and repeated courses

Further new data of a pooled analysis presented at EULAR confirmed the safety profile of rituximab identified in the original randomised clinical trials. The analysis included all RA patients treated with MabThera during clinical development which amounted to over 1,600 patient years with some patients being followed for over 3 years, many of whom had received multiple courses of treatment. This analysis did not reveal any unexpected safety signals.

Patient perspectives

Importantly, data presented at EULAR show improvements in clinical scores are reflected in patient reported outcomes.

"While it is important to a physician to address a disease from a clinical perspective, what matters most to the patient is whether they are able to function normally and how well they feel. For example, the impact of fatigue is often underestimated, but this is something which really impacts patients' lives. MabThera has demonstrated continuous improvements in physical and mental health aspects with repeated courses of therapy", said Professor Tak, Director, Division of Clinical Immunology and Rheumatology at the Academic Medical Centre/University of Amsterdam, The Netherlands.

Approval Status

On 2 June 2006 MabThera received a recommendation for approval from the Committee for Medicinal Products for Human Use (CHMP) for the treatment of rheumatoid arthritis (RA) in Europe. MabThera, in combination with methotrexate, has been recommended for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARDs). On 28 February 2006, after priority review, Genentech and Biogen Idec received US approval for Rituxan® (rituximab in the US) for the treatment of adult patients with moderately to severely active RA in combination with methotrexate for reducing signs and symptoms in those RA patients who have had an inadequate response to one or more tumour necrosis factor (TNF) antagonist therapies.

About radiographic analysis of joint damage

Data on the progression of joint damage are obtained by taking X-rays of specific joints (typically in the hands and feet) before treatment and at various points after treatment has been initiated. The Genant-modified Sharp score method focuses on 14 specific sites for evidence of bone erosion and 13 sites for narrowing of the joint space – both key measures of ongoing structural damage to the joints. Joint space narrowing scores are assigned to each of the specified sites, with 0 representing “no narrowing” and 4 representing “total loss of the joint space.” Erosion scores are assigned to each of the specified sites, with 0 representing “no erosion” and 3.5 representing “destruction of the joint.” Increases in the scores indicate the extent of additional joint space narrowing, erosion or overall structural damage (both scores combined) that have occurred since treatment began.

About the REFLEX study

The REFLEX study (Randomised Evaluation of Long-term Efficacy of MabThera in RA) is a multi-centre, randomized, double-blind, placebo-controlled Phase III study. In this trial, patients who received a single course of only two infusions of MabThera with a stable dose of methotrexate (MTX) displayed a statistically significant improvement in symptoms measured at 24 weeks, compared to those receiving placebo and MTX. Patients receiving additional courses did so between 6 and 12 months after the initial course. Consistent with previous findings, analysis of the REFLEX 56-week data did not reveal any unexpected safety signals. The companies continue to monitor the long-term safety of rituximab in all clinical trials.

A further phase III development programme for MabThera therapy in patients with rheumatoid arthritis who have had an inadequate response to disease modifying anti-rheumatic drugs (DMARDs) is ongoing.

About MabThera in rheumatoid arthritis

MabThera selectively targets a subset of B cells that express CD20, leaving stem, pro-B and plasma cells unaffected. This subset of B cells plays a key role in the autoimmune process of RA and MabThera aims to interrupt this process by inhibiting a series of reactions inflaming the synovia and leading to cartilage loss and bone erosion that is characteristic of the disease. More than 1,000 patients with RA have been treated with MabThera in clinical trials to date. A comprehensive Phase III clinical development programme is also currently underway to further investigate the potential clinical benefit of MabThera in earlier RA.

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 (www.roche.com).

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Conference call

Roche Investor Relations is hosting a conference call to present and discuss new data and results presented at EULAR. The conference call will take place:

Friday, June 23, 2006 from 14:30 to 15:30 CET / 08:30 to 09:30 EST

Participants will be:

Dr. Karl Mahler, Head of Investor Relations, Roche

Dr. Urs Schleuniger, Business Director, Hematology & Autoimmune Diseases, Roche

Prof. Paul Emery, arc Professor of Rheumatology, Academic Unit of Musculoskeletal Disease, University of Leeds, Leeds Teaching Hospitals Trust, UK

Prof. Edward C Keystone, Professor of Medicine, University of Toronto, Canada

Analysts and investors are invited to dial in to the conference call using the following dial-in numbers:

+41 (0) 91 610 56 00 (Europe and ROW)

+44 (0) 207 107 06 11 (UK)

+1 (1) 866 291 41 66 (USA Toll Free)

Please dial in to the conference call 10 – 15 minutes before the call is scheduled to start. Alternatively, a live audio webcast can be accessed via <http://ir.roche.com>. Ahead of the call, the presentation will be available from the IR website at <http://ir.roche.com>.

A replay of the conference call will be available one hour after the conference call, for 48 hours. Access is by dialling:

+41 (0) 91 612 43 30 (Europe and ROW)

+44 (0) 207 108 62 33 (UK)

+1 (1) 866 416 25 58 (USA)

Listeners will be asked to enter the ID 487 followed by the # sign.

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