Phase III PEMPHIX study showed that Roche's Mabthera/Rituxan (rituximab) is superior to standard of care in achieving sustained remission in patients with pemphigus vulgaris

- **MabThera/Rituxan met the primary and secondary endpoints in the phase III PEMPHIX study**
- **MabThera/Rituxan was the first and only biologic therapy approved by the US Food and Drug Administration (FDA), in June 2018 for the treatment of pemphigus vulgaris based on results from the Ritux 3 clinical trial**
- **Results will be submitted to health authorities around the world, including the FDA**

Basel, 13 June 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced positive topline results from the Roche-sponsored phase III PEMPHIX study, evaluating the efficacy and safety of MabThera®/Rituxan® (rituximab) compared to mycophenolate mofetil (MMF) in adults with moderate to severe pemphigus vulgaris (PV). The study met the primary endpoint, and demonstrated that MabThera is superior to MMF in achieving sustained complete remission.

"The PEMPHIX study provides additional clinical evidence for the use of MabThera/Rituxan for the treatment of pemphigus vulgaris," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "These data also demonstrated that MabThera/Rituxan may provide complete remission rates and successful tapering of corticosteroid therapy that is superior to MMF in adults with pemphigus vulgaris."

The primary endpoint was the percentage of participants who achieved sustained complete remission off corticosteroid therapy (no disease activity, as evaluated by Pemphigus Disease Area Index, without the use of steroids for 16 consecutive weeks or more) at week 52. MabThera/Rituxan also met the secondary endpoints, including cumulative corticosteroid dose, number of flares, time to sustained remission and time to disease flare. Adverse events were generally consistent with those seen in previous MabThera/Rituxan clinical studies for other autoimmune indications.

PV is a rare, serious and potentially life-threatening condition characterised by progressive painful blistering of the skin and mucous membranes. [1] MMF is an unapproved treatment for PV that is accepted as standard of care. In June 2018, MabThera/Rituxan became the first biologic therapy approved by the FDA and the European Commission for PV and the first major advancement in the treatment of the disease in more than 60 years. This approval was based on the Ritux 3 clinical trial. [2] The PEMPHIX trial provided additional clinical evidence on the effectiveness of MabThera/Rituxan for PV. Complete data from the PEMPHIX study will be presented at an upcoming medical congress.

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About the PEMPHIX study
PEMPHIX is a phase III, randomised, double-blind, double-dummy, active-comparator, parallel-arm multicenter study (NCT02383589) designed to evaluate the efficacy and safety of MabThera/Rituxan compared with mycophenolate mofetil (MMF) in patients with moderate to severe active pemphigus vulgaris requiring 60-120 mg/day oral prednisone (or equivalent). Participants were randomly assigned to receive MabThera/Rituxan plus MMF placebo or MabThera/Rituxan placebo plus MMF. MabThera/Rituxan was administered at a dose of 1000 mg via IV infusion on day 1 and 15, with a repeat administration on days 168 and 182. MMF was administered at a dose of 2 grams orally daily from day 1 to week 52. The primary endpoint is the percentage of participants who achieved sustained complete remission, evaluated by the Pemphigus Disease Area Index (PDAI) Activity Score, for at least 16 consecutive weeks at week 52. Secondary endpoints include cumulative oral corticosteroid dose, number of disease flares, time to sustained complete remission, time to disease flare and health-related quality of life, as measured by the Dermatology Life Quality Index.

About Pemphigus Vulgaris
Pemphigus vulgaris is an autoimmune, blistering disease, occurring within the epidermis, affecting the skin and mucous membranes. [1] It is the most common type of a group of autoimmune disorders collectively called pemphigus. [3] It is estimated that around three in every 100,000 people are diagnosed with this disease globally. [4]

About MabThera/Rituxan
MabThera (Rituxan in the US) in combination with methotrexate is indicated for the treatment of adults with severe active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARD) including one or more tumour necrosis factor (TNF) inhibitor therapies. MabThera/Rituxan, in combination with glucocorticoids, is indicated for the treatment of adults with severe, active granulomatosis with polyangiitis (Wegener's, GPA) and microscopic polyangiitis (MPA). People with serious infections should not receive MabThera/Rituxan. It is not known if MabThera/Rituxan is safe or effective in children.

About Roche in rheumatology and beyond
For more than 50 years, Roche has followed the science to pioneer medicines for immune-mediated rheumatic diseases. First-in-class anti-IL-6 receptor therapy Actemra®/RoActemra® (tocilizumab) has treated more than one million people with debilitating conditions, such as rheumatoid arthritis (RA), polyarticular and systemic juvenile idiopathic arthritis, giant cell arteritis and chimeric antigen receptor T-cell-induced cytokine release syndrome. Rituxan/MabThera (rituximab), which targets CD20, has significant clinical and real-world experience treating rheumatic conditions including RA, granulomatosis with polyangiitis and microscopic polyangiitis. Roche aims to provide solutions for people that need new treatments most, particularly those with severe or life-threatening conditions and limited treatment options. Our pipeline consists of treatments designed to target immune pathways including a glycoengineered type II anti-CD20 antibody in lupus nephritis.

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 diabetes management. 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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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