Media & Investor Release

New England Journal of Medicine publishes phase III ALLEGORY data showing Roche's Gazyva/Gazyvaro significantly reduces disease activity in the most common form of lupus

- **Over three quarters of people on Gazyva/Gazyvaro plus standard therapy achieved at least a four-point improvement in SRI-4, a measure that assesses disease severity and symptoms**
- **Gazyva/Gazyvaro has the potential to become a new standard of care for people living with systemic lupus erythematosus (SLE)**
- **If approved, Gazyva/Gazyvaro would be the first Type II anti-CD20 therapy for SLE to directly target B cells, a key driver of inflammation and disease activity[1]**
- **SLE is a potentially life-threatening autoimmune disease that affects more than three million people worldwide**

Basel, 06 March 2026 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that a detailed analysis of the phase III ALLEGORY trial of Gazyva®/Gazyvaro® (obinutuzumab) in adults with systemic lupus erythematosus (SLE) was published in the *New England Journal of Medicine (NEJM)*. The study demonstrated a statistically significant and clinically meaningful benefit in the primary endpoint. Over three quarters (76.7%) of people treated with Gazyva/Gazyvaro plus standard therapy achieved a minimum four-point improvement in SLE Responder Index 4 (SRI-4) at 52 weeks, compared to 53.5% with placebo plus standard therapy (adjusted difference 23.1%, 95% confidence interval [CI]: 12.5-33.6, p<0.001). These data are also being presented today at the 15th European Lupus meeting, SLEuro 2026.

Gazyva/Gazyvaro was superior to placebo in all key and additional secondary endpoints. The study showed an improvement in median time to first flare - which can lead to permanent organ damage - as defined by the British Isles Lupus Assessment Group (BILAG) index (could not be estimated versus 52.3 weeks, hazard ratio [HR]: 0.58, 95% CI: 0.40-0.82, p=0.002) and more than doubled remission rate (35.1% versus 13.8%, adjusted difference 21.2%, 95% CI: 11.8-30.5).

"The ALLEGORY study of Gazyva represents one of the most compelling late-stage successes in years for the treatment of patients with systemic lupus erythematosus (SLE), showing important evidence that targeting B cells can deliver significant reductions in disease activity," said Dr. Richard Furie, MD, Chief of the Division of Rheumatology at Northwell Health and professor in the Institute of Molecular Medicine at the Feinstein Institutes for Medical Research. "With the ALLEGORY study, we are seeing the potential to deliver more robust and sustained disease control with less reliance on steroids. These benefits matter profoundly to

patients, physicians and families, marking Gazyva as an important step forward in the treatment of this autoimmune disease."

"For decades, people living with SLE have faced a cycle of unpredictable disease activity, limited treatment options and long-term steroid burden. These results from the ALLEGORY trial show that Gazyva/Gazyvaro can provide significant, clinically meaningful, and sustained disease control, which is critical to preventing life threatening damage to major organs," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "We look forward to working with health authorities around the world to bring this potentially transformative new treatment to patients with lupus as quickly as possible. "

Data are being discussed with health authorities, including the US Food and Drug Administration and the European Medicines Agency, with the goal of making this potential new standard of care for people with SLE available as soon as possible. If approved, Gazyva/Gazyvaro would be the first Type II anti-CD20 therapy for SLE to directly target B cells, an underlying cause of disease.[3]

Safety was consistent with the well-characterised profile of Gazyva/Gazyvaro, and no new safety signals were identified. All five key secondary endpoints were met, including the British Isles Lupus Assessment Group-based Composite Lupus Assessment (BICLA) response at 52 weeks and glucocorticoid reduction to ≤7.5 mg/day, sustained from week 40 to 52.

Results from all key and additional secondary endpoints can be found in the table below. These endpoints are important indicators for achieving better disease control in SLE.

Key secondary endpoints	**Gazyva/Gazyvaro (n=151)**	**Placebo (n=152)**	**Adjusted difference or hazard ratio** (95% CI)	***P*-value**
Key secondary endpoints				
BICLA response at Week 52 (%)	62.0 (54.2 to 69.8)	40.1 (32.1 to 48.1)	21.9 (10.8 to 32.9)	<0.001
Reduction in glucocorticoid dose to ≤7.5 mg/day, sustained from Week 40 to 52 (%)	80.0 (71.5 to 88.5)	54.1 (43.5 to 64.7)	30.2 (15.3 to 45.1)	<0.001
SRI-4 response at Week 40, sustained to Week 52 (%)	72.0 (64.6 to 79.3)	46.4 (38.3 to 54.6)	25.4 (14.6 to 36.2)	<0.001

SRI-6 response at Week 52 (%)	68.9 (61.4 to 76.5)	38.9 (31.0 to 46.9)	30.0 (19.2 to 40.7)	<0.001
Median time to first SLE BILAG flare through Week 52 (weeks)	Could not be estimated	52.3	Hazard ratio: 0.58 (0.40 to 0.82)	0.002
Additional secondary endpoints				
Definition of Remission in SLE (DORIS) response at Week 52 (%)	35.1	13.8	21.2 (11.8 to 30.5)	
LLDAS at Week 52 (%)	57.6	25.0	32.6 (22.3 to 43.0)	

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. DORIS, Definition of Remission in SLE; LLDAS, Lupus Low Disease Activity State

SLE affects over three million people worldwide, mostly women diagnosed between the ages of 15 and 45, with women of colour disproportionately impacted.[4-6] Frequent flares of disease activity inflame and irreversibly damage multiple organs. Around half of the patients will progress to lupus nephritis, a potentially life-threatening kidney complication, within five years of diagnosis.[7-9] Achieving better disease control can reduce flares, limit further damage to the organs and lower the risk of developing lupus nephritis.[10,11]

ALLEGORY is one of four positive phase III studies for Gazyva/Gazyvaro in immune-mediated diseases, in addition to REGENCY in lupus nephritis, INShore in idiopathic nephrotic syndrome and MAJESTY in primary membranous nephropathy. This growing body of evidence supports the potential of Gazyva/Gazyvaro to address disease activity across a spectrum of immune-mediated diseases.

Gazyva/Gazyvaro is approved in the US and EU for the treatment of adults with active lupus nephritis based on data from the REGENCY and NOBILITY studies and is being investigated in a global phase II study of children and adolescents with lupus nephritis.[12,13] Beyond Gazyva/Gazyvaro, we have a broad pipeline as part of our ambition to be leaders in immunology, in particular in immune-mediated kidney and rheumatological 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).[14] CD20 is a protein found on certain types of B cells.

Gazyva/Gazyvaro is approved for adults with lupus nephritis in the US and EU. 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 placebo 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 is rising.[4,15] It is a chronic disease that causes inflammation in various parts of the body; for this reason it can affect multiple organ systems, especially the skin, joints and kidneys.[16] As multiple organ systems are affected, it can cause varying symptoms, often taking 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.[10,17,18]

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, posing a risk of kidney failure, where dialysis and transplant are the only treatment options.

There is a need for additional targeted therapies that can effectively control SLE disease activity and potentially delay or prevent the onset of lupus nephritis.[19,20]

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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