

## **FDA grants Breakthrough Therapy Designation for Roche's Gazyva (obinutuzumab) in Lupus Nephritis**

- **There are currently no U.S. FDA-approved medicines for lupus nephritis**
- **The designation is based on the results of the phase II NOBILITY study that showed Gazyva, in combination with standard of care, helped more people achieve a complete renal response than standard of care alone**
- **Full results from the NOBILITY study will be presented at a medical meeting later this year**

Basel, 18 September 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) to Gazyva® (obinutuzumab) for adults with lupus nephritis. This designation was granted based on data from the phase II NOBILITY study in adult patients with proliferative lupus nephritis which showed Gazyva, in combination with standard of care (mycophenolate mofetil or mycophenolic acid and corticosteroids), demonstrated enhanced efficacy compared to placebo plus standard of care alone in achieving complete renal response at one year.

“New treatment options are needed for lupus nephritis, a potentially life-threatening inflammation of the kidneys that most commonly affects women,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “We are committed to developing Gazyva as a potential new therapy for lupus nephritis and plan to begin enrolling patients in a phase III trial next year.”

Lupus nephritis is a potentially life-threatening manifestation of systemic lupus erythematosus resulting from inflammation of the kidneys and is associated with a high risk of end-stage renal disease or death. Breakthrough Therapy Designation is designed to accelerate the development and review of medicines intended to treat serious or life-threatening conditions with preliminary evidence that indicates they may demonstrate a substantial improvement over existing therapies. This is the 27th Breakthrough Therapy Designation for Roche’s portfolio of medicines.

### **About the NOBILITY Study**

The phase II, randomised, double-blind, placebo-controlled, multi-center study, NOBILITY (NCT02550652), compared the safety and efficacy of Gazyva, combined with mycophenolate mofetil (MMF) or mycophenolic acid (MPA) and corticosteroids, to placebo, combined with MMF or MPA and corticosteroids, in adult patients with ISN/RPS 2003 class III or IV proliferative lupus nephritis. The study enrolled 126 people who were randomised to receive Gazyva or placebo infusions on days 1, 15, 168, and 182. The primary endpoint was the proportion of participants who achieved a protocol-defined complete renal response (CRR) at 52 weeks.

The study met its primary endpoint, showing Gazyva, in combination with standard of care (mycophenolate mofetil or mycophenolic acid and corticosteroids), demonstrated enhanced efficacy compared to placebo

plus standard of care alone in achieving complete renal response at one year. In addition, Gazyva met key secondary endpoints showing improved overall renal responses (complete and partial renal response) and serologic markers of disease activity as compared to placebo. No new safety signals were observed with Gazyva in the study at the time of this analysis. The full results from the study will be presented at a future medical meeting.

### **About Lupus Nephritis**

Lupus nephritis is a severe and potentially life-threatening disorder of the kidneys. Lupus nephritis is a complication of systemic lupus erythematosus (SLE), an autoimmune disease where a person's own immune system attacks healthy cells and organs.<sup>1</sup> It is estimated that SLE affects 24 per 100,000 in the population globally.<sup>2</sup> Up to 60% of people with SLE will develop lupus nephritis, and up to 25% of people with the condition develop end-stage renal disease.<sup>1,3</sup> Lupus overwhelmingly impacts women, making up 90% of the patient population. Women from African, Hispanic and Asian ethnic groups are two to three times more likely than Caucasian women to be diagnosed with lupus.<sup>4</sup> Currently, there is no cure for lupus or lupus nephritis.<sup>4</sup>

### **About Gazyva**

Gazyva is an engineered monoclonal antibody designed to attach to CD20, a protein found only on certain types of B-cells. It is thought to work by attacking targeted cells both directly and together with the body's immune system. In the United States, Gazyva is part of a collaboration between Genentech and Biogen. Combination studies investigating Gazyva with other approved or investigational medicines, including cancer immunotherapies and small molecule inhibitors, are underway across a range of blood cancers.

### **About Roche in Immunology**

The Roche Group's immunology medicines include: Actemra®/RoActemra® (tocilizumab) for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis (pJIA), systemic juvenile idiopathic arthritis (sJIA) and giant cell arteritis (GCA) and for the treatment of severe or life-threatening chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS); Rituxan®/MabThera® (rituximab) for rheumatoid arthritis granulomatosis with polyangiitis and microscopic polyangiitis and for pemphigus vulgaris (PV); Xolair® (omalizumab) for allergic asthma and chronic idiopathic urticaria (CIU); Pulmozyme® (dornase alfa) for cystic fibrosis; and Esbriet® (pirfenidone) for idiopathic pulmonary fibrosis (IPF). Roche has several investigational medicines in clinical development for immunological diseases including autoimmune disorders, rheumatoid arthritis, ulcerative colitis and Crohn's disease.

### **About Roche**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 billion. 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](http://www.roche.com).

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

## References

- [1] A. de Zubiria Salgado and C. Herrera-Diaz. Lupus Nephritis: An Overview of Recent Findings. *Autoimmune Diseases*. 2012; 2012: 221.
- [2] Lupus UK. Epidemiology of Lupus. [Internet; cited May 2019]. Available from: <https://www.lupusuk.org.uk/medical/gp-guide/introduction-to-lupus/epidemiology-of-lupus/>
- [3] R. Saxena et al. Lupus Nephritis: Current Update. *Arthritis Research & Therapy*. 2011; 13:240.
- [4] Lupus Research Alliance. Lupus Fact Sheet. [Internet; cited May 2019]. Available from: <http://www.lupusresearch.org/wp-content/uploads/2017/09/Lupus-Fact-Sheet.pdf>.

## Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: [media.relations@roche.com](mailto:media.relations@roche.com)

- Nicolas Dunant (Head)
- Patrick Barth
- Ulrike Engels-Lange
- Daniel Grotzky
- Karsten Kleine
- Nathalie Meetz
- Barbara von Schnurbein