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MabThera approved in Europe for use in patients with previously-treated chronic lymphocytic leukaemia

New hope for patients with most common form of leukaemia in adults

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission has approved MabThera (rituximab) for use in patients with relapsed or refractory chronic lymphocytic leukaemia (CLL), the most common form of the disease in adults. The approval is supported by the impressive results from REACH, the largest randomised clinical trial ever reported in previously-treated CLL. Physicians can now prescribe MabThera in combination with chemotherapy to patients who have been treated for the disease but whose cancer has returned or who have not responded appropriately to therapy. MabThera is already the standard of care for initial treatment of CLL.

“This approval will make MabThera plus chemotherapy the gold-standard therapy for people living with relapsed or refractory CLL”, said Professor Tadeusz Robak, Medical University of Lodz, Poland and principal investigator for the REACH trial. “Although all patients with CLL will unfortunately eventually relapse, treatment with MabThera significantly prolongs remission. This will help ease the burden of the cancer and enable patients to enjoy the relative freedom that comes with this relief from symptoms.”

The results of REACH showed that patients with relapsed or refractory CLL who were treated with 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 At present, CLL is considered incurable and the aim of treatment is to control the disease by managing symptoms and extending the time patients live without their disease worsening.

“Today’s approval of MabThera in CLL throws a life line to patients suffering from this terrible disease”, said William M. Burns, CEO, Roche Pharmaceuticals Division. “After the approval for use in patients with previously untreated CLL earlier this year, this latest license extension means that MabThera can now offer real hope to all patients with CLL.”

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 women.² 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.

Earlier this year, Roche received marketing approval for MabThera in combination with chemotherapy in previously-untreated patients with advanced CLL.

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 1.7 million patient exposures with MabThera in haematological malignancies have been recorded worldwide since its launch.

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 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: http://www.roche.com/media/media_backgrounder/media_oncology.htm
- Cancer: www.health-kiosk.ch/start_krebs.htm
- World Health Organization: www.who.int

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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