Media & Investor Release

CHMP recommends EU approval of Roche's Gazyva/Gazyvaro for systemic lupus erythematosus (SLE)

- **Positive recommendation is based on phase III ALLEGORY study data showing Gazyva/Gazyvaro significantly reduced disease activity in patients with SLE compared with placebo[1]**
- **If approved, Gazyva/Gazyvaro would be the first glycoengineered, Type II anti-CD20 therapy for SLE, potentially becoming the new standard of care**
- **SLE, commonly known as lupus, is a potentially life-threatening autoimmune disease that frequently leads to recurrent flares, progressive organ damage and requires long-term steroid use[2,3]**
- **EMA approval would further strengthen Gazyva/Gazyvaro's role across immune-mediated diseases and reinforce the potential of B cell-driven innovation across nephrology and rheumatology**

Basel, 13 November 2026 - Roche (SIX: RO, ROP; 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) as an add-on therapy for the treatment of adult patients with moderate-to-severe, active, autoantibody-positive systemic lupus erythematosus (SLE) despite standard therapy. A final decision from the European Commission is expected in the near future. In addition, the US Food and Drug Administration (FDA) accepted Roche's supplemental Biologics License Application (sBLA) for Gazyva/Gazyvaro in SLE earlier this year. This recommendation builds on a growing list of approvals across immune-mediated diseases for Gazyva/Gazyvaro, including active lupus nephritis (LN) in more than 65 countries and idiopathic nephrotic syndrome (INS) in the US.[4]

"Many people with systemic lupus erythematosus experience recurring flares, progressive organ damage, and chronic steroid dependence," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "This positive CHMP recommendation brings Gazyva/Gazyvaro a step closer to offering people with SLE a new option that may achieve meaningful and sustained disease control."

The positive recommendation is based on results from the phase III ALLEGORY study, which demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint.[1] At 52 weeks, 76.7% of people treated with Gazyva/Gazyvaro plus standard therapy achieved at least a four-point improvement in the SLE Responder Index (SRI-4), compared with

53.5% of people receiving placebo plus standard therapy (adjusted difference 23.1%, 95% confidence interval [CI]: 12.5-33.6, p<0.001).[1]

Gazyva/Gazyvaro also demonstrated superiority across all key secondary endpoints, including British Isles Lupus Assessment Group-based Composite Lupus Assessment (BICLA) response, sustained glucocorticoid reduction, sustained SRI-4 response, SRI-6 response and time to first disease flare.[1] Notably, based on the Definition of Remission in SLE (DORIS) standard, treatment more than doubled remission rates compared with placebo (33.8% versus 13.8%, adjusted difference 19.9%, 95% CI: 10.6-29.2) and significantly increased the proportion of patients achieving Lupus Low Disease Activity State (57.6% versus 25.0%, adjusted difference 32.6%, 95% CI: 22.3-43.0).[1] Gazyva/Gazyvaro demonstrated a well-tolerated safety profile in ALLEGORY, consistent with its established profile, with no new safety signals identified.[1]

SLE, commonly known as lupus, is a potentially life-threatening autoimmune disease affecting three million people worldwide and up to 270,000 people in Europe.[2,5] The disease can affect multiple organ systems and may lead to recurrent disease flares, progressive organ damage and a substantial impact on quality of life.[3]

ALLEGORY is one of four positive phase III studies for Gazyva/Gazyvaro in immune-mediated diseases, alongside REGENCY in LN, INShore in INS and MAJESTY in primary membranous nephropathy (pMN).[6-8] The recent regulatory approvals in LN and INS, as well as the FDA filing acceptance in pMN, support the potential of Gazyva/Gazyvaro to address disease activity across a spectrum of immune-mediated diseases.

Beyond Gazyva/Gazyvaro, Roche has a broad pipeline to bring breakthrough innovation across immunology, including immune-mediated kidney diseases and lupus. Lunsumio® (mosunetuzumab), a first-in-class CD20xCD3 T-cell-engaging bispecific antibody, is being investigated in patients with SLE with or without active lupus nephritis.[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 more than 65 countries and for idiopathic nephrotic syndrome in children and young adults in the US.[4] Gazyva/Gazyvaro is also approved in 100 countries for various types of haematological cancers.[4]

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.[1]

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.[1] The primary endpoint is the percentage of people who achieve SLE Responder Index four at week 52.[1]

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.[2,11] 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.[3] As multiple organ systems are affected, it can cause varying symptoms, often taking three to five years for an accurate diagnosis.[3,12] During this time, disease severity and organ damage, due to repeated flares of disease activity, typically worsens and quality of life declines.[3,13]

Around half of people with SLE will develop lupus nephritis within five years of a diagnosis.[14] 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.[15]

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.

About Roche in Immunology

For over two decades, Roche has advanced immune system research, creating groundbreaking targeted treatments that have transformed care for people with blood disorders, neurological conditions and autoimmune diseases. With a development pipeline exploring more than 20 medical approaches, we are targeting widespread, complex conditions like chronic lung disease (COPD) and inflammatory bowel disease (IBD), alongside lupus and autoimmune kidney diseases. Our ultimate goal is to lessen the burden of chronic immune disorders on patients, healthcare systems, and society.

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of

providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

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