MabThera approved in Europe for first line maintenance treatment of follicular lymphoma, a common type of blood cancer

Prolonged treatment with MabThera allows patients with follicular lymphoma to be protected for longer from their disease getting worse

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission has approved the use of MabThera (rituximab) as a maintenance treatment for people suffering from follicular lymphoma who have responded to initial induction therapy. The approval of MabThera maintenance expands effective treatment options for people with this common type of incurable blood cancer, doubling the likelihood of them living longer without their disease worsening. Maintenance treatment is an important approach to blood cancer management as it reduces the risk of relapse and the use of repeated chemotherapy, ultimately improving the lives of follicular lymphoma patients.

“The approval of MabThera maintenance therapy in the EU is a significant step that will change the way we manage this chronic disease,” said Professor Gilles Salles, Centre Hospitalier Lyon Sud, France, and principal investigator for the PRIMA trial. “Having access to this new treatment option will enable patients with this serious form of blood cancer to live their lives with their disease under better control.”

The approval is based on the results from the phase III PRIMA study which demonstrated that continuing MabThera for two years (maintenance treatment) in patients who responded to initial treatment with MabThera plus chemotherapy doubled the likelihood of these patients living without their disease worsening (known as progression-free survival) compared to those who did not receive maintenance therapy (based on a hazard ratio of 0.50, 95% CI, 0.39 - 0.64; p=0.0001). After two years of follow-up, 82% of patients who received MabThera maintenance were in remission compared to 66% of patients who did not. The benefit of maintenance treatment was seen across all major patient groups analysed within the trial, regardless of their tumour burden, age, gender or their response to initial treatment.

“The European approval of first line MabThera maintenance treatment of follicular lymphoma is excellent news for patients,” said Hal Barron, M.D., Head of Global Development and Chief Medical Officer at Roche.
“Reducing the number of times the disease relapses and requires subsequent treatments will improve the lives of patients with this specific type of blood cancer.”

Based on the PRIMA study data, Genentech also submitted a sBLA (supplemental Biologics License Application) for MabThera (known as Rituxan in the United States, Japan and Canada) in March 2010 to the U.S. Food and Drug Administration (FDA).

About Follicular Lymphoma
Follicular lymphoma (FL), a cancer of the blood, is a common type of non-Hodgkin’s lymphoma (NHL). Approximately 286,000 people worldwide are diagnosed with NHL each year, and FL accounts for about one in four of these cases. Follicular lymphoma unfortunately remains incurable and despite substantial progress, patients ultimately relapse and relapses require additional treatments and can lead to fatal outcomes.

Follicular lymphoma can occur at any time during adulthood, though people are typically diagnosed during their fifties and sixties, affecting both men and women.

About PRIMA
Sponsored by the Groupe d’Etude des Lymphomes de l’Adulte (GELA), PRIMA is an international, multicenter, randomised, phase III clinical study that enrolled 1,217 patients with previously untreated advanced follicular lymphoma. The study evaluated the efficacy and safety profile of maintenance MabThera in patients who responded to initial treatment with MabThera plus chemotherapy (induction treatment).

In the PRIMA study, eight cycles of MabThera plus either CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CVP (cyclophosphamide, vincristine, prednisone) or FCM (fludarabine, cyclophosphamide, mitoxantrone) chemotherapy was used as initial treatment. Patients who responded and were eligible for maintenance treatment (1,018/1,217) were randomised to receive MabThera alone, given once every two months for two years, or observation alone.

The safety profile was consistent with those previously reported in pivotal studies of MabThera alone or in combination with chemotherapy. Serious adverse events (Grade 3 or 4) were reported in 23% of patients who received MabThera maintenance compared to 16% who did not, including low white blood cell (neutrophil) counts (4% vs. 1%) and infections (4% vs. 1%).
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 in the EU:

- For the treatment of patients with previously untreated or relapsed/refractory chronic lymphocytic leukaemia (CLL) in combination with chemotherapy; only limited data are available on efficacy and safety for patients previously treated with monoclonal antibodies including MabThera or patients refractory to previous MabThera plus chemotherapy
- For the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy
- As maintenance treatment 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

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 2009, Roche had over 80'000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 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.

All trademarks used or mentioned in this release are protected by law.
Additional information
- Cancer: www.health-kiosk.ch/start_krebs.htm
- World Health Organization: www.who.int
- Groupe d'Etude des Lymphomes de l'Adulte (GELA): www.gela.org

Roche Group Media Relations
Phone: +41 -61 688 8888 / e-mail: basel.mediaoffice@roche.com
- Alexander Klauser (Head)
- Silvia Dobry
- Claudia Schmitt
- Annette Walz

References

1 Salles, G. et al PRIMA: Rituximab Maintenance For Two Years Significantly Improves the Outcome of Patients With Untreated High Tumor Burden Follicular Lymphoma After Response to Immunochemotherapy: Results of the PRIMA Study: Abstract #8004; 46th Annual Meeting of the American Society of Clinical Oncology, 2010.
2 http://www.lymphomacoalition.org accessed September 2010