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MabThera receives positive opinion in Europe for treating patients whose chronic lymphocytic leukaemia returns

Patients with relapsed or refractory disease can live ten months longer without their disease progressing

Roche announced today that the European Union's Committee on Human Medicinal Products (CHMP) has issued a positive recommendation for the use of MabThera (rituximab) in patients with relapsed or refractory chronic lymphocytic leukaemia (CLL). Physicians will soon be able to prescribe MabThera, the first monoclonal antibody therapy approved for previously untreated CLL, in combination with chemotherapy to patients who have been treated for the disease but whose cancer has returned or have not appropriately responded to therapy.

This recommendation is based on the important results from REACH, the largest randomised clinical trial ever reported in previously treated CLL. These results showed that patients with relapsed or refractory CLL who received MabThera in combination with chemotherapy lived an average ten months longer without their disease progressing compared to those receiving chemotherapy alone (30.6 months vs. 20.6 months).¹ MabThera is already approved for first-line use in previously untreated CLL in the EU and many other countries and, pending final approval by the EU authorities, physicians will be able to prescribe MabThera to those patients with relapsed or refractory disease.

“MabThera has been shown to give patients significantly more time without their disease worsening compared to those receiving chemotherapy alone”, said William M. Burns, CEO Roche Pharma. “The positive opinion will, therefore, be welcomed by doctors and patients alike as it represents hope for the future management of a disease that remains notoriously difficult to treat.”

CLL is the most common type of leukaemia in adults, accounting for approximately 30-40% of all forms of leukaemia in Western countries. Overall incidence of CLL is around three per 100,000 and is 30% more common in men than women². The incidence of CLL is markedly increased in patients older than 65 with a median age at diagnosis of 72 years³. While CLL is generally considered a disease that is slow to progress, a

significant proportion of patients have rapidly progressing forms of the disease.

About REACH

The REACH study is a randomised 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 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.

In oncology, MabThera is indicated:

- For previously untreated patients with CLL in combination with chemotherapy
- For the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy
- As maintenance therapy for patients with relapsed/refractory follicular lymphoma responding to induction therapy with chemotherapy with or without MabThera
- For the treatment of patients with CD20 positive diffuse large B cell non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy
- As monotherapy for treatment of patients with stage III-IV follicular lymphoma who are chemoresistant or are in their second or subsequent relapse after chemotherapy

In addition, in rheumatology 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. Over 1.5 million patient exposures with MabThera have been recorded worldwide since its launch.

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

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2008, Roche had over 80,000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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Further Information:

- Roche in Oncology: www.roche.com/pages/downloads/company/pdf/mboncology05e_b.pdf
- Cancer: www.health-kiosk.ch/start_krebs.htm
- World Health Organization: www.who.int

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References:

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2. Watson L et al., Disease burden of chronic lymphocytic leukaemia within the European Union European Journal of Haematology 2008 ; 81(4), 253-258.
3. Ries LAG, Melbert D, Krapcho M, Stinchcomb DG, Howlader N, Horner MJ, et al. SEER Clinical Statistics. Review, 1975–2005. Bethesda, MD: National Cancer Institute;2008