Basel, 12 January 2017

Roche’s subcutaneous formulation of MabThera approved in Switzerland for the treatment of common types of non-Hodgkin lymphoma
Administration time significantly reduced with subcutaneous formulation

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the Swiss Agency for Therapeutic Products (Swissmedic) has approved a new subcutaneous formulation of MabThera (rituximab) for the treatment of two types of non-Hodgkin lymphoma – follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL).

“We are pleased that the time-saving subcutaneous formulation of MabThera has now also been approved in Switzerland for the treatment of common types of non-Hodgkin lymphoma,” said Professor Anja-Alexandra Dünne, Country Medical Director, Roche Pharma (Switzerland) Ltd. “Because the treatment is simpler and faster to administer, the burden on the patient is considerably reduced.”

With the new formulation, the time required for the administration of MabThera can be reduced to five to seven minutes, compared to the roughly 2.5-hour infusion time for intravenous MabThera. In the extensive study, subcutaneous administration was preferred by 80% of patients who had received both intravenous and subcutaneous MabThera in the course of treatment. The latter was felt to be more comfortable during administration and had a lower psychological impact.

About the pivotal studies
The Swiss approval was largely based on data from the pivotal SABRINA study, which demonstrated that subcutaneous MabThera is non-inferior to the intravenous formulation with regard to efficacy and safety in the FL indication. In addition, for the DLBCL indication, the MABEASE study showed that similar safety and efficacy outcomes are achieved in patients switching from intravenous to subcutaneous administration.
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.

Over the past 20 years, MabThera has been shown to be effective in a wide variety of indications. MabThera was first approved in Switzerland in 1997 for induction therapy in patients with relapsed FL. There followed a number of additional approvals for non-Hodgkin lymphoma indications – previously untreated FL and DLBCL – and for chronic lymphocytic leukemia (CLL). In addition, MabThera has been approved in Switzerland for the treatment of certain non-oncology diseases – rheumatoid arthritis (RA) and ANCA-associated vasculitis (AAV).

About subcutaneous MabThera
The subcutaneous form of MabThera is a ready-to-use liquid formulation that is administered as a 1400 mg/11.7 ml fixed dose. This simplifies healthcare procedures by removing the need for reconstitution or dose calculation according to individual body weight.

The subcutaneous formulation of MabThera uses a recombinant human hyaluronidase technology that produces temporary local degradation of hyaluronan in subcutaneous tissue. This leads to a temporary increase in the subcutaneous space, permitting pain-free administration of larger volumes of liquid into the abdominal wall. This enables the 11.7 ml volume of the subcutaneous formulation of MabThera to be dispersed and absorbed over a greater area in approximately 5 minutes. The subcutaneous tissue returns to its original state about 24 hours after subcutaneous administration.
About non-Hodgkin lymphoma

There are two main types of lymphoma: Hodgkin lymphoma and non-Hodgkin lymphoma (NHL). NHL represents approximately 85% of all lymphomas diagnosed.

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.

Follicular lymphoma (FL) is the most common type of indolent NHL, accounting for around 25% of all cases of NHL. As the progression of FL is usually slow and painless, the majority of patients are diagnosed at a late stage. Like most other lymphomas, FL occurs more frequently in older patients.

Diffuse large B-cell lymphoma (DLBCL) is the most common type of malignant lymphoma in the Western world, accounting for approximately 30% of all cases of NHL. It has an aggressive course, with a median survival of less than a year in untreated patients. Typical of DLBCL are fast-growing tumour masses which can occur almost anywhere in the body and, as well as pain, can cause various symptoms such as fever, weight loss and night sweats. DLBCL is a potentially curable lymphoma; indeed, more than 50% of patients can be permanently cured. DLBCL most commonly affects older patients, with the median age at the time of diagnosis being 70 years.

About Roche in haematology

For more than 20 years, Roche has been developing medicines that redefine treatment in haematology. In addition to MabThera and Gazyvaro, Roche’s pipeline includes further potential haematology medicines.
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 eight 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.

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