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Roche's new time-saving subcutaneous formulation of MabThera approved in Europe for the treatment of common forms of non-Hodgkin Lymphoma

MabThera SC offers a faster treatment experience for patients while saving valuable time for health systems

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission (EC) has approved a new subcutaneous (SC) formulation of MabThera (rituximab) for the treatment of patients with follicular lymphoma and diffuse large B-cell lymphoma. Following the approval of Herceptin SC in September 2013, this is the second European approval for a novel subcutaneous formulation of one of Roche's oncology products.

“As part of our mission to improve people's lives, we are pleased that MabThera SC has been approved for patients with common forms of non-Hodgkin lymphoma”, said Sandra Horning, M.D., Chief Medical Officer and Head, Global Product Development. “We believe that the faster five minute administration will significantly improve the treatment experience for patients and providers compared to the approximate 2.5 hour infusion time for intravenous MabThera.”

The European approval was based primarily on data from the pivotal SABRINA study, which was recently published in *The Lancet Oncology*ⁱ.

Roche expects to begin launching MabThera SC in a number of European markets throughout 2014.

About MabThera

MabThera is a therapeutic monoclonal 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 defenses 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 (Rituxan in the United States, Japan and Canada), discovered by Biogen Idec, first received FDA approval for the treatment of relapsed indolent non-Hodgkin Lymphoma (NHL) in 1997 and was the first targeted cancer medicine approved by the U.S. Food and Drug Administration (FDA). MabThera was approved in the EU in June 1998, and has since been used to treat more than 2.7 million people with specific blood cancers. For more than 15 years, the efficacy and safety of MabThera has been documented in more than 300 phase II/III clinical studies. MabThera has been approved for the treatment of several blood cancers, specifically, certain types of NHL and for chronic lymphocytic leukemia (CLL). It continues to be studied in other types of blood cancers and disease areas where CD20-positive cells are believed to play a role.

MabThera is known as Rituxan in the United States, Japan and Canada. Genentech, a member of the Roche Group, and Biogen Idec collaborate on Rituxan 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 non-Hodgkin lymphoma

There are two main types of lymphoma: Hodgkin lymphoma and non-Hodgkin lymphoma (NHL). NHL represents approximately 85% of all lymphoma diagnosedⁱⁱ and was responsible for approximately 200,000 annual deaths worldwide in 2012ⁱⁱⁱ.

Lymphomas are a cancer of the lymphatic system (composed of lymph vessels, lymph nodes and organs) which helps to keep the bodily fluid levels balanced and to defend the body against invasion by disease. Lymphoma develops when white blood cells (usually B-lymphocytes) in the lymph fluid become cancerous and begin to multiply and collect in the lymph nodes or lymphatic tissues such as the spleen. Some of these cells are released into the bloodstream and spread around the body, interfering with the body's production of healthy blood cells.

About Roche in hematology

For more than 20 years, Roche has been developing medicines that redefine treatment in hematology. Today, we're investing more than ever in our effort to bring innovative treatment options to people with cancers of the blood.

In addition to MabThera and Gazyva, Roche's pipeline of potential hematology medicines includes an anti-CD79b antibody drug conjugate (RG7596/polatuzumab vedotin), a small molecule antagonist of MDM2

(RG7112) and in collaboration with AbbVie, a small molecule BCL-2 inhibitor (RG7601/GDC-0199/ABT-199).

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, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in *in vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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ⁱ Davies, A. et al. (2014) Pharmacokinetics and safety of subcutaneous rituximab in follicular lymphoma (SABRINA): stage 1 analysis of a randomised phase 3 study *The Lancet Oncology*, Early Online Publication, 10 February 2014
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ⁱⁱ Globocan (2012) Table by cancers. Worldwide incidence of cancers in males and females.
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ⁱⁱⁱ Globocan (2012) Cancer Incidence and Mortality Worldwide. World, non-Hodgkin lymphoma, 2010. (URL accessed 18.09.13).
http://globocan.iarc.fr/Pages/fact_sheets_population.aspx (URL accessed 03.03.14).