

Media Release



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MabThera/Rituxan effective in treatment of Rheumatoid Arthritis

Interim study results show targeted drug MabThera can help improve lives of Rheumatoid Arthritis patients

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Encouraging new study results show that the biologically engineered drug MabThera (rituximab) is effective in fighting the debilitating symptoms associated with Rheumatoid Arthritis (RA). These interim results, presented at the annual American College of Rheumatology meeting in New Orleans, USA, show that a short course of treatment with MabThera led to a significant reduction in disease symptoms in a high number of patients with RA.

Exceptionally, just two infusions of MabThera, in combination with methotrexate, were shown to reduce RA symptoms by 70% in one in five patients; in addition, a reduction of 50% of symptoms was seen in half of patients.

Study investigator, Professor Jonathan Edwards, from the UK's University College London Centre for Rheumatology, is excited about these initial findings. He commented: "For patients and physicians alike these interim results are promising. With MabThera it looks as if we can reduce the usual frequency of RA treatment, while at the same time achieving a remarkable level of reduction in the debilitating symptoms of the disease."

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¹ MabThera (rituximab) is currently indicated for use in the treatment of the most common form of blood cancer, non-Hodgkin's lymphoma (NHL) and marketed by Roche and Genentech. MabThera/ Rituxan is marketed in Europe as MabThera and in the US, Canada and Japan as Rituxan. NHL is the most common form of blood cancer and affects approximately 1.5 million people around the world. Approx. 250,000 patients have received MabThera.

About the study

The interim study results performed with the first 122 out of 161 patients enrolled in an initial Phase II, randomised controlled trial show that MabThera plus the standard RA treatment methotrexate led to:

- Over 20% of patients achieved a 70% improvement in their disease at 6 months. This is an exceptional level of improvement, rarely obtained with existing therapies.
- Half of patients achieved at least a 50% improvement in their disease signs and symptoms at 6 months (ACR50²)
- Over 80% of patients achieved at least a 20% improvement in their disease signs and symptoms (ACR20) at 6 months.

Plans are underway for further clinical studies of MabThera, with the aim of providing RA patients with a new, effective, form of treatment in the coming years.

About Rheumatoid Arthritis

RA affects almost 6 million people around the world and is a debilitating disease that hinders the daily activities of sufferers. In Europe, RA affects up to 2 million people. It is characterised by inflammation of multiple joints, cartilage loss and bone erosion, which leads to joint destruction and ultimately reduced joint function. Additionally, since RA is a systematic disease, it can have effects in other tissues, such as lungs, eyes and bone marrow. After ten years of RA, fewer than 50% of patients can continue to work or function normally on a day to day basis.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-orientated healthcare groups. The company's two core businesses in pharmaceuticals and diagnostics provide innovative products and services, that address prevention, diagnosis and treatment of diseases, thus enhancing people's health and quality of life. The two core businesses achieved a turnover of 19.3 billion Swiss Francs in the first three quarters of 2002 and employed about 57'000 employees world-wide.

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² ACR 20, 50 and 70 responses represent a 20%, 50% and 70% improvement in disease signs and symptoms respectively.

Notes to Editors

1. The Phase II trial is a randomised, double-blind, placebo-controlled, parallel group study, that is being conducted in centres throughout Europe, Australia, Israel and Canada. Patients enrolled are those with RA, who have not responded to more than one disease modifying anti-rheumatoid drug (DMARD) and are currently only partial responders to methotrexate. This is a four arm study: Group A methotrexate alone; Group B rituximab alone; Group C MabThera plus cyclophosphamide; Group D MabThera plus continuing methotrexate. Recruitment into this trial commenced early 2001.

2. In another, small exploratory independent, trial in 1999 (conducted by Professor Edwards) and presented at ACR in 2000, MabThera was shown to be effective in relieving symptoms in 5 patients with rheumatoid arthritis who had failed to respond to existing therapies.