

Basel, 23 June 2017

Roche presents new data from GALLIUM study reinforcing clinical benefit of Gazyva/Gazyvaro in people with previously untreated follicular lymphoma

- **Longer follow-up showed sustained benefit in progression-free survival of Gazyva/Gazyvaro-based treatment over MabThera/Rituxan-based treatment regardless of chemotherapy regimens**
- **People with follicular lymphoma who received Gazyva/Gazyvaro-based treatment reported improvement in health-related quality of life from baseline**
- **Preliminary analyses suggest positron emission tomography may be useful as an early predictor of progression-free survival and overall survival in untreated follicular lymphoma**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that new data from additional analyses of the pivotal phase III GALLIUM study in people with previously untreated follicular lymphoma will be presented at the 22nd European Hematology Association (EHA) annual congress, 22-25 June, in Madrid, Spain. The data confirmed that the improvement in progression-free survival (PFS) with Gazyva®/Gazyvaro® (obinutuzumab)-based treatment over MabThera®/Rituxan®(rituximab)-based treatment was sustained in an updated analysis with a further six months of follow-up, irrespective of chemotherapy regimen. In addition, health-related quality of life (HRQoL) as reported by people in the Gazyva/Gazyvaro treatment group improved from the baseline assessment, suggesting that lymphoma-related symptoms were reduced by treatment and that this improvement was not diminished by treatment-related side effects. Additional preliminary analyses support the potential use of positron emission tomography (PET) as an early predictor of progression-free survival and overall survival in untreated follicular lymphoma.

“These data add to the growing body of evidence that Gazyva/Gazyvaro plays an important role in advancing the treatment of follicular lymphoma,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “Gazyva/Gazyvaro helped people with follicular lymphoma live longer without their disease worsening compared to MabThera/Rituxan, regardless of chemotherapy regimen. Importantly, this benefit did not come at the expense of health-related quality of life, an important measure of the patient’s treatment experience.”

The following new data from the GALLIUM study will be presented:

- A subanalysis by chemotherapy regimen showed that improvement in investigator-assessed PFS was superior for Gazyva/Gazyvaro-based treatment vs MabThera/Rituxan-based treatment across CHOP, CVP and bendamustine chemotherapy regimens. The benefit in PFS with Gazyva/Gazyvaro-based treatment was sustained over time. After a further six months of follow-up, for a total follow-up period of 41.1 months, the reduction in the risk of disease progression or death in the Gazyva/Gazyvaro-treated group remained consistent with the previous analysis (HR= 0.68; 95% CI 0.54-0.87; p=0.0016). [Abstract S775, to be presented in an oral presentation on Sunday, 25 June at 8:15 CET].
- An additional subanalysis demonstrated that around 50% of people in both the Gazyva/Gazyvaro-based treatment group and the MabThera/Rituxan-based treatment group reported clinically meaningful improvements in HRQoL from their baseline. This effect underscores the importance of treatment in effect in alleviating symptoms of follicular lymphoma that impact patients' HRQoL. Importantly, the improvement seen was not diminished by treatment-related side effects. When viewed in the context of longer PFS, these results further support the relative benefit of Gazyva/Gazyvaro-based treatment over MabThera/Rituxan-based treatment in this setting. [Abstract S502 to be presented in an oral presentation on Saturday, 24 June at 16:15 CET].
- Data from GALLIUM provides the first large-scale prospective comparison of standard contrast-enhanced CT versus PET scanning. After a median follow-up of 34.5 months, PET status at end of induction, as determined by independent review committee, was highly predictive of PFS (PET-complete remission (CR) vs PET non-CR: HR 0.39; 95% CI 0.25-0.60; p<0.0001) and overall survival (OS) (HR 0.41; 95% CI 0.19-0.86; p=0.018). [Abstract S774, to be presented in an oral presentation on Sunday, 25 June at 8:00 CET].

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/Gazyvaro plus chemotherapy followed by Gazyva/Gazyvaro alone for up to two years, as compared head-to-head against MabThera/Rituxan plus chemotherapy followed by MabThera/Rituxan alone for up to two years or until disease progression (whichever occurs first). Chemotherapies (CHOP, CVP or bendamustine) were selected by each participating study site prior to beginning enrolment. GALLIUM included 1401 patients with previously untreated indolent non-Hodgkin lymphoma (iNHL), of which 1202 patients had follicular lymphoma.

The primary endpoint of the study was investigator-assessed PFS in patients with follicular lymphoma, with secondary endpoints including PFS assessed by independent review committee (IRC), PFS in the overall study population (iNHL), response rate (overall response, ORR; and complete response, CR), overall survival (OS), and safety. The GALLIUM study is being conducted in cooperation with the NCRI (United Kingdom), GLSG (Germany), the East German Study Group Hematology and Oncology (OSHO; Germany).

About Gazyva/Gazyvaro (obinutuzumab)

Gazyva/Gazyvaro 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/Gazyvaro is designed to attack and destroy targeted B-cells both directly and together with the body's immune system.

Gazyva/Gazyvaro is currently approved in more than 80 countries in combination with chlorambucil, for people with previously untreated chronic lymphocytic leukaemia (CLL), and in combination with bendamustine for people with certain types of previously treated follicular lymphoma. The approvals in CLL were based on the CLL11 study, showing significant improvements with Gazyva/Gazyvaro plus chlorambucil across multiple clinical endpoints, including PFS, overall response rate (ORR), complete response rate (CR), and minimal residual disease (MRD) when compared head-to-head with MabThera/Rituxan plus chlorambucil.

The approvals in certain types of previously treated follicular lymphoma were based on the phase III GADOLIN study, in people with follicular lymphoma who did not respond to or who progressed during or within six months of prior MabThera/Rituxan-based therapy, showing a significant improvement in PFS and overall survival (OS) with Gazyva/Gazyvaro-based therapy compared to bendamustine alone.

Gazyva is marketed as Gazyvaro in the EU and Switzerland. Additional combination studies investigating Gazyva/Gazyvaro 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.¹ It is considered incurable and relapse is common. Every day, more than 50 people in Europe are diagnosed with this type of NHL.² It is estimated that more than 75,000 people are diagnosed with follicular lymphoma each year worldwide.²

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 Venclextra™/Venclxyto™ (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 investigational haemophilia A treatment emicizumab.

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 eight 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.

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

Roche Group Media Relations

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

- Nicolas Dunant (Head)
- Patrick Barth
- Ulrike Engels-Lange
- Simone Oeschger
- Anja von Treskow

References

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

² Ferlay J, et al. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet; cited 2017 May]. Available from: http://globocan.iarc.fr/old/summary_table_pop.html.asp?selection=224900&title=World&sex=0&type=0&window=1&sort=0&submit=%C2%A0Execute (accessed on 14/03/2016).