

Basel, 18 September 2017

Phase III data showed that Venclexta/Venclyxto plus MabThera/Rituxan helped people with previously treated chronic lymphocytic leukaemia live longer without their disease worsening compared to bendamustine plus MabThera/Rituxan

- **Data from pivotal phase III study will be submitted to health authorities and presented at an upcoming medical meeting**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the phase III MURANO study, which evaluated Venclexta®/Venclyxto® (venetoclax) in combination with MabThera®/Rituxan® (rituximab) in people with relapsed or refractory chronic lymphocytic leukaemia (CLL), met its primary endpoint and showed a statistically significant improvement in the time people lived without their disease progressing (progression-free survival [PFS] as assessed by investigator) when treated with Venclexta/Venclyxto plus MabThera/Rituxan compared to bendamustine plus MabThera/Rituxan. No new safety signals or increase in known toxicities of Venclexta/Venclyxto were observed with the treatment combination of Venclexta/Venclyxto plus MabThera/Rituxan. Venclexta/Venclyxto (venetoclax) is being developed by AbbVie and Roche. It is jointly commercialised by AbbVie and Genentech, a member of the Roche Group, in the United States and commercialised by AbbVie outside of the United States.

“Chronic lymphocytic leukaemia is considered incurable and becomes harder to treat with each relapse,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “This is the first study to show that Venclexta/Venclyxto plus MabThera/Rituxan can help people with this type of leukaemia live significantly longer without their disease worsening compared to a standard-of-care regimen. We will work with health authorities to bring this potential chemotherapy-free treatment option to the people who need it as quickly as possible.”

In January 2016, Roche announced that the US Food and Drug Administration (FDA) granted breakthrough therapy designation for Venclexta/Venclyxto in combination with MabThera/Rituxan for the treatment of relapsed or refractory CLL based on promising results from the phase Ib M13-365 study. Breakthrough therapy designation is intended to expedite the development and review of medicines with early evidence of potential clinical benefit in serious or life-threatening diseases and to help ensure that patients receive access to medicines as soon as possible.

Venclexta/Venclyxto was granted accelerated approval by the FDA in April 2016 for the treatment of people with CLL with 17p deletion, as detected by an FDA approved test, who have received at least one prior therapy. The MURANO study is part of the company's commitment in the United States to convert the current accelerated approval of Venclexta/Venclyxto to a full approval. Data from the MURANO study will be presented at an upcoming medical meeting and submitted to global health authorities.

About the MURANO Study

MURANO (NCT02005471) is a phase III open-label, international, multicentre, randomized study evaluating the efficacy and safety of Venclexta/Venclyxto in combination with MabThera/Rituxan compared with bendamustine in combination with MabThera/Rituxan. All treatments were of fixed duration. The study included 389 patients with relapsed or refractory CLL who had been previously treated with at least one but not more than three lines of therapy. Patients were randomly assigned in a 1:1 ratio to receive either Venclexta/Venclyxto plus MabThera/Rituxan (Arm A) or bendamustine plus MabThera/Rituxan (Arm B). The primary endpoint of the study is investigator-assessed PFS. Secondary endpoints include PFS assessed by independent review committee (IRC), best overall response, complete response, duration of response, overall survival, event-free survival, time to next CLL treatment and minimal residual disease (MRD) status.

About Venclexta/Venclyxto

Venclexta/Venclyxto is a small molecule designed to selectively bind and inhibit the BCL-2 protein, which plays an important role in a process called apoptosis (programmed cell death). Overexpression of the BCL-2 protein in CLL has been associated with resistance to certain therapies. It is believed that blocking BCL-2 may restore the signaling system that tells cells, including cancer cells, to self-destruct. Venclexta/Venclyxto is being developed by AbbVie and Roche. It is jointly commercialised by AbbVie and Genentech, a member of the Roche Group, in the United States and commercialised by AbbVie outside of the United States.

Together, the companies are committed to further research with Venclexta/Venclyxto, which is currently being evaluated in phase III clinical trials for the treatment of CLL, along with studies in several other types of cancers. In the United States, Venclexta has been granted four breakthrough therapy designations by the FDA: in combination with Rituxan for people with relapsed or refractory CLL; as a monotherapy for people with relapsed or refractory CLL with 17p deletion; in combination with hypomethylating agents (azacitidine or decitabine) for people with untreated acute myeloid leukemia (AML) ineligible for intensive chemotherapy; and in combination with low-dose cytarabine (LDAC) for people with untreated AML ineligible for intensive chemotherapy.

About Chronic Lymphocytic Leukaemia (CLL)

Chronic lymphocytic leukaemia (CLL) is the most common type of leukaemia in the Western world.¹ CLL mainly affects men and the median age at diagnosis is about 70 years.² Worldwide, the incidence of all leukaemias is estimated to be over 350,000¹ and CLL is estimated to affect around one-third of all people newly diagnosed with leukaemia.³

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.

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² SEER Stat Fact Sheets: Chronic Lymphocytic Leukemia (CLL) [Internet; cited 2014]. Available from:

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³ Wendtner CM, et al. Chronic lymphocytic leukemia. Onkopedia guidelines 2012 [Internet; cited 2012]. Available from:

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