Media & Investor Release

FDA accepts application for Roche's Gazyva/Gazyvaro for the treatment of the most common form of lupus

- **Filing acceptance based on phase III ALLEGORY data for Gazyva/Gazyvaro showing a significant reduction in disease activity compared with placebo in people with systemic lupus erythematosus (SLE)**
- **If approved, Gazyva/Gazyvaro would be the first anti-CD20 therapy to directly target B cells in SLE, potentially becoming the new standard of care for this condition[1]**
- **SLE is a potentially life-threatening autoimmune disease affecting more than three million people worldwide – achieving better disease control can reduce flares and may prevent irreversible organ damage**

Basel, 21 April 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) for Gazyva®/Gazyvaro® (obinutuzumab) for the treatment of systemic lupus erythematosus (SLE). The filing acceptance is based on positive results from the phase III ALLEGORY study, which demonstrated a statistically significant and clinically meaningful benefit in the primary endpoint of SLE Responder Index 4 (SRI-4) at 52 weeks – a measure that assesses changes in disease severity, symptoms and physical condition.[2] The FDA is expected to make a decision on an approval by December 2026. Gazyva/Gazyvaro is already approved for adults with lupus nephritis in the US and EU.

"The FDA's sBLA acceptance for Gazyva/Gazyvaro brings us one step closer to providing a highly effective new treatment option for people living with this unpredictable and potentially life-threatening disease," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "Gazyva/Gazyvaro may offer meaningful improvements in disease control and increase the likelihood of achieving complete remission in SLE while reducing the burden of long-term steroid use."

"For people living with SLE, the daily challenges of the disease can be both physically and emotionally overwhelming," said Albert T. Roy, President and CEO, Lupus Research Alliance. "We are hopeful for the approval of Gazyva as a new treatment for SLE – given its potential to manage symptoms as well as drive higher rates of clinical remission and reduce the frequency of debilitating flares."

These data were simultaneously presented at the 15th European Lupus meeting, SLEuro 2026 and published in the *New England Journal of Medicine* in March 2026.[2]

The phase III ALLEGORY results showed over three quarters (76.7%) of people treated with Gazyva/Gazyvaro plus standard therapy achieved a minimum four-point improvement in 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). Safety was consistent with the well-characterised profile of Gazyva/Gazyvaro, and no new safety signals were identified.[2]

Gazyva/Gazyvaro was also superior to placebo in all key secondary endpoints, and met additional secondary endpoints, 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. The study showed that people receiving Gazyva/Gazyvaro, plus standard therapy, were less likely to have a flare through to week 52, as defined by the British Isles Lupus Assessment Group (BILAG) index (Hazard ratio [HR]: 0.58, 95% CI: 0.40-0.82, p=0.002). A relevant finding as flares can lead to permanent organ damage. The median time to first flare could not be estimated. In addition, treatment with Gazyva/Gazyvaro plus standard therapy, versus placebo plus standard therapy, more than doubled the remission rate at 52 weeks (Definition of Remission in SLE (DORIS) - 33.8% versus 13.8%, adjusted difference 19.9%, 95% CI: 10.6-29.2). Lupus Low Level Disease Activity State (LLDAS) at week 52 weeks also more than doubled with Gazyva/Gazyvaro compared to placebo (57.6% versus 25.0%, adjusted difference 32.6%, 95% CI: 22.3-43.0).[2]

Data from the phase III ALLEGORY study have also been used for a filing submission with the European Medicines Agency. 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. Beyond Gazyva/Gazyvaro, we have a broad pipeline as part of our ambition to bring breakthrough innovation to 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).[3] CD20 is a protein found on certain types of B cells.

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.[2]

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.[4,5] 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.[6] 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.[7,8,9]

Around half of people with SLE will develop lupus nephritis within five years of a lupus diagnosis.[10,11] 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.[12,13]

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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