Media & Investor Release

FDA grants Priority Review to Roche's Gazyva/Gazyvaro for adults with primary membranous nephropathy

- **Priority Review decision is based on phase III MAJESTY results, where Gazyva/Gazyvaro achieved significantly higher complete remission rates at two years compared to tacrolimus[1]**
- **If approved, Gazyva/Gazyvaro will be the first FDA-approved therapy for primary membranous nephropathy (pMN), following global approvals in lupus nephritis and ongoing regulatory filings in lupus and idiopathic nephrotic syndrome**
- **pMN is a chronic autoimmune disease with no FDA or EMA approved therapies to date; when left untreated, up to 30% of patients progress to kidney failure over 10 years[2,3]**

Basel, 15 July 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has granted Priority Review to the company's supplemental Biologics License Application (sBLA) for Gazyva®/Gazyvaro® (obinutuzumab) for the treatment of primary membranous nephropathy (pMN). The priority review is based on the positive phase III MAJESTY results, which show superiority of Gazyva/Gazyvaro over an immunosuppressive therapy, tacrolimus, in adults with pMN.[1] The FDA has already granted Breakthrough Therapy Designation (BTD) to Gazyva/Gazyvaro in pMN and is expected to make a decision on approval by November 2026. This is the second indication in recent months for which the US FDA has granted priority review to Gazyva/Gazyvaro, following idiopathic nephrotic syndrome in May 2026.

"This priority review represents an important step for patients living with primary membranous nephropathy, a chronic disease with no FDA-approved treatments," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "By targeting tissue-resident B cells, Gazyva/Gazyvaro addresses an underlying cause of pMN and has the potential to help more patients achieve complete remission - a necessary step to maintaining kidney function."

The phase III MAJESTY study met its primary endpoint, with 36.9% of adults achieving complete remission (CR) at two years (104 weeks) with Gazyva/Gazyvaro versus 5.7% with tacrolimus (adjusted difference 31.1%; 95% confidence interval [CI] 18.2 to 44.0; p<0.001). Complete remission is the ultimate goal in pMN and can help prevent progression to kidney failure. Key secondary endpoints showed that Gazyva/Gazyvaro was superior to tacrolimus in achieving overall remission (complete or partial remission) at week 104 and complete

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remission at week 76. Safety was in line with the well-characterised profile of Gazyva/Gazyvaro and no new safety signals were identified.

The data were featured at the 63rd European Renal Association (ERA) Congress in June 2026 as a late-breaking oral presentation and published in the *New England Journal of Medicine (NEJM).*[1] In April 2026, the FDA granted Breakthrough Therapy Designation for Gazyva/Gazyvaro in pMN.

Data from MAJESTY are also being submitted to other global health authorities, including the European Medicines Agency.

pMN is a chronic autoimmune condition that causes potentially irreversible kidney damage and can lead to kidney failure, which has a significant impact on patients and their families, while carrying substantial burden to health systems.[2,3] Achieving complete remission is important to help maintain kidney function and delay or prevent the onset of serious and potentially fatal complications.[3]

MAJESTY is the fourth positive phase III study of Gazyva/Gazyvaro in immune-mediated diseases, following REGENCY in lupus nephritis, ALLEGORY in systemic lupus erythematosus (SLE) and INShore in idiopathic nephrotic syndrome – where it also received priority review and Breakthrough Therapy Designation by the FDA.[4,5,6] Gazyva/Gazyvaro is approved in the US and EU for the treatment of adults with active lupus nephritis who are receiving standard therapy based on data from the REGENCY and NOBILITY studies,[4,7] and is being investigated in the phase II POSTERITY study for children and adolescents with lupus nephritis.[8] This growing body of evidence supports Gazyva/Gazyvaro's potential in addressing disease activity across a spectrum of immune-mediated diseases.

Beyond Gazyva/Gazyvaro, we have a broad pipeline to bring breakthrough innovation across immunology, including immune-mediated kidney diseases. This includes Lunsumio® (mosunetuzumab), a first-in-class CD20xCD3 T-cell-engaging bispecific antibody being investigated in SLE.[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 the US and the EU. Gazyva/Gazyvaro is also approved in 100 countries for various types of haematological cancers.

About the MAJESTY study

MAJESTY [NCT04629248] is a phase III, randomised, open-label, multicentre study designed to evaluate the efficacy and safety of Gazyva®/Gazyvaro® (obinutuzumab) in adults with primary membranous nephropathy. The study enrolled 142 adults who were randomised 1:1 to receive Gazyva/Gazyvaro or tacrolimus. The primary endpoint is the percentage of adults who achieve complete remission at two years (week 104).

About primary membranous nephropathy

Primary membranous nephropathy is a chronic autoimmune condition where the body's immune system attacks the filtering units of the kidney, the glomeruli, causing protein to leak into the urine and potentially a gradual decline in kidney function. Over time, the damage to the kidneys can become irreversible, increasing the risk of life-threatening complications, such as kidney failure, idiopathic nephrotic syndrome, blood clots and cardiovascular diseases. Achieving complete remission is important to help maintain kidney function and delay or prevent the onset of serious and potentially fatal complications.

Primary membranous nephropathy has an estimated incidence of 1.2 per 100,000 people in the United States per year.[11]

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, autoimmune kidney diseases and severe skin conditions (atopic dermatitis). 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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