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## **New data from largest-ever clinical trials in CLL show MabThera enables leukaemia patients to live longer without their disease progressing**

**Pivotal phase III results suggest MabThera is set to change the face of Chronic Lymphocytic Leukaemia management**

Significant new data from two pivotal phase III studies, to be presented at the 50<sup>th</sup> Annual Meeting of the American Society of Hematology in San Francisco this week, show that patients with chronic lymphocytic leukaemia (CLL) treated with MabThera (rituximab) in combination with chemotherapy live considerably longer without their disease progressing, compared to patients treated with chemotherapy alone. The results could pave the way to a new approach to treating this incurable form of adult leukaemia.

The key results of the two studies are:

- **Previously untreated patients:** The CLL-8 study showed that at two years, more than three quarters (76.6%) of patients on MabThera plus chemotherapy lived without their disease progressing compared to 63.3 % of those treated with chemotherapy alone.
- **Relapsed/refractory patients:** The REACH study demonstrated that with MabThera, patients who had relapsed lived an average 10 months longer without their disease progressing compared to those receiving chemotherapy alone (30.6 months vs 20.6 months).

“The positive results from both of these trials is very encouraging news for patients suffering from a disease that remains life-threatening and incurable ,” said William M. Burns, CEO Pharmaceuticals Division of Roche. “The outcome of these trials clearly demonstrates the important role MabThera will have in the treatment of this devastating disease.” [\\_ more](#)

“MabThera has already revolutionised the treatment of people living with non-Hodgkin’s lymphoma”, said Professor Tadeusz Robak, Medical University of Lodz, Poland, and principle investigator for the REACH trial. “These results add to a growing body of evidence that underscores the important role MabThera has to play in the management of CLL, which currently remains a life-threatening and incurable disease.”

Professor Michael Hallek, University Hospital Cologne, Germany, who led the German CLL Study Group (GCLLSG) in conducting the CLL8 trial said, “With new therapies emerging, the management of CLL is set to change markedly, with physicians having more options and greater treatment expectations for their patients. These data, which come from the largest randomised clinical trials in CLL ever reported, suggest that MabThera used in combination with chemotherapy has the potential to become the new standard of care for CLL patients.”

CLL is the most common type of leukaemia in adults, accounting for approximately 25-30% of all forms of leukaemia. Incidence of CLL in Western countries is around 2-4 per 100,000, and is twice as common in men compared to women. It mainly affects the elderly with 95% of patients diagnosed after the age of 55. While CLL is generally considered a disease that it is slow to progress, a significant proportion of patients have rapidly progressing forms of the disease.

#### **About CLL8**

The CLL8 study is an international study and included 817 patients with CLL receiving first-line treatment. The study was conducted at 191 study sites across 11 countries. In this randomized study, patients received either MabThera in combination with chemotherapy (fludarabine and cyclophosphamide) or chemotherapy alone. The primary endpoint of the study was progression-free survival. No new or unexpected safety signals were observed.

#### **About REACH**

The REACH study is a randomized international study that included 552 patients with relapsed or refractory CLL. It was conducted at 88 study sites across 17 countries. The study was set up to investigate whether treatment of patients with relapsed or refractory CLL with MabThera in combination with chemotherapy (fludarabine and cyclophosphamide) was more beneficial than treatment with chemotherapy alone. The primary endpoint of the study was to show an increase in terms of median progression-free survival.

#### **About MabThera**

MabThera is a therapeutic antibody that binds to a particular protein - the CD20 antigen - on the surface of normal and malignant B-cells. It then recruits the body's natural defences to attack and kill the marked B-cells. Stem cells (B-cell progenitors) in bone marrow lack the CD20 antigen, allowing healthy B-cells to regenerate after treatment and return to normal levels within several months.

MabThera is indicated for the treatment of patients with stage III and IV follicular non-Hodgkin's Lymphoma and patients with CD20 positive diffuse large B cell non-Hodgkin's lymphoma. MabThera in combination with methotrexate is indicated 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 (DMARD) including one or more tumour necrosis factor (TNF) inhibitor therapies. MabThera is known as Rituxan in the United States, Japan and Canada. To date, patients have received more than 1 million treatments with MabThera worldwide.

Genentech and Biogen Idec co-market MabThera in the United States, and Roche markets MabThera in the rest of the world, except Japan, where MabThera is co-marketed by Chugai and Zenyaku Kogyo Co. Ltd.

#### **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, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totalled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at [www.roche.com](http://www.roche.com).

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#### **Further Information:**

- Roche in Oncology: [http://www.roche.com/media/media\\_backgrounder/media\\_oncology.htm](http://www.roche.com/media/media_backgrounder/media_oncology.htm)
- Lymphoma: [www.lymphoma-net.org](http://www.lymphoma-net.org)
- The Lymphoma Coalition: [www.lymphomacoalition.org](http://www.lymphomacoalition.org)
- Cancer: [www.health-kiosk.ch/start\\_krebs.htm](http://www.health-kiosk.ch/start_krebs.htm)
- World Health Organization: [www.who.int](http://www.who.int)

**Roche Group Media Office**

Phone: +41 61 688 8888/E-mail: [basel.mediaoffice@roche.com](mailto:basel.mediaoffice@roche.com)

- Daniel Piller (Head)
- Alexander Klauser
- Martina Rupp
- Claudia Schmitt
- Elina Ämmälä