

Roche's Gazyva (obinutuzumab), in combination with standard of care, more than doubles the percentage of lupus nephritis patients achieving complete renal response, compared to standard of care alone

- **NOBILITY phase II study showed 40% of patients treated with Gazyva plus standard of care achieved complete renal response at Week 76, compared to 18% of patients treated with placebo plus standard of care**
- **Roche plans to initiate enrollment in a phase III programme**

Basel, 11 November 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced data from the phase II NOBILITY study, investigating the safety and efficacy of Gazyva® (obinutuzumab) for adults with proliferative lupus nephritis.¹ The study met the primary endpoint with Gazyva, in combination with standard of care (mycophenolate mofetil or mycophenolic acid and corticosteroids), demonstrating superiority compared to placebo plus standard of care. Patients treated with Gazyva showed increasing rates of complete renal response (CRR) from week 52 to week 76, with 40% of patients in the Gazyva group achieving CRR, compared to 18% of patients in the placebo group at week 76 (p=0.007). Gazyva additionally met key secondary efficacy endpoints showing improved overall renal response (complete or partial renal responses) and serologic markers of disease activity as compared to placebo. No new safety signals were observed with Gazyva in the study at the time of this analysis. Through week 76, serious adverse events (24% vs. 29% in placebo group) and serious infections (6% vs. 18% in placebo group) were not increased with Gazyva. These data were presented as a late-breaking oral presentation at the American Society of Nephrology's (ASN) Kidney Week 2019 in Washington, DC, US, on 8 November (Abstract FR-OR136), and at the 2019 American College of Rheumatology (ACR) Annual Meeting in Atlanta, Georgia, US, on 10 November (Abstract 939).²

"We are very encouraged by the positive results from the NOBILITY study, which suggest that Gazyva may provide a clinically meaningful benefit for adults with proliferative lupus nephritis; a condition for which there is a strong need for more effective and targeted treatment options," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "These results support the continued development of Gazyva for people with lupus nephritis and underscore our longstanding commitment to pursue new treatment options that may benefit the lupus community."

Lupus nephritis is a severe and potentially life-threatening manifestation of systemic lupus erythematosus resulting from inflammation of the kidneys, with proliferative lupus nephritis being the most severe form and associated with high-risk of end-stage renal disease and death.^{3,4} In September 2019, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to Gazyva for adults with lupus nephritis based on the phase II NOBILITY study data.

An audio webcast for analysts and investors on the phase II NOBILITY study data will be held on Tuesday 12 November 2019 from 4:30-5:30 pm CET / 10:30-11:30 am EST. Further details are available [here](#).

About the NOBILITY Study

The phase II, randomised, double-blind, placebo-controlled, multi-center study, NOBILITY (NCT02550652), compared 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 125 people who were randomised to receive Gazyva or placebo infusions on days 1, 15, 168, and 182. The primary endpoint was the proportion of participants who achieved a protocol-defined complete renal response (CRR) at 52 weeks. Key secondary endpoints included overall renal responses (complete or partial renal response) and serologic markers of disease activity, as compared to placebo. Patients were followed in a blinded fashion through Week 104, and patients with persistent B-cell depletion are being followed for safety and continued B-cell measurements.

About Lupus Nephritis

Lupus nephritis is a severe and potentially life-threatening disorder of the kidneys. Lupus nephritis is one of the most severe manifestations of systemic lupus erythematosus (SLE), an autoimmune disease where a person's own immune system attacks healthy cells and organs, including, in the case of lupus nephritis, the kidneys.³ This causes kidney inflammation and may lead to blood and/or protein in the urine, high blood pressure, poor kidney function, or kidney failure. It is estimated that SLE affects 24 per 100,000 in the population globally.⁵ 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.^{3,4} Lupus overwhelmingly impacts women, making up 90% of the patient population. Women from African, Hispanic and Asian ethnic groups are two to three times more likely than Caucasian women to be diagnosed with lupus.⁶ Currently, there is no cure for lupus or lupus nephritis.⁶

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 Immunology

The Roche Group's immunology medicines include: Actemra®/RoActemra® (tocilizumab) for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis (pJIA), systemic juvenile idiopathic arthritis (sJIA) and giant cell arteritis (GCA) and for the treatment of severe or life-threatening chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS); Rituxan®/MabThera® (rituximab) for rheumatoid arthritis granulomatosis with polyangiitis and microscopic polyangiitis and for pemphigus vulgaris (PV); Xolair® (omalizumab) for allergic asthma and chronic idiopathic urticaria (CIU); Pulmozyme® (dornase alfa) for cystic fibrosis; and Esbriet® (pirfenidone) for idiopathic pulmonary fibrosis (IPF). Roche has several investigational medicines in clinical development for immunological diseases including autoimmune disorders, rheumatoid arthritis, ulcerative colitis and Crohn's disease.

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. More than 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 eleventh consecutive year, Roche has been recognised as one of the most sustainable companies 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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