Media & Investor Release

Roche's Gazyva/Gazyvaro becomes the first FDA-approved treatment for primary membranous nephropathy

- **Approval based on phase III MAJESTY results demonstrating Gazyva/Gazyvaro superiority over tacrolimus in achieving complete remission of proteinuria at two years (36.1% vs. 5.7%; p<0.001)**
- **Primary membranous nephropathy (pMN) is a rare, chronic autoimmune disease; when left untreated, up to 30% of patients progress to kidney failure within 10 years**
- **This approval further strengthens Gazyva/Gazyvaro's role across multiple immune-mediated kidney diseases and reinforces the potential of B cell-driven innovation in nephrology and rheumatology**

Basel, 16 November 2026 – Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has approved Gazyva®/Gazyvaro® (obinutuzumab) for the treatment of adult patients with primary membranous nephropathy (pMN) at risk of disease progression, to induce remission of proteinuria. Gazyva/Gazyvaro becomes the first and only therapy to receive FDA approval for this disease, having previously been granted Breakthrough Therapy Designation. A chronic autoimmune disease that can lead to kidney failure, pMN carries a substantial human and economic burden for patients, caregivers and health systems alike.[1,2] Proteinuria is a key indicator of kidney damage characterised by high urine protein levels.

"The FDA approval of Gazyva/Gazyvaro represents an important step forward for people living with primary membranous nephropathy, where targeting B cells addresses a critical underlying driver of disease," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "With Gazyva/Gazyvaro, we are turning decades of specialised antibody engineering into tangible outcomes for patients with immune-mediated kidney diseases. By achieving significantly higher complete remission rates compared to tacrolimus, Gazyva/Gazyvaro offers a more effective approach to help achieve durable disease control."

The approval is based on positive results from the phase III MAJESTY study.[3] The trial met its primary endpoint, with 36.1% of adults achieving complete remission (CR) of proteinuria 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). Key secondary endpoints showed that Gazyva/Gazyvaro was superior to tacrolimus in achieving overall remission (complete or partial remission) at week 104 (50% vs. 12.9%; adjusted difference 37.8%; 95% CI: 23.9 to 51.8; p<0.001) and complete remission at week 76 (36.1% vs. 8.6%; adjusted difference 27.4%; 95% CI: 13.4 to 39.8; p<0.001). Safety was in line with the well-characterised profile of Gazyva/Gazyvaro and no new safety signals were identified. MAJESTY 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).* Data are also being submitted to other global health authorities, including the European Medicines Agency.

“People living with primary membranous nephropathy face the risk of progressive kidney damage and significant uncertainty about their health,” said Marc Hurlbert, PhD, Chief Executive Officer of the National Kidney Foundation. “The first FDA approval of a treatment specifically for this condition is a milestone, finally giving patients and clinicians more treatment options. Our hope is that the approval of Gazyva/Gazyvaro provides a turning point for people navigating pMN.”

pMN is a rare, chronic autoimmune condition that causes potentially irreversible kidney damage and can lead to kidney failure. People living with pMN often experience fatigue, edema (swelling) and significant emotional and social challenges that deeply affect both patients and their families.[1,4] Beyond the individual impact, pMN places a substantial burden on healthcare systems.[2,5] Achieving complete remission is important to help maintain kidney function and delay or prevent the onset of serious and potentially fatal complications.[2]

“pMN can lead to debilitating physical and psychological symptoms that place a heavy burden on patients, families and healthcare systems alike,” said Teresa Graham, Chief Executive Officer, Roche Pharmaceuticals. “This first-ever FDA approval delivers an important targeted treatment option for the pMN community and expands how many people may benefit from Gazyva/Gazyvaro across multiple severe immune-mediated kidney diseases.”

This is the third FDA approval of Gazyva/Gazyvaro in immune-mediated kidney diseases, following approvals in idiopathic nephrotic syndrome (INS) and lupus nephritis (LN). The FDA is currently evaluating Gazyva/Gazyvaro for adults with systemic lupus erythematosus (SLE) and is expected to make a decision by December 2026. Additionally, the European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) recently issued a positive opinion recommending the approval of Gazyva/Gazyvaro for adults with SLE, with a final decision from the European Commission expected in the near future. Beyond Gazyva/Gazyvaro, Roche has a broad pipeline to bring breakthrough innovation across immunology, including immune-mediated kidney 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).[6] 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 adults and paediatric patients in the US. 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 of proteinuria 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.[7]

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.

All trademarks used or mentioned in this release are protected by law.

References

[1] Chung EYM, Carter SA, Jaure A, et al. Patients' perspectives on living with primary membranous nephropathy: a semi-structured interview study. *Am J Kidney Dis*. 2025;86(3):343-352.e1. doi:10.1053/j.ajkd.2025.03.028.
[2] Kanigicherla DAK, et al. Long-term outcomes of persistent disease and relapse in primary membranous nephropathy. Nephrol Dial Transplant. 2016 Dec:31(12):2108-2114. doi: 10.1093/ndt/gfv435. Epub 2016 Jan 13.
[3] Fervenza FC, Hou FF, Hao CM, et al. Obinutuzumab or Tacrolimus in Primary Membranous Nephropathy. *N Engl J Med*. 2026;395(10):959-971. doi:10.1056/NEJMoa2602678.
[4] American Kidney Fund. Primary membranous nephropathy (PMN): causes, symptoms, diagnosis and treatment. Updated October 10, 2025. [Internet; cited 2026 November]. Available from: https://www.kidneyfund.org/all-about-kidneys/other-kidney-diseases/pmn
[5] Keri KC, et al. Primary membranous nephropathy: comprehensive review and historical perspective. Postgrad Med J. 2019 Jan;95(1119). doi: 10.1136/postgradmedj-2018-135729.
[6] Herter S, et al. Preclinical activity of the type II CD20 antibody GA101 (obinutuzumab) compared with rituximab and ofatumumab in vitro and in xenograft models. Mol Cancer Ther. 2013 Oct;12(10):2031-42.
[7] Alok A, Yadav A. Membranous Nephropathy. [Updated 2023 June 5]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. [Internet; cited 2026 November]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559169.

Roche Holding Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

Roche Global Media Relations

Phone: +41 61 688 88 88 / e-mail: media.relations@roche.com

Tristan Schmitz
Phone: +41 79 529 70 35

Lorena Corfas
Phone: +41 79 568 24 95

Karsten Kleine
Phone: +41 79 461 86 83

Yvette Petillon
Phone: +41 79 961 92 50

Albert Thottiyil
Phone: +41 79 775 66 12

Nathalie Altermatt
Phone: +41 79 771 05 25

Simon Goldsborough
Phone: +44 797 32 72 915

Kirti Pandey
Phone: +41 79 398 38 53

Irène Stephan
Phone: +41 79 377 83 75

Roche Investor Relations

Dr Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com