Presentation confirms Venclexta/Venclyxto monotherapy benefit in certain patients with high-risk chronic lymphocytic leukaemia and its potential in other hard-to-treat blood cancers

- First in class BCL2-specific oral inhibitor represents a potential new way of treating different blood cancers
- Efficacy and tolerability confirmed in high-risk patients with relapsed or refractory chronic lymphocytic leukaemia, including those with 17p chromosomal deletion
- Preliminary anti-cancer activity seen in phase Ib study of people with acute myeloid leukaemia and multiple myeloma

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced new data from multiple studies of Venclexta®/Venclyxto® (venetoclax), presented at the 22nd European Hematology Association (EHA) Annual Congress, 22-25 June, in Madrid. Data presented in relapsed or refractory chronic lymphocytic leukaemia (CLL) confirmed the efficacy of Venclexta/Venclyxto with high and durable response rates and a well-tolerated safety profile in this high-risk population, including people with 17p chromosomal deletion who had previously received treatment. Additionally, phase Ib data demonstrated the anti-cancer activity of Venclexta/Venclyxto in acute myeloid leukaemia (AML) and relapsed or refractory multiple myeloma (MM), further supporting the potential of this treatment in a broader range of blood cancers.

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.

“Confirmation that Venclexta/Venclyxto achieves a high response rate in relapsed or refractory chronic lymphocytic leukaemia in people with 17p deletion is very promising, as these patients have a particularly poor prognosis,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “We are also pleased to see early data highlighting the potential central role of BCL-2 in other difficult-to-treat blood cancers and look forward to validating these results in further studies.”
The safety and efficacy of Venclexta/Venclyxto is being evaluated in a number of clinical studies in patients with CLL, some of which have led to European Medicines Agency (EMA) conditional marketing authorisation (M13-982 and M14-032) of Venclyxto and Food and Drug Administration (FDA) accelerated approval (M13-982) for Venclexta monotherapy in CLL. Data being presented at EHA include:

- Oral presentation of phase II monotherapy data in high-risk patients with relapsed/refractory CLL with 17p deletion showed an acceptable safety profile and a high response rate of 79%. Minimal residual disease (MRD)-negativity, an exploratory endpoint that is a measure of absence of residual blood cancer in patients’ blood or bone marrow, correlated with a progression-free survival (PFS) rate of 100% at 24 months. [Study M13-982 - Abstract S771, oral presentation Sunday, 25 June, 8:30 CET]. In addition, Venclexta/Venclyxto monotherapy demonstrated improved quality of life (QoL), with sustained and clinically meaningful improvement of several key aspects of functioning and health-related QoL. [Study M13-982 - Abstract S771, oral presentation Sunday 25 June, 8:30 CET and Study M14-032 - Abstract P728, poster presentation Saturday, 24 June, 17:30 CET].

- Phase Ib data with Venclexta/Venclyxto in combination with MabThera®/Rituxan® (rituximab) in patients with relapsed/refractory CLL/small lymphocytic leukaemia (SLL) showed an acceptable safety profile and deep and durable responses, with 51% patients achieving a complete response (CR/CRi), 59% achieving marrow MRD-negativity and an overall response rate (ORR) of 86%. Data in patients achieving MRD-negativity suggested a prolonged treatment-free remission period even after Venclexta/Venclyxto treatment was stopped. [M13-365 study - Abstract P247, poster presentation Friday, 23 June, 17:15 CET].

The safety and efficacy of Venclexta/Venclyxto is also being evaluated in other blood cancers, including AML, an aggressive form of leukaemia that starts in myeloid cells, and MM, a cancer formed from malignant plasma cells.

- In AML, Venclexta/Venclyxto has shown an acceptable safety profile in combination with decitabine or azacitidine and a high ORR of 68% in elderly patients with previously untreated AML. [Study M14-358 - Abstract S472, oral presentation Saturday, 24 June, 16:15 CET]. A further open-label phase I/II study in previously untreated elderly patients with AML showed durable efficacy with an acceptable safety profile for Venclexta/Venclyxto in combination with low-dose cytarabine. [Study M14-387 - Abstract E911 to be presented as an Eposter].
• In MM, data from a phase Ib study of Venclexta/Venclyxto in combination with bortezomib and dexamethasone demonstrated an acceptable safety profile and anti-myeloma activity. When treated with Venclexta/Venclyxto, an overall response rate of 67% was achieved in patients with relapsed or refractory MM. [Study M12-901- Abstract S460, oral presentation Saturday, 24 June, 17:00 CET].

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 signalling system that tells cells, including cancer cells, to self-destruct.

Venclexta/Venclyxto is being co-developed by AbbVie and Roche. Together, the companies are committed to research with Venclexta/Venclyxto, which is currently being evaluated in phase III clinical trials for the treatment of relapsed, refractory and previously untreated CLL, along with studies in several other cancers. Venclexta/Venclyxto is commercialised jointly by AbbVie and Genentech, a member of the Roche Group, in the United States and commercialised by AbbVie outside of the United States.

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 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.

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