Basel, 31 May 2016

Roche’s subcutaneous formulation of MabThera receives approval in Europe for people with chronic lymphocytic leukaemia

- Subcutaneous (SC) formulation of MabThera saves time and eases treatment burden compared with intravenous form
- The phase Ib SAWYER study demonstrated comparable safety and efficacy between MabThera SC and intravenous MabThera in combination with chemotherapy

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission (EC) has approved the subcutaneous (SC) formulation of MabThera® (rituximab) for people with previously untreated and relapsed/refractory chronic lymphocytic leukaemia (CLL). The approved dose for CLL is 1600mg. Following the approval of MabThera SC (1400 mg) for common forms of non-Hodgkin lymphoma in March 2014, this is the second European approval for the formulation.

“MabThera SC provides patients with significantly faster treatment administration and the opportunity to enjoy more time outside the clinical setting compared to intravenous delivery of the medicine,” said Sandra Horning, M.D., Chief Medical Officer and Head, Global Product Development. “Today’s approval in CLL means the benefit of MabThera SC can be offered to even more patients.”

The European approval was based primarily on data from the phase Ib SAWYER study, in which previously untreated CLL patients received either MabThera SC (1600 mg) or intravenous MabThera (500mg/m2) in combination with chemotherapy (fludarabine and cyclophosphamide), a current standard of care. SAWYER demonstrated treatment with MabThera SC resulted in comparable levels of the medicine in the blood (serum concentrations), as well as efficacy and safety, to intravenous MabThera, and results were recently published in The Lancet Haematology1.
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 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 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 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 Chronic Lymphocytic Leukaemia (CLL)

Chronic lymphocytic leukaemia (CLL) is the most common type of leukaemia in the Western world². CLL mainly affects men and the median age at diagnosis is about 70 years³. Worldwide, the incidence of all leukaemias is estimated to be over 350,000² and CLL is estimated to affect around one-third of all people newly diagnosed with leukaemia⁴.

About Roche in haematology

For more than 20 years, Roche has been developing medicines that redefine treatment in haematology. Today, we’re investing more than ever in our effort to bring innovative treatment options to people with diseases of the blood. In addition to approved medicines MabThera/Rituxan (rituximab), Gazyva/Gazyvaro (obinutuzumab), and Venclexta™ (venetoclax) in collaboration with AbbVie, Roche’s pipeline of investigational haematology medicines includes Tecentriq (atezolizumab), an anti-CD79b antibody drug conjugate (polatuzumab vedotin/RG7596) and a small molecule antagonist of MDM2 (idasanutlin/RG7388). Roche’s dedication to developing novel molecules in haematology expands beyond oncology, with the development of the investigational haemophilia A treatment emicizumab (ACE910).
About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives.

Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 billion. 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.

All trademarks used or mentioned in this release are protected by law.

Roche Group Media Relations
Phone: +41 61 688 8888 / e-mail: roche.mediarelations@roche.com
- Nicolas Dunant (Head)
- Catherine Dürr
- Ulrike Engels-Lange
- Anja von Treskow
References