Media & Investor Release

CHMP recommends EU approval of Roche's Gazyva/Gazyvaro for lupus nephritis

- **Positive recommendation based on phase II NOBILITY and phase III REGENCY data showing Gazyva/Gazyvaro's superiority over standard therapy alone[1,2]**
- **Gazyva/Gazyvaro is the only anti-CD20 antibody to demonstrate a complete renal response benefit in lupus nephritis in a randomised phase III study[2]**
- **Lupus nephritis is a debilitating condition that severely impacts a person's quality of life and affects more than 1.7 million people worldwide[3,4]**

Basel, 17 October, 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of 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 final decision from the European Commission is expected in the near future.

"As the only anti-CD20 to demonstrate a complete renal response benefit in a randomised phase III study of lupus nephritis, Gazyva/Gazyvaro has the potential to address an important unmet need for many people with this disease," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "Recognising the challenges faced by people with lupus nephritis and their caregivers, Gazyva/Gazyvaro may offer a new treatment option that can limit kidney damage and potentially prevent or delay end-stage kidney disease."

The recommendation 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 plus standard therapy (mycophenolate mofetil and glucocorticoids) achieved a complete renal response (CRR) compared to 33.1% on standard therapy alone. This was accompanied by a statistically significant and clinically meaningful reduction of corticosteroid use, and an improvement in proteinuric response, all signalling improved disease control. The safety profile of Gazyva/Gazyvaro was consistent with the well-characterised profile observed in its haematology-oncology indications.[2]

Earlier this year, data from the phase III REGENCY study were used to file a supplemental Biologics License Application with the US Food and Drug Administration (FDA). The FDA is expected to make a decision on approval this year.

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Gazyva/Gazyvaro is being investigated in systemic lupus erythematosus, membranous nephropathy, idiopathic nephrotic syndrome, and in children and adolescents with lupus nephritis.[5-8] In addition to Gazyva/Gazyvaro, Roche has a broad pipeline dedicated to target 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.[9] In lupus nephritis, disease-causing B cells drive persistent inflammation that damages the kidneys and reduces their ability to function properly.[10] 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 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.[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 within 10 years, where dialysis or transplant are the only options and life expectancy and quality of life are substantially reduced.[12]

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