Media Release

Basel, 22 September 2017

Roche receives EU approval of Gazyvaro for people with previously untreated advanced follicular lymphoma

- **Approval is based on phase III GALLIUM study results, which showed superior progression-free survival for Gazyva/Gazyvaro compared to MabThera/Rituxan**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission has approved Gazyvaro® (obinutuzumab) in combination with chemotherapy, followed by Gazyvaro maintenance in people achieving a response, as a new treatment for previously untreated advanced follicular lymphoma. The approval is based on results from the GALLIUM study, the first phase III study in previously untreated follicular lymphoma to show superior progression-free survival (PFS) over MabThera® (rituximab)-based treatment, the current standard of care.

"Every year an estimated 19,000 people in Europe are diagnosed with follicular lymphoma, which is considered to be incurable. We are pleased that with today's approval of Gazyvaro, these patients now have an improved initial treatment option available to them," said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. "By challenging our own MabThera medicine head-to-head, we have been able to set a new standard of care for people with follicular lymphoma."

Results from the phase III GALLIUM study showed that Gazyvaro-based treatment reduced the risk of disease progression or death (progression-free survival; PFS), as evaluated by investigator assessment, by 34 percent (HR=0.66; 95% CI 0.51-0.85, p=0.001). As supported by an independent review committee (IRC), the risk of disease progression or death was reduced by 29 percent (HR=0.71; 95% CI 0.54-0.93, p=0.014) compared to MabThera-based treatment. Median PFS has not yet been reached in either treatment arm. Investigator assessment showed that at three years, 80 percent of patients who received Gazyvaro-based treatment were progression-free compared to 73 percent of patients who received MabThera-based treatment.

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland
Group Communications Roche Group Media Relations
Tel. +41 61 688 88 88 www.roche.com

This is also supported by the IRC analysis, which found that 81.9 percent of patients who received Gazyvaro-based treatment were progression-free compared to 77.9 percent of patients who received MabThera-based treatment. Adverse events observed with either Gazyvaro or MabThera were consistent with those seen in previous clinical trials when each was combined with various chemotherapies.

This is the third approval for Gazyvaro in the EU. It was approved in 2014, in combination with chlorambucil, for people with previously untreated chronic lymphocytic leukaemia with comorbidities that make them unsuitable for full-dose fludarabine-based therapy. In June 2016 Gazyvaro was also approved in combination with bendamustine, followed by Gazyvaro maintenance, in people with follicular lymphoma who did not respond or who progressed during or up to six months after treatment with MabThera or a MabThera-containing regimen.

About the GALLIUM study

GALLIUM (NCT01332968) is a global phase III open-label, multi-centre, randomised two-arm study examining the efficacy and safety of Gazyvaro plus chemotherapy followed by Gazyvaro alone for up to two years, as compared head-to-head against MabThera plus chemotherapy followed by MabThera alone for 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 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 Gazyvaro (obinutuzumab)

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. Gazyvaro 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. 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 Gazyvaro plus chlorambucil across multiple clinical endpoints, including PFS, ORR, CR, and minimal residual disease (MRD) when compared head-to-head with MabThera 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-based therapy, showing a significant improvement in PFS and OS with Gazyvaro-based therapy compared to bendamustine alone.
Additional combination studies investigating 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 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 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 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.

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 2012]. 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