

Basel, 23 May 2014

## **CHMP recommends EU approval of Roche's Gazyvaro™ for people with chronic lymphocytic leukemia**

- **In the pivotal phase III CLL11 study, treatment with Gazyvaro (obinutuzumab) plus chlorambucil has been shown to significantly reduce the risk of disease worsening or death by 86% and increase survival time for previously untreated CLL patients compared to those who received treatment with chlorambucil alone**
- **As compared to MabThera® plus chlorambucil, Gazyvaro plus chlorambucil significantly reduced the risk of disease worsening or death by 61%**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the EU Committee for Medicinal Products for Human Use (CHMP) recommended that the European Commission approve Gazyvaro in combination with chlorambucil for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) who have comorbidities making them unsuitable for a certain type of chemotherapy (full-dose fludarabine). Gazyvaro is marketed as Gazyva in the U.S. and the rest of the world.

“We are delighted the CHMP has recognized the strength of the Gazyvaro data established in the CLL11 study,” said Sandra Horning, M.D., Roche’s Chief Medical Officer and Head, Global Product Development. “Typically, around half of patients diagnosed with CLL have comorbidities that make full-dose fludarabine based treatment unsuitable for them. We are pleased to be one step closer to making Gazyvaro available as a new foundation of treatment for their disease.”

The CHMP opinion is based primarily on data from the phase III CLL11 study that was conducted in close collaboration with the German CLL Study Group. The study showed that Gazyvaro plus chlorambucil met its primary endpoint by significantly lengthening the amount of time people lived without their disease worsening (progression free survival; PFS) compared to chlorambucil alone and compared to MabThera® (rituximab) plus chlorambucil while also increasing the depth of remissions as measured by Minimal Residual Disease (MRD). Gazyvaro plus chlorambucil also increased survival time for previously untreated

CLL patients compared to those who received treatment with chlorambucil alone. Data from the study was recently published in the *New England Journal of Medicine*<sup>i</sup>.

Roche expects a final decision from the European Commission in the coming months.

### **About Chronic Lymphocytic Leukemia**

Chronic lymphocytic leukemia is the most common type of leukemia in the Western world. Each year, CLL is responsible for approximately 10,000 deaths across Europe<sup>ii,iii</sup>.

### **About Gazyvaro**

Gazyvaro, marketed as Gazyva in the U.S. and the rest of the world is a new monoclonal antibody designed to attach to CD20, a protein found only on B cells. It attacks targeted cells both directly and together with the body's immune system.

Gazyvaro was discovered by Roche Glycart AG, now known as Roche Innovation Center Zurich, a part of the company's Pharma Research and Early Development organization. In the U.S., Gazyva was approved in November 2013 in combination with chlorambucil for people with previously untreated chronic lymphocytic leukemia. Globally, Gazyvaro is also being investigated in a large clinical program, including multiple head-to-head phase III studies compared to MabThera/Rituxan in indolent non-Hodgkin lymphoma (NHL) and diffuse large B-cell lymphoma (DLBCL).

### **About the CLL11 study**

CLL11 is a phase III, multicentre, open-label, randomised three-arm study conducted in close collaboration with the German CLL Study Group which is investigating the efficacy and safety profile of Gazyvaro plus chlorambucil, MabThera/Rituxan plus chlorambucil and chlorambucil alone in 781 previously untreated people with CLL and co-existing medical conditions who are in need of therapy. Stage 1 (n=589) compared Gazyvaro plus chlorambucil to chlorambucil alone and MabThera/Rituxan plus chlorambucil to chlorambucil alone. Stage 2 (n=663) compared Gazyvaro plus chlorambucil directly with MabThera/Rituxan plus chlorambucil.

The primary endpoint of the study was PFS with secondary endpoints including overall response rate (ORR), overall survival (OS), disease free survival (DFS), MRD and safety profile.

### **About Roche in hematology**

For more than 20 years, Roche has been developing medicines that redefine treatment in hematology. Today, we're investing more than ever in our effort to bring innovative treatment options to people with cancers of the blood.

In addition to MabThera and Gazyvaro, Roche's pipeline of potential hematology 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 (RG7601/GDC-0199/ABT-199).

### **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-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 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 [www.roche.com](http://www.roche.com).

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#### References

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<sup>i</sup> N Engl J Med 2014; 370:1101-1110 March 20, 2014 DOI: 10.1056/NEJMoa1313984

<sup>ii</sup> Ferlay J, Steliarova-Foucher E, Lortet-Tieulent J, Rosso S, Coebergh JWW, Comber H, Forman D, Bray F. Cancer incidence and mortality patterns in Europe: estimates for 40 countries in 2012. Eur J Cancer. 2013 Apr;49(6):1374-403. doi: 10.1016/j.ejca.2012.12.027.

<sup>iii</sup> American Cancer Society. (2014) *Cancer Facts and Figures 2014*. Retrieved from <http://www.cancer.org/acs/groups/content/@research/documents/webcontent/acspc-042151.pdf>