FDA approves label update for Roche’s Mabthera/Rituxan (rituximab) in two rare forms of vasculitis

- MabThera/Rituxan label updated to include information for follow up treatment in adult patients with Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) who have achieved disease control with induction treatment
- MabThera/Rituxan in combination with glucocorticoids (GCC) is the only FDA-approved therapy for these rare, potentially life-threatening blood vessel disorders

Basel, 19 October 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has approved an update to the MabThera/Rituxan® (rituximab) label to include information on follow up treatment of adult patients with Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) who have achieved disease control with induction treatment. The label update was based on data from a Roche-supported study by the French Vasculitis Study Group showing that treatment with the rituximab regimen* resulted in fewer major relapses by month 28 compared to treatment with azathioprine. The observed safety profile was consistent with that previously observed in this patient population. MabThera/Rituxan, in combination with glucocorticoids (GCC), was approved by the FDA in 2011 for adult patients with GPA and MPA.

“Options for continued treatment in GPA and MPA, chronic autoimmune diseases in which patients experience periods of flares, are currently limited,” said Sandra Horning, M.D., Roche’s Chief Medical Officer and Head of Global Product Development. “As part of our commitment to support people living with rare diseases, we are pleased to provide updated prescribing information for MabThera/Rituxan to help physicians make more informed decisions about therapeutic options for patients who have achieved disease control with induction treatment.”

GPA and MPA are two types of ANCA-associated vasculitis (AAV), a form of vasculitis, or inflammation of the blood vessels, that largely affects the small blood vessels of the kidneys, lungs and a variety of other organs.[1] MabThera/Rituxan, in combination with glucocorticoids (GCC), was approved by the FDA in 2011 for adult patients with GPA and MPA, with the precaution that limited data were available on the safety and efficacy of subsequent courses of MabThera/Rituxan in patients with GPA and MPA, and that the safety and efficacy of retreatment with MabThera/Rituxan had not been established. As part of this label update, the precaution has been removed from the MabThera/Rituxan prescribing information.

The U.S. label update is based on data from the MAINRITSAN trial, a Roche-supported, randomised, controlled clinical trial, conducted by the French Vasculitis Study Group, that used Roche-manufactured, European Union (EU)-approved rituximab product as the clinical trial material. The study evaluated the efficacy and safety of the rituximab regimen* compared to azathioprine as follow up treatment in 115 patients (86 with GPA, 24 with MPA, and 5 with renal-limited AAV), who had achieved disease control after induction of remission with GCC and cyclophosphamide.[2] The primary endpoint was the
occurrence of major relapse† through month 28. By month 28, major relapse occurred in 3 patients (5 percent) on the rituximab regimen* and 17 patients (29 percent) in the azathioprine group.

*Rituximab regimen = Roche-manufactured, European Union (EU)-approved rituximab + glucocorticoids

†Major relapse in the trial was defined by the reappearance of clinical and/or laboratory signs of vasculitis activity that could lead to organ failure or damage, or could be life threatening.

About Granulomatosis with Polyangiitis and Microscopic Polyangiitis
Granulomatosis with Polyangiitis (GPA) (formerly known as Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) are two types of ANCA-associated vasculitis (AAV).†[1] AAV is a form of vasculitis, or blood vessel inflammation, that primarily affects small blood vessels.†[1] In general, GPA and MPA both affect the small blood vessels of the kidneys, lungs, sinuses, and a variety of other organs, but the diseases may affect each person differently.†[3,4] Historically, untreated AAV has a poor prognosis: more than 80 percent of untreated patients die within one year of diagnosis, most frequently from renal or respiratory failure.†[5] Both GPA and MPA are considered rare diseases, with an estimated prevalence in the United States of up to three cases per 100,000 people.†[3,4]

About MabThera/Rituxan
MabThera/Rituxan is approved to treat rheumatoid arthritis (RA) in combination with another prescription medicine called methotrexate, to reduce the signs and symptoms of moderate to severe active RA in adults, after treatment with at least one other medicine called a tumour necrosis factor (TNF) antagonist has been used and did not work well enough.

MabThera/Rituxan, in combination with glucocorticoids, is indicated for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's, GPA) and microscopic polyangiitis (MPA), and for follow up treatment of adult patients with GPA and MPA who have achieved disease control with induction treatment.

MabThera/Rituxan is indicated to treat adult patients with moderate to severe pemphigus vulgaris (PV).

People with serious infections should not receive MabThera/Rituxan. It is not known if MabThera/Rituxan is safe or effective in children.

About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives. 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.

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
Roche is committed to improving patient care and advancing medical knowledge. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty 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. Moreover, for the tenth consecutive year, Roche has been recognised as the most sustainable company in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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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