Roche's Gazyva (obinutuzumab) delivers positive topline results for phase II lupus nephritis study

- **NOBILITY showed that Gazyva helped more patients achieve a complete renal response when added to standard of care**
- **The phase II study met both primary and key secondary endpoints**
- **There are currently no US Food and Drug Administration (FDA) approved therapies for lupus nephritis**

Basel, 11 June 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced positive topline results for NOBILITY, a phase II clinical trial investigating the safety and efficacy of Gazyva® (obinutuzumab) for adults with proliferative lupus nephritis. The study met its primary endpoint, showing Gazyva, in combination with standard of care (mycophenolate mofetil or mycophenolic acid and corticosteroids), demonstrated enhanced efficacy compared to placebo plus standard of care alone in achieving complete renal response at one year. In addition, Gazyva met key secondary endpoints showing improved overall renal responses (complete and partial renal response) and serologic markers of disease activity as compared to placebo.

"There are no FDA-approved treatments for lupus nephritis, a potentially life-threatening condition in which patients are at high risk for progressing to end-stage renal disease or death," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We have been investigating a possible treatment for lupus nephritis for more than a decade and have integrated key learnings from that experience in how we study the condition. We are encouraged by the NOBILITY results, which showed a statistically significant difference in achievement of complete renal response, overall renal response, and other measures of disease activity, and support the potential for a new treatment option for people living with lupus nephritis."

Lupus nephritis is a severe and potentially life-threatening manifestation of systemic lupus erythematosus (SLE) resulting from inflammation of the kidneys, with proliferative lupus nephritis being the most severe form and associated with the highest risk of end-stage renal disease and death.[1,2] In addition to meeting the primary endpoint, the study's key secondary endpoint, defined as achievement of overall renal response (complete or partial renal response) at one year, was also met. No new safety signals were observed with Gazyva in the study at the time of this analysis. The full results from the study will be presented at a future medical meeting.

About the NOBILITY Study
The phase II, randomised, double-blind, placebo-controlled, multi-center study, NOBILITY (NCT02550652), compares the safety and efficacy of Gazyva, combined with mycophenolate mofetil (MMF) or mycophenolic acid (MPA) and corticosteroids, to placebo, combined with MMF or MPA and corticosteroids, in adult patients with ISN/RPS 2003 class III or IV proliferative lupus nephritis. The study enrolled 126 people who were randomised to receive Gazyva or placebo infusions on days 1, 15, 168, and 182.

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland
Investor Relations email: investor.relations@roche.com
Tel. +41 61 68-88880 Fax +41 61 69-10014 www.roche.com

The primary endpoint was the proportion of participants who achieved a protocol-defined complete renal response (CRR) at 52 weeks.

About Lupus Nephritis
Lupus nephritis is a severe and potentially life-threatening disorder of the kidneys. Lupus nephritis is a complication of systemic lupus erythematosus (SLE), an autoimmune disease where a person's own immune system attacks healthy cells and organs.[1] It is estimated that SLE affects 24 per 100,000 in the population globally.[3] Up to 60% of people with SLE will develop lupus nephritis, and up to 25% of people with the condition develop end-stage renal disease.[1,2] Lupus nephritis overwhelmingly impacts women, particularly young women of colour. About 90% of those diagnosed are women, and African-American, Hispanic, Native American and Asian-American women are two to three times more likely than Caucasian women to get lupus.[4] Currently, there is no cure for lupus or lupus nephritis.[4]

About Gazyva
Gazyva is an engineered monoclonal antibody designed to attach to CD20, a protein found only on certain types of B-cells. It is thought to work by attacking targeted cells both directly and together with the body's immune system. In the United States, Gazyva is part of a collaboration between Genentech and Biogen. Combination studies investigating Gazyva with other approved or investigational medicines, including cancer immunotherapies and small molecule inhibitors, are underway across a range of blood cancers.

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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Roche Investor Relations

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Jon Kaspar Bayard
Phone: +41 61 68-83894
e-mail: jon_kaspar.bayard@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com

Dr. Lisa Tuomi
Phone: +1 650 467 8737
e-mail: tuomi.lisa@gene.com