

Basel, 30 May 2015

Roche's Gazyva/Gazyvaro extended the time people with refractory indolent non-Hodgkin's lymphoma lived without their disease worsening

- **GADOLIN is the second positive phase III study in the Gazyva/Gazyvaro clinical development programme**
- **Roche will submit data from the GADOLIN study to regulatory authorities in the US, Europe and around the world for approval consideration**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced results from the Phase III GADOLIN study showing that Gazyva®/Gazyvaro® (obinutuzumab) plus bendamustine followed by Gazyva/Gazyvaro alone provided significant benefit for people with indolent non-Hodgkin's lymphoma (NHL) that is refractory to MabThera®/Rituxan® (rituximab)-based treatment. In the study, Gazyva/Gazyvaro plus bendamustine followed by Gazyva/Gazyvaro alone reduced the risk of disease worsening or death (progression-free survival, PFS) by 45 percent (HR=0.55, p=0.0001), compared to bendamustine alone. The study was stopped prior to its protocol-specified final analysis due to the high level of benefit seen in the Gazyva/Gazyvaro arm compared to the bendamustine arm. There were no unexpected safety signals identified with Gazyva/Gazyvaro.

“Unfortunately, some people with indolent non-Hodgkin's lymphoma have disease that is refractory to MabThera/Rituxan-based therapy, a standard of care treatment. We're excited by these data showing that Gazyva/Gazyvaro could help these people who have few treatment options remaining,” said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development.

The late-breaking data from the GADOLIN study will be featured in the official press programme of the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on Saturday, 30 May, 2015 at 8.00AM CDT. The data will be presented thereafter during ASCO's 51st Annual Meeting by Dr Laurie Sehn, MD, British Columbia Cancer Agency/University of British Columbia (Abstract [LBA8502], 1 June at 9.45 AM CDT), and subsequently at the 20th annual congress of the European Hematology Association (EHA)

and the 13th International Conference on Malignant Lymphoma (ICML) in June 2015.

Data from this pivotal study will be submitted to the US Food and Drug Administration, European Medicines Agency and other health authorities around the world for approval consideration.

About the GADOLIN study

GADOLIN is a Phase III open-label, multicentre, randomised two-arm study evaluating Gazyva/Gazyvaro plus bendamustine followed by Gazyva/Gazyvaro alone for up to two years, compared to bendamustine alone. GADOLIN included 413 patients with indolent NHL whose disease progressed during or within six months of prior MabThera/Rituxan-based therapy. The primary endpoint of the study is progression-free survival (PFS) as assessed by an independent review committee (IRC), with secondary endpoints including PFS as assessed by investigator review, response rate (RR), best response and overall survival (OS).

Results presented at ASCO showed:

- The median PFS was not reached in the Gazyva/Gazyvaro-based treatment group versus 14.9 months with bendamustine alone (HR=0.55, p=0.0001), as assessed by IRC.
- The median PFS with Gazyva/Gazyvaro-based treatment was more than double that with bendamustine alone (29.2 months versus 14.0 months, HR=0.52 p<0.0001), as assessed by investigator review.
- No unexpected safety signals were identified in the Gazyva/Gazyvaro-based treatment arm. Grade 3-4 adverse events that occurred in at least two percent of patients in the Gazyva/Gazyvaro-treated group or bendamustine alone group included low white blood cell count (33% versus 26.3%), low blood platelet count (10.8% versus 16.2%), infusion-related reactions (10.8% versus 5.6%), low red blood cell count (7.7% versus 10.1%), low white blood cell count with fever (4.6% versus 3.5%), nausea (1% versus 3%), fatigue (1.5% versus 2.5%), diarrhoea (1% versus 2.5%), vomiting (2.1% versus 1%), respectively.

About Gazyva/Gazyvaro (obinutuzumab)

Gazyva/Gazyvaro is an engineered monoclonal antibody designed to attach to CD20, a protein found only on B-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 50 countries in combination with chlorambucil, for

people with previously untreated chronic lymphocytic leukaemia. The approval was 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.

Gazyva is marketed as Gazyvaro in the EU and Switzerland.

Gazyva/Gazyvaro is being studied in a large clinical programme, including the Phase III GOYA and GALLIUM studies. GOYA is comparing Gazyva/Gazyvaro head-to-head with MabThera/Rituxan plus chemotherapy in first line diffuse large B-cell lymphoma (DLBCL) and GALLIUM is comparing Gazyva/Gazyvaro head-to-head with MabThera/Rituxan plus chemotherapy in first line indolent NHL. Additional combination studies investigating Gazyva/Gazyvaro with other approved or investigational medicines, including cancer immunotherapies and small molecule inhibitors, are planned or underway across a range of blood cancers.

About non-Hodgkin's lymphoma

There are two main types of lymphoma: Hodgkin's lymphoma and non-Hodgkin's lymphoma (NHL). NHL represents approximately 85 percent of all lymphomas diagnosed.¹ Approximately 200,000 people die each year from NHL worldwide and approximately one person is newly diagnosed every 90 seconds.¹

There are more than 60 different types of NHL that fall under two subsets, aggressive and indolent (slow-growing). The most common type of indolent NHL is follicular lymphoma (FL), found in about 25 percent of all NHL patients.²

Most cases of NHL start in B-lymphocytes, cells that are part of the body's immune system and help to defend the body against infections. B-cell lymphoma develops when these cells become cancerous and begin to multiply and collect in the lymphatic system such as in lymph nodes, lymphatic tissues or the spleen.

About Roche in haematology

For more than 20 years, Roche has been developing medicines that redefine treatment in haematology. Today, we're 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 and Gazyva/Gazyvaro, Roche's pipeline of investigational haematology medicines includes an anti-CD79b antibody drug conjugate (RG7596/polatuzumab vedotin), a small molecule antagonist of MDM2 (RG7112) and in collaboration with

AbbVie, a small molecule BCL-2 inhibitor (venetoclax/RG7601/GDC-0199/ABT-199). Roche's dedication to developing novel molecules in haematology expands beyond oncology, with the development of the investigational haemophilia A treatment ACE910.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-eight medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. 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 roche.com.

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2. Salles, GA. Clinical features, prognosis and treatment of follicular lymphoma. *Hematology Am Soc Hematol Educ Program*. 2007: 216–225.