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## **Latest data show MabThera<sup>®</sup> provides significant and sustained relief from signs and symptoms of rheumatoid arthritis**

### **Patients experience consistent safety profile with subsequent courses of therapy**

**Barcelona, Spain.** New data presented at the EULAR meeting (European League Against Rheumatism) demonstrate that MabThera's (rituximab) effectiveness in relieving patients of the distressing symptoms of rheumatoid arthritis (RA) is sustained or further improved with subsequent courses of treatment, as is the number of patients achieving remission<sup>1</sup>. Importantly, the safety profile of MabThera remained unchanged in patients who had received as many as seven courses of treatment at 6-12 month intervals.

Commenting on the findings, Professor Keystone, Rheumatology Department at the University of Toronto, Canada, said: "As physicians gain experience with MabThera and the long-term efficacy and safety data are collected, we are able to make treatment decisions with confidence for the ultimate benefit of our patients".

### **Results following subsequent courses of therapy**

A total of 1053 RA patients was treated with MabThera with almost 70% of patients followed up for more than two years and 11% for more than three years. The study was conducted in patients who had an inadequate response to treatment with either tumour necrosis factor (TNF) inhibitors or disease-modifying anti-rheumatic drugs (DMARDs), both of which are commonly used classes of RA drugs. All study patients received multiple courses of MabThera (2 x1000mg infusion, 2 weeks apart) based on disease activity.

The data showed that after three courses of MabThera in patients who had an inadequate response to TNF inhibitors:

- The number of patients achieving the hard-to-reach goal of a 70% improvement in disease signs and symptoms (ACR70 response<sup>2</sup>) almost tripled from 11% to 25%
- The number of patients achieving remission improved from 6% to 12%

Equally, in patients with an inadequate response or intolerance to DMARDs, the remission rate increased almost threefold from 5% to 14% confirming the benefit of providing subsequent courses to responding patients.

#### **Long-term safety of MabThera**

Further pooled data examining the safety of MabThera when used long-term revealed that the safety profile of MabThera remained consistent with a low, unchanging rate of serious infections in 1053 patients, receiving up to seven treatment courses. These results add to the wealth of data contributing to MabThera's safety profile with 2438 patient-years of follow-up now collected.

-ENDS-

#### **Editor's Notes**

##### **About Rheumatoid Arthritis and MabThera**

Rheumatoid arthritis is an autoimmune disease characterised by inflammation that leads to stiff, swollen and painful joints. Current treatments include disease-modifying drugs (DMARDs) and biologic therapy such as the TNF inhibitor drugs.

MabThera is a first-in-class therapy that selectively targets B cells early in the inflammatory cascade of rheumatoid arthritis. B cells are known to play a key role in the inflammation associated with rheumatoid arthritis and MabThera breaks the inflammatory cascade of RA – a series of reactions inflaming the synovia and leading to the cartilage loss and bone erosion that is characteristic of the disease, and may provide an innovative new treatment even in patients with severe and long-standing disease. MabThera has a strong heritage in the treatment of a form of lymphatic cancer called non-Hodgkin's lymphoma (NHL) and the safety profile of MabThera has now been established in more than 960,000 patient exposures over the last nine years in oncology and autoimmune disease.

##### **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, 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 is Roche's second novel medicine and is a humanised monoclonal antibody to the interleukin-6 (IL-6) receptor, inhibiting 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 for 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 the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolism and central nervous system. In 2006 sales by the Pharmaceuticals Division totalled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche employs approximately 75,000 worldwide and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche

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To view and download high resolution stills and media materials please visit the MabThera Virtual Press Office at [www.mabthera-ra.com](http://www.mabthera-ra.com)

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**References**

<sup>1</sup>Disease activity is measured by a Disease Activity Score (DAS), where low disease activity is defined as  $DAS_{28} \leq 3.2$  and remission is defined as  $DAS_{28} \leq 2.6$

<sup>2</sup>The 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%, 50% or 70% level of reduction 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.