Media & Investor Release

FDA approves Roche's Gazyva/Gazyvaro for the treatment of lupus nephritis

- **FDA approval based on superiority of Gazyva/Gazyvaro over standard therapy alone, as shown in phase II NOBILITY and phase III REGENCY data[1,2]**
- **Gazyva/Gazyvaro is the only anti-CD20 monoclonal antibody to demonstrate a complete renal response benefit in lupus nephritis in a randomised phase III study[2]**
- **Lupus nephritis affects more than 1.7 million people worldwide, predominantly women of colour and childbearing age, with up to one-third of patients progressing to end-stage kidney disease[3-6]**

Basel, 20 October 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has approved Gazyva®/Gazyvaro®(obinutuzumab) for the treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy, as well as a shorter 90-minute infusion time after the first infusion, for eligible patients. Following four initial doses in the first year, Gazyva/Gazyvaro can be administered twice yearly, offering an effective and potentially more convenient treatment option than traditional targeted therapies.

"People with lupus nephritis who achieve a complete renal response are more likely to experience preserved kidney function and delay, or even prevention, of progression to end-stage kidney disease," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "The approval of Gazyva/Gazyvaro by the FDA marks an important step towards a potential new standard of care for lupus nephritis, one that could allow clinicians to offer their patients more effective disease control."

"As a severe and potentially life-threatening disease, lupus nephritis greatly disrupts daily life with chronic pain, fatigue, and the constant fear of worsening kidney health," said Louise Vetter, President and Chief Executive Officer, Lupus Foundation of America. "The FDA's approval of Gazyva/Gazyvaro offers renewed hope for people with lupus nephritis and their loved ones, as it provides an important new treatment option that has the potential to prevent long-term complications, including kidney failure."

This approval is based on positive results from the phase II NOBILITY and phase III REGENCY studies. In REGENCY, data showed that nearly half of the participants (46.4%) on Gazyva/Gazyvaro in combination with standard therapy achieved a complete renal response (CRR) compared to 33.1% on standard therapy alone. This was accompanied by clinically meaningful improvements in complement levels and reductions in anti-dsDNA, corticosteroid use, and proteinuria, all signalling improved disease control. The safety profile of

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Gazyva/Gazyvaro was consistent with the well-characterised profile observed in its haematology-oncology indications.[2]

Lupus nephritis affects more than 1.7 million people worldwide.[3,4] It disproportionately impacts women, mostly women of colour and of childbearing age, who often face more severe disease.[6] If left untreated, up to one-third of individuals can progress to end-stage kidney disease, which often requires dialysis or transplantation.[5]

Gazyva/Gazyvaro was granted Breakthrough Therapy Designation by the FDA in 2019 based on data from the phase II NOBILITY study. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recently issued a positive opinion recommending the approval of Gazyva/Gazyvaro for adults with active lupus nephritis, with a final decision from the European Commission expected in the near future.

Gazyva/Gazyvaro is being investigated in people with systemic lupus erythematosus, membranous nephropathy, idiopathic nephrotic syndrome, and in children and adolescents with lupus nephritis.[8-11] In addition to Gazyva/Gazyvaro, Roche has a broad pipeline targeting the immune drivers of rare and common kidney and kidney-related diseases.

About Gazyva/Gazyvaro

Gazyva®/Gazyvaro® (obinutuzumab) is a Type II engineered humanised monoclonal antibody designed to attach to CD20, a protein found on certain types of B cells.[12] In lupus nephritis, disease-causing B cells drive persistent inflammation that damages the kidneys and reduces their ability to function properly.[13] Data suggests that Gazyva/Gazyvaro depletes disease-causing B cells, helping to limit further damage to the kidneys and potentially preventing or delaying progression to end-stage kidney disease.[2]

Gazyva/Gazyvaro is already approved in 100 countries for various types of haematological cancers. In the United States, Gazyva/Gazyvaro is part of a collaboration between Genentech and Biogen.

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.[7] 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.[5]

Lupus nephritis affects more than 1.7 million people worldwide - predominantly women, mostly of colour and usually of childbearing age.[6] Currently, there is no cure.[7]

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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