Media & Investor Release

Roche announces positive phase III results for Gazyva/Gazyvaro in primary membranous nephropathy, marking a significant milestone in this autoimmune disease

- **MAJESTY, the first global phase III study in primary membranous nephropathy, met its primary endpoint of complete remission at two years**
- **Up to 30% of people with membranous nephropathy progress to kidney failure over 10 years despite current treatment approaches; achieving complete remission can help delay or prevent this[1,2]**
- **Gazyva/Gazyvaro could become the first approved treatment for primary membranous nephropathy, having already achieved positive results in lupus nephritis, systemic lupus erythematosus and idiopathic nephrotic syndrome**
- **Gazyva/Gazyvaro is a glycoengineered, anti-CD20 monoclonal antibody designed to achieve deep tissue B cell depletion**

Basel, 16 February 2026 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the phase III MAJESTY study in adults with primary membranous nephropathy met its primary endpoint, showing statistically significant and clinically meaningful results with Gazyva®/Gazyvaro® (obinutuzumab). Results show that significantly more people achieved complete remission at two years (104 weeks) with Gazyva/Gazyvaro versus tacrolimus. Safety was in line with the well-characterised profile of Gazyva/Gazyvaro and no new safety signals were identified.

“These results demonstrate that Gazyva/Gazyvaro may help more people with primary membranous nephropathy achieve complete remission, maintain kidney function for longer and delay or potentially prevent the onset of life-threatening complications,” said Levi Garraway, MD, PhD, Roche’s Chief Medical Officer and Head of Global Product Development. “If approved, Gazyva/Gazyvaro would be the first therapy specifically indicated for people with primary membranous nephropathy, where there are limited treatment options.”

Analysis of key secondary endpoints showed statistically significant and clinically meaningful benefits with Gazyva/Gazyvaro versus tacrolimus in overall remission (complete or partial remission) at week 104 and complete remission at week 76.

Data will be presented at an upcoming medical meeting and shared with health authorities including the US Food and Drug Administration and the European Medicines Agency.

Primary membranous nephropathy is a chronic autoimmune condition that causes potentially irreversible kidney damage and reduced kidney function, and it is estimated that it affects

nearly 88,000 people in the EU and over 96,000 in the US. Up to 30% of people with primary membranous nephropathy will develop kidney failure over 10 years, which requires invasive intervention like dialysis or transplant and has a significant impact on patients and their families, as well as carrying substantial cost to health systems.[1,2] Gazyva/Gazyvaro has the potential to address this by targeting an underlying cause of the condition, which may help maintain kidney function for longer and prevent the onset of life-threatening complications.

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 and INShore in idiopathic nephrotic syndrome. This growing body of evidence supports Gazyva/Gazyvaro's potential in addressing 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.[3,4] Beyond Gazyva/Gazyvaro, we have a broad pipeline as part of our ambition to be leaders in immunology, in particular in immune-mediated and kidney-related 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). 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 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 people with primary membranous nephropathy. The study enrolled 142 people who were randomised 1:1 to receive Gazyva/Gazyvaro or tacrolimus. The primary endpoint is the percentage of people 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

disease. Achieving complete remission is critical to help maintain kidney function and delay or prevent the onset of serious and potentially fatal complications.

About Roche in kidney and kidney-related diseases

For more than 20 years, we have combined innovation, scientific expertise and commitment to patients to address unmet needs in kidney diseases. Today, our industry-leading programme includes Gazyva®/Gazyvaro® (obinutuzumab), approved in the US and EU for adults with active lupus nephritis, and more than 10 phase II-III clinical studies in immune-mediated kidney and kidney-related diseases with some of the highest unmet needs.

Our aim is to continue delivering meaningful value for those affected, healthcare systems and society, and help address this growing public health burden.

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.

References

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Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Nathalie Altermatt
Phone: +41 79 771 05 25

Lorena Corfas
Phone: +41 79 568 24 95

Simon Goldsborough
Phone: +44 797 32 72 915

Karsten Kleine
Phone: +41 79 461 86 83

Kirti Pandey
Phone: +49 172 6367262

Yvette Petillon
Phone: +41 79 961 92 50

Dr Rebekka Schnell
Phone: +41 79 205 27 03

Roche Investor Relations

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

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

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

Investor Relations North America

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