

Basel, 17 November 2017

## **FDA approves Roche's Gazyva for previously untreated advanced follicular lymphoma**

- **The first treatment option to demonstrate superior progression-free survival over standard-of-care Rituxan-based therapy**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) approved Gazyva® (obinutuzumab) in combination with chemotherapy, followed by Gazyva alone in those who responded, for people with previously untreated advanced follicular lymphoma (stage II bulky, III or IV). The approval is based on results from the phase III GALLIUM study, which showed superior progression-free survival (PFS) for patients who received this Gazyva-based regimen compared with those who received a Rituxan® (rituximab)-based regimen as an initial (first-line) therapy. Follicular lymphoma, the most common slow-growing (indolent) form of non-Hodgkin lymphoma (NHL), is incurable and becomes harder to treat each time it returns.

“Today’s Gazyva approval is an important advance for the thousands of people diagnosed each year with follicular lymphoma who hope to delay disease progression for as long as possible,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “We’re pleased we can now offer patients with this incurable blood cancer an initial treatment option shown to improve upon Rituxan, the standard of care in this setting for more than 10 years.”

The GALLIUM study showed the Gazyva-based regimen significantly reduced the risk of disease worsening or death compared to a Rituxan-based regimen by 28% (PFS as assessed by independent review committee [IRC]; HR=0.72; 95% CI 0.56-0.93; p=0.0118). The most common Grade 3-5 side effects (occurring in at least 5% of patients) observed more frequently in the Gazyva arm were low white blood cell count, infusion reactions, low white blood cell count with fever and low platelet count. The most common side effects (occurring in at least 20% of patients) observed at least 2% more frequently in the Gazyva arm included infusion reactions, low white blood cell count, upper respiratory tract infection, cough, constipation and diarrhoea.

Gazyva’s supplemental Biologics License Application based on the GALLIUM data was granted Priority Review, a designation given to medicines that the FDA has determined to have the potential to provide significant improvements in the treatment, prevention or diagnosis of a disease. With this approval, Gazyva is available in the US for three different indications across two common types of blood cancer.

**About the GALLIUM study**

GALLIUM (NCT01332968) is a global phase III open-label, multicentre, randomised two-arm study examining the efficacy and safety of Gazyva plus chemotherapy followed by Gazyva alone for up to two years, as compared head-to-head against Rituxan plus chemotherapy followed by Rituxan alone for up to two years. Chemotherapies used (CHOP, CVP or bendamustine) were selected by each participating study site prior to beginning enrolment. GALLIUM included 1,385 patients with previously untreated non-Hodgkin lymphoma (NHL), of whom 1,202 patients had advanced follicular lymphoma (stage II bulky, III or IV). Efficacy results in follicular lymphoma with a median observation time of 38 months were the following:

<b>Treatment arm</b>	Gazyva + chemotherapy (N=601)	Rituxan + chemotherapy (N=601)
<b>Median PFS* (primary endpoint)</b>	Not reached (NR)	NR
	HR=0.72; 95% CI 0.56-0.93, p=0.0118	
<b>Overall Response Rate** (ORR, secondary endpoint)</b>	91%	88%
<b>Complete Remission Rate** (CR, secondary endpoint)</b>	28%	27%

\*As assessed by IRC; investigator-assessed PFS was consistent with these data

\*\*After completion of combination therapy, assessed by CT without PET

Safety was evaluated based on 1,385 patients with previously untreated follicular lymphoma (86%) or marginal zone lymphoma (14%). The most common Grade 3-5 side effects that occurred more often with Gazyva plus chemotherapy followed by Gazyva alone compared to Rituxan plus chemotherapy followed by Rituxan alone were low white blood cell count, infusion reactions, low white blood cell count with fever and low platelet count.

**About Gazyva (obinutuzumab)**

Gazyva is an engineered monoclonal antibody designed to attach to CD20, a protein expressed on certain B cells, but not on stem cells or plasma cells. Gazyva is designed to attack and destroy targeted B-cells both directly and together with the body's immune system. Gazyva is marketed as Gazyvaro in the EU and Switzerland.

Gazyva is currently approved in more than 80 countries in combination with chlorambucil for people with previously untreated chronic lymphocytic leukaemia (CLL), in combination with bendamustine for people with certain types of previously treated follicular lymphoma, in combination with chemotherapy for previously untreated, follicular lymphoma.

Additional 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 Follicular Lymphoma**

Follicular lymphoma is the most common indolent (slow-growing) form of non-Hodgkin lymphoma (NHL), accounting for about one in five cases of NHL.<sup>1</sup> It is considered incurable and relapse is common. It is estimated that more than 75,000 people are diagnosed with follicular lymphoma each year worldwide.<sup>2</sup>

### **About Roche in haematology**

For more than 20 years, Roche has been developing medicines that redefine treatment in haematology. Today, we are investing more than ever in our effort to bring innovative treatment options to people with diseases of the blood. In addition to approved medicines MabThera®/Rituxan® (rituximab), Gazyva®/Gazyvaro® (obinutuzumab), and Venclexta™/Venclyxto™ (venetoclax) in collaboration with AbbVie, Roche's pipeline of investigational haematology medicines includes Tecentriq® (atezolizumab), an anti-CD79b antibody drug conjugate (polatuzumab vedotin/RG7596) and a small molecule antagonist of MDM2 (idasanutlin/RG7388). Roche's dedication to developing novel molecules in haematology expands beyond malignancy, with the development of the Hemlibra® (emicizumab), a bispecific monoclonal antibody for the treatment of haemophilia A.

### **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.

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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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).

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### **References**

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<sup>1</sup> Shankland KR, Armitage JO, Hancock BW. Non-Hodgkin lymphoma. Lancet. 2012 ;380(9844): 848-57.

<sup>2</sup> Ferlay J, et al. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet; cited 2012]. Available from: [http://globocan.iarc.fr/old/summary\\_table\\_pop.html.asp?selection=224900&title=World&ssex=0&type=0&window=1&sort=0&submit=%C2%A0Execute](http://globocan.iarc.fr/old/summary_table_pop.html.asp?selection=224900&title=World&ssex=0&type=0&window=1&sort=0&submit=%C2%A0Execute)