Media & Investor Release

European Commission approves Roche's Gazyva/Gazyvaro for adults with active lupus nephritis

- **Approval based on phase II NOBILITY and phase III REGENCY studies showing superiority of Gazyva/Gazyvaro over standard therapy alone[1,2]**
- **Gazyva/Gazyvaro is the only anti-CD20 antibody to demonstrate a benefit in a complete renal response in lupus nephritis in a randomised phase III study[2]**
- **Gazyva/Gazyvaro could become a new standard of care for up to an estimated 135,000 people affected by lupus nephritis in the European Union, potentially helping to delay or prevent end-stage kidney disease[3,4]**

Basel, 9 December 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission has approved Gazyva®/Gazyvaro® (obinutuzumab) in combination with mycophenolate mofetil (MMF) for the treatment of adult patients with active Class III or IV, with or without concomitant Class V, lupus nephritis. These disease classifications describe the extent and nature of damage to the kidneys and renal function, a key characteristic of lupus nephritis.

"This approval marks a major advance in the treatment of lupus nephritis for people across Europe who wrestle with this disease," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "By controlling disease activity, Gazyva/Gazyvaro could help delay or prevent progression to end-stage kidney disease and the need for dialysis or transplant, underscoring its potential to become a new standard of care in Europe."

The approval is based on positive results from the phase II NOBILITY and phase III REGENCY studies. Key results from REGENCY, published in the *New England Journal of Medicine*, demonstrated that 46.4% of people on Gazyva/Gazyvaro plus standard therapy (MMF and glucocorticoids) achieved a complete renal response compared to 33.1% on standard therapy alone. Data showed a statistically significant and clinically meaningful reduction of corticosteroid use and an improvement in proteinuric response, all signalling improved disease control. Additionally, clinically meaningful improvements in complement levels and reductions in anti-dsDNA were observed, both markers of disease activity and inflammation. The safety profile of Gazyva/Gazyvaro was consistent with the well-characterised profile observed in its haematology-oncology indications.[2]

"The symptoms of lupus nephritis and their unpredictable nature can impact quality of life, emotional wellbeing and limit future family and career prospects," said Jeanette Andersen, Chair of Lupus Europe. "This approval for Gazyva/Gazyvaro offers a much needed treatment

that may help ease the burden of living with this complex disease and reflects the vital role of patient community experts in trial development."

Lupus nephritis is a potentially life-threatening disease that predominantly affects women of colour and childbearing age, with up to an estimated 135,000 people currently living with the condition across the European Union.[3-5] With current treatments, up to one third of people will progress to end-stage kidney disease (ESKD) within 10 years, where the only options are dialysis or transplant.[6] New treatments that can effectively control the disease may help delay or prevent the onset of ESKD.[6,7]

This approval follows the Gazyva/Gazyvaro approval by the US Food and Drug Administration for the treatment of adults with active lupus nephritis who are receiving standard therapy in October 2025. Additionally, recent positive phase III read-outs in childhood idiopathic nephrotic syndrome and adult systemic lupus erythematous support the potential of Gazyva/Gazyvaro to help address disease activity across a spectrum of autoimmune or immune-related diseases.

Gazyva/Gazyvaro continues to be investigated in children and adolescents with lupus nephritis and adults with membranous nephropathy, as part of our ambition to be leaders in immune-mediated rheumatology and nephrology diseases.[8,9]

About Gazyva/Gazyvaro

Gazyva®/Gazyvaro® (obinutuzumab) is a humanised monoclonal antibody designed with a Type II anti-CD20 region, for direct B cell death, and a glycoengineered Fc region, for higher binding affinity and increased antibody-dependent cellular cytotoxicity (ADCC).[10] CD20 is a protein found on certain types of B cells.

Gazyva/Gazyvaro is approved for adults with lupus nephritis in the United States and European Union and in over 100 countries for various types of haematological cancers.

About the REGENCY study

REGENCY [NCT04221477] is a phase III, randomised, double-blind, placebo-controlled, multicentre study investigating the efficacy and safety of Gazyva®/Gazyvaro® (obinutuzumab) plus standard therapy (mycophenolate mofetil and glucocorticoids) in people with active/chronic International Society of Nephrology/Renal Pathology Society 2003 proliferative Class III or IV lupus nephritis, with or without Class V. The study enrolled 271 people, who were randomised 1:1 to receive either Gazyva/Gazyvaro plus standard therapy or placebo plus standard therapy. REGENCY was designed based on robust phase II data and conducted during the COVID-19 pandemic. The study population was representative of the real-world population of people with lupus nephritis.

About Lupus nephritis

Lupus nephritis is a potentially life-threatening manifestation of systemic lupus erythematosus, an autoimmune disease that commonly affects the kidneys.[11] Lupus nephritis is characterised by an irreversible loss of nephrons, the filtering structures of the kidneys. Periods of intense disease activity, known as flares, can speed up the loss of nephrons and, if left unchecked, may lead to a progressive loss of kidney function. Even with the latest treatments, up to a third of people will progress to end-stage kidney disease, where dialysis or transplant are the only options and life expectancy and quality of life are substantially reduced.[6]

Lupus nephritis affects more than 1.7 million people worldwide – predominantly women, mostly of colour and usually of childbearing age.[5,12,13] Currently, there is no cure.[11]

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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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