Media Release

Positive phase III results for Roche's Gazyva/Gazyvaro in children and young adults with idiopathic nephrotic syndrome

- **Gazyva/Gazyvaro versus mycophenolate mofetil shows significantly more children and young adults achieved sustained complete remission at week 52**
- **If approved, Gazyva/Gazyvaro could help children and young adults sustain remission, potentially with a reduced need for steroids to manage their disease[1]**
- **INShore is the first global phase III study of a targeted therapy in this chronic kidney disease commonly diagnosed in early childhood**

Basel, 28 October 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today statistically significant and clinically meaningful results from the phase III INShore study of Gazyva®/Gazyvaro® (obinutuzumab) in children and young adults (aged >= 2-25 years) with idiopathic nephrotic syndrome (INS). The study met its primary endpoint, with more people achieving sustained complete remission at one year (week 52) with Gazyva/Gazyvaro compared with mycophenolate mofetil (MMF). Sustained complete remission was defined by the absence of relapses during the study together with a low amount of protein in the urine (protein to creatine of 0.2 or less) at week 52.[1] Certain important key secondary endpoints were also met. No new safety signals were identified and safety was in line with the well-characterised profile of Gazyva/Gazyvaro in adults.

"These results show that Gazyva/Gazyvaro may achieve robust disease control with a reduced need for corticosteroids, which are associated with serious side effects over time," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "Idiopathic nephrotic syndrome is a severe and chronic kidney disease usually diagnosed in early childhood, yet meaningful treatment progress has been limited. As a targeted therapy, Gazyva/Gazyvaro has the potential to help address this unmet need and we look forward to sharing the data with health authorities."

For several decades, treatment for idiopathic nephrotic syndrome has primarily relied on steroids yet relapse rates remain high and long-term use is limited by serious side effects.[2-4] Newer approaches that target specific immune cells - such as B cells, thought to be a key driver of disease activity - may help control symptoms more effectively.[5,6]

Analysis of key secondary endpoints showed statistically significant and clinically meaningful benefits with Gazyva/Gazyvaro with an increase in those with overall relapse-free survival (RFS), median time to relapse or death, reduction in cumulative corticosteroid dose from baseline to week 52, and fewer relapses from baseline to week 52, all compared with MMF. Other key secondary endpoints showed no significant difference with Gazyva/Gazyvaro versus MMF.*

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.

INShore data add to a growing body of evidence, including the phase III REGENCY study in lupus nephritis, that shows targeting disease-causing B cells with Gazyva/Gazyvaro may help address disease activity across a spectrum of immune-mediated kidney and kidney-related diseases.[7-10] In October 2025, Gazyva/Gazyvaro was approved in the US for the treatment of adults with active lupus nephritis who are receiving standard therapy, based on data from the phase III REGENCY and phase II NOBILITY studies.

In addition to idiopathic nephrotic syndrome, Gazyva/Gazyvaro is being investigated in membranous nephropathy, lupus nephritis, rare immune-mediated kidney diseases and systemic lupus erythematosus an autoimmune disease that can lead to lupus nephritis, as part of our ambition to be leaders in immune-mediated kidney and kidney-related diseases.[11-13]

About Gazyva/Gazyvaro

Gazyva®/Gazyvaro® (obinutuzumab) is a Type II engineered humanised monoclonal antibody designed to attach to CD20, a protein found on certain types of B cells.[14]

Gazyva/Gazyvaro is approved for adults with lupus nephritis who are receiving standard therapy in the US. In October 2025, the European Medicines Agency's Committee for Medicinal Products for Human Use recommended approval in the European Union, with a final decision expected from the European Commission in the near future. Gazyva/Gazyvaro is also approved in 100 countries for various types of haematological cancers.

In the US, Gazyva is part of a collaboration between Genentech and Biogen.

About the INShore study

INShore [NCT05627557] is a phase III open-label, randomised, multicentre study investigating Gazyva®/Gazyvaro® (obinutuzumab) compared with mycophenolate mofetil (MMF) in children and young adults in clinical remission (aged >=2-25 years) with frequently relapsing or steroid-dependent nephrotic syndrome. The study enrolled 85 children or young adults who were randomised 1:1 to receive Gazyva/Gazyvaro at weeks 0,2, 24 and 26, or MMF daily. The primary endpoint is the percentage of participants with sustained complete remission at one year (week 52).

About idiopathic nephrotic syndrome

Idiopathic nephrotic syndrome is a rare kidney-related autoimmune disease, usually diagnosed in early childhood.[2] It is characterised by unpredictable relapses that cause fatigue, swelling, weight gain and increased susceptibility to infections and clotting, as well as anxiety, depression and reduced self-esteem, brought on by the fear of relapse and social

isolation.[2,15] The current mainstay of treatment is steroids, however relapse rates remain high (>70%) and the serious side effects limit long-term use.[2-4]

There is an urgent need for new targeted treatment approaches that can sustain remission and reduce the physical and psychosocial burden of the disease.

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 for adults with 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.

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*Sustained complete remission (week 76), probability of relapse free survival (week 52), proportion of participants experiencing oedema associated relapse (during 52 week treatment period), mean change in CureGN Edema scale (from baseline to week 52), mean change in "General Fatigue" domain of PedsQL-Multidimensional Fatigue Scale total score (from baseline to week 52), mean change in "Physical Functioning" domain of PedsQL (from baseline to week 52).

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