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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

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 the progression of bone erosions and progression of narrowing of joint spaces in patients in the MabThera group were reduced by more than 50 % compared to patients receiving MTX alone (erosion scores of 0.59 and 1.32 respectively; joint space narrowing scores of 0.41 and 0.99 respectively).

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.

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.

-ENDS-

Editors notes:

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 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.

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.

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

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- British Society for Rheumatology: www.rheumatology.org.uk
- American College of Rheumatology: www.rheumatology.org
- About Genentech: www.gene.com
- About BiogenIdec: www.biogenidec.com.

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