# Media & Investor Release

## Positive phase III data for Roche's Gazyva/Gazyvaro show significant reduction in disease activity for systemic lupus erythematosus

- **Phase III ALLEGORY study met primary and all key secondary endpoints with Gazyva/Gazyvaro, an anti-CD20 monoclonal antibody designed for enhanced B cell depletion**
- **Gazyva/Gazyvaro has the potential to be a transformative new standard of care for up to 3.4 million people affected by systemic lupus erythematosus (SLE) worldwide**
- **If approved, Gazyva/Gazyvaro would be the first anti-CD20 therapy for SLE to directly target B cells, a key driver of inflammation and disease activity[1]**
- **These positive results follow the recent US FDA approval and positive EU CHMP opinion for Gazyva/Gazyvaro in lupus nephritis, alongside positive phase III data from the INShore study in idiopathic nephrotic syndrome**

Basel, 3 November 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today statistically significant and clinically meaningful results from the phase III ALLEGORY study of Gazyva®/Gazyvaro® (obinutuzumab) in adults with systemic lupus erythematosus (SLE) on standard therapy. The study met its primary endpoint showing a higher percentage of people achieved a minimum four-point improvement in SLE Responder Index 4 (SRI-4) at one year (52 weeks) with Gazyva/Gazyvaro versus standard therapy.[2] SRI is a tool that assesses changes in disease severity, symptoms and physical condition to indicate whether treatment is effective at controlling disease activity. All key secondary endpoints were also met. No new safety signals were identified, and safety was in line with the well-characterised profile of Gazyva/Gazyvaro.

"Systemic lupus erythematosus is a lifelong condition that can cause irreversible damage to the major organs in the body, leading to life-threatening complications. These pivotal results are unprecedented in demonstrating that by effectively controlling disease activity, Gazyva/Gazyvaro may delay or prevent further organ damage in people with SLE," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "We look forward to sharing the data with global health authorities, with the goal of making this potentially transformative new standard of care available as quickly as possible."

All key secondary endpoints were met, with results showing statistically significant and clinically meaningful benefits with Gazyva/Gazyvaro versus standard therapy including British Isles Lupus Assessment Group based Composite Lupus Assessment (BICLA) response at week 52, sustained corticosteroid control from week 40 to 52, sustained SRI-4 from week 40 to 52, a

six-point improvement in SLE disease activity score (SRI-6) at 52 weeks, and time to first flare over 52 weeks as defined by the British Isles Lupus Assessment Group (BILAG) index.[1]

SLE affects over three million people worldwide, mostly women diagnosed between the ages of 15 and 45, with women of colour disproportionately impacted.[3-5] Frequent flares of disease activity inflame and damage multiple organs. Around half of the patients will progress to lupus nephritis, a potentially life-threatening kidney complication, within five years of diagnosis.[6-8] Achieving better disease control can reduce flares, limit further damage to the organs and lower the risk of developing lupus nephritis.[9,10]

Data will be presented at an upcoming medical meeting and shared with health authorities as soon as possible, including the US Food and Drug Administration and the European Medicines Agency. If approved, Gazyva/Gazyvaro would be the first anti-CD20 therapy for SLE to directly target B cells, an underlying cause of disease.[2]

ALLEGORY is the third positive phase III study for Gazyva/Gazyvaro in immune-mediated diseases, in addition to REGENCY in lupus nephritis and INShore in idiopathic nephrotic syndrome. This growing evidence suggests that Gazyva/Gazyvaro, designed to attack and destroy targeted B cells, both directly and together with the body's immune system, may help address disease activity across a spectrum of autoimmune or immune-related diseases.

In addition to SLE, Gazyva/Gazyvaro is being investigated in children and adolescents with lupus nephritis, as well as adults with membranous nephropathy, as part of our ambition to be leaders in immune-mediated rheumatology and nephrology diseases.

## 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).[11] CD20 is a protein found on certain types of B cells. Gazyva/Gazyvaro is approved for adults with lupus nephritis in the US who are receiving standard therapy. In October 2025, the European Medicines Agency's Committee for Medicinal Products for Human Use recommended approval in the European Union, with a final decision expected from the European Commission in the near future. Gazyva/Gazyvaro is also approved in 100 countries for various types of haematological cancers.

## About the ALLEGORY study

ALLEGORY [NCT04963296] is a phase III, randomised, double-blind, placebo-controlled, multicentre study, investigating the efficacy and safety of Gazyva®/Gazyvaro® (obinutuzumab) compared with standard therapy in adults with systemic lupus erythematosus (SLE) on standard therapy. The study enrolled approximately 300 people, who were randomised 1:1 to receive Gazyva/Gazyvaro or placebo for up to one year (52 weeks), followed by an open-label

period with Gazyva/Gazyvaro for up to 104 weeks. The primary endpoint is the percentage of people who achieve SLE Responder Index four at week 52.

## About systemic lupus erythematosus

Systemic lupus erythematosus (SLE) is a potentially life-threatening autoimmune disease that affects more than three million people worldwide, and rising.[3,12] Due to the non-specific symptoms, it can take two to six years for an accurate diagnosis. During this time, disease severity and organ damage, due to repeated flares of disease activity, typically worsens and quality of life declines.[9,13,14]

Around half of people with SLE will develop lupus nephritis within five years of a lupus diagnosis.[7,8] In lupus nephritis, the disease activity primarily affects the kidneys and there is a risk of end-stage kidney disease, where dialysis and transplant are the only treatment options.

There is a need for additional targeted therapies that can effectively control disease activity and potentially delay or prevent the onset of lupus nephritis.[15,16]

## 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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