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Roche presents new data across a range of blood cancers at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

- **Further data demonstrate polatuzumab vedotin's clinical efficacy across a range of diffuse large B-cell lymphoma subgroups**
- **Additional results from the randomised phase III MURANO study support fixed-duration Venclexta/Venclyxto plus MabThera/Rituxan as a new chemotherapy-free treatment option in previously treated chronic lymphocytic leukaemia**
- **Updated data highlight Venclexta/Venclyxto's potential in previously untreated acute myeloid leukaemia**

Roche (SIX: RO, ROG; OTCQX: RHHBY) presented new data from studies in several blood cancers, including diffuse large B-cell lymphoma (DLBCL), chronic lymphocytic leukaemia (CLL) and acute myeloid leukaemia (AML) at the 2018 ASCO Annual Meeting, 1-5 June, in Chicago, IL, United States. These include additional data from the phase II GO29365 study in relapsed or refractory DLBCL. Additional data from the randomised phase III MURANO study of Venclexta®/Venclyxto® (venetoclax) plus MabThera®/Rituxan® (rituximab) in relapsed or refractory CLL were also presented. Results showed that fixed-duration Venclexta/Venclyxto plus MabThera®/Rituxan® (rituximab) achieved deep and durable minimal residual disease (MRD)-negativity, meaning that no cancer could be detected using a specific test, in people with relapsed or refractory CLL. These results occurred early and were independent of high-risk factors such as the genetic features 17p deletion, mutated TP53 and IGVH unmutated. Data from the MURANO study are under review by the US Food and Drug Administration (FDA). 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.

"We're excited to be presenting a range of data highlighting potential advances in different blood cancers at ASCO this year," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "Roche is committed to bringing practice changing treatments to people with blood cancer through its large and broad development programmes in haematology".

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AML has one of the lowest survival rates of all types of leukaemia.[1] Updated data from the phase Ib M14-358 study showed that Venclexta/Venclyxto in combination with azacitidine or decitabine had a clinical benefit and a tolerable safety profile, in elderly people (≥65) with previously untreated AML, ineligible for standard induction therapy. Results suggest that Venclexta/Venclyxto produced a complete remission rate (with or without full recovery of normal blood cell count; CR/CRi) of 73%. Additionally, MRD-negativity was achieved in 40% of people treated with Venclexta/Venclyxto at a dose of 400mg. Venclexta has previously been granted two breakthrough therapy designations by the FDA in AML in combination with low dose cytarabine or hypomethylating agents. A robust clinical development programme for Venclexta/Venclyxto is ongoing in several other cancer types, including multiple myeloma (MM).

DLBCL is an aggressive type of non-Hodgkin lymphoma, which can be difficult to treat if patients relapse. Additional data from the randomised DLBCL cohort of the phase II GO29365 study showed that polatuzumab vedotin in combination with MabThera/Rituxan plus bendamustine (BR) significantly improved complete response, progression free survival and overall survival vs. BR across a range of subgroups, including second-line patients, third-line patients, relapsed patients and refractory patients. Based on results from this study, polatuzumab vedotin was granted Breakthrough Therapy Designation by the FDA and PRIME (PRIority MEdicines) designation by the European Medicines Agency for the treatment of people with relapsed or refractory DLBCL. Polatuzumab vedotin was also investigated in relapsed or refractory follicular lymphoma as part of the GO29365 study and early data were presented at ASCO 2018. Data from this study will also be presented at the 23rd European Hematology Association (EHA) Annual Congress, 14-17 June, in Stockholm.

About the MURANO Study

MURANO (NCT02005471) is a phase III open-label, international, multicentre, randomised study evaluating the efficacy and safety of Venclexta/Venclyxto (venetoclax) in combination with MabThera/Rituxan (rituximab) compared to standard of care bendamustine in combination with MabThera/Rituxan (BR) in patients with relapsed or refractory CLL. All treatments were of fixed duration. Patients on the Venclexta/Venclyxto plus MabThera/Rituxan arm received six cycles of Venclexta/Venclyxto plus MabThera/Rituxan followed by Venclexta/Venclyxto monotherapy for up to two years total. Patients on the BR arm received six cycles of BR. The study included 389 patients CLL who had been previously treated with at least one line of therapy. Patients were randomly assigned in a 1:1 ratio to receive either Venclexta/Venclyxto plus MabThera/Rituxan or BR. The primary endpoint of the study was progression-free

survival (PFS). Secondary endpoints included overall survival (OS), overall response rate (ORR), complete response rate (with or without complete blood count recovery, CR/CRi) and minimal residual disease.

About the M14-358 study

MI4-358 study is an open-label, phase Ib dose escalation and expansion study evaluating the safety and efficacy of Venclexta/Venclyxto (venetoclax) in combination with azacitidine or decitabine in elderly people (≥65) with previously untreated acute myeloid leukaemia (AML) unfit to receive intensive chemotherapy. The study included 145 patients with untreated AML to receive doses of Venclexta/Venclyxto at 400mg, 800mg and 1200mg in the escalation phase, and 400mg and 800mg in the expansion phase. Adverse events, complete remission (CR) / CR with incomplete blood count recovery (CRi) and overall survival (OS) were evaluated.

About the GO29365 study

GO29365 is a global, phase Ib/II study evaluating the safety, tolerability and activity of polatuzumab vedotin in combination with MabThera/Rituxan (rituximab) or Gazyva/Gazyvaro (obinutuzumab) plus bendamustine in relapsed or refractory follicular lymphoma or diffuse large B-cell lymphoma (DLBCL). The phase II stage randomised 80 patients with previously treated relapsed or refractory DLBCL to receive either bendamustine plus MabThera/Rituxan (BR), or BR in combination with polatuzumab vedotin. Patients enrolled had received a median of two prior therapies (a range of 1-7 prior therapies in the polatuzumab vedotin arm and a range of 1-5 prior therapies in the BR alone arm). The primary endpoint was complete response (CR) at the end of treatment, as measured by positron emission tomography (PET) and assessed by an independent review committee (IRC). Other key endpoints included objective response (OR; CR and partial response, PR) by investigator and IRC assessment, best objective response at the end of treatment by investigator assessment, duration of response (DOR), progression-free survival (PFS), event-free survival (EFS) and overall survival (OS).

About Venclexta/Venclyxto

Venclexta/Venclyxto (venetoclax) 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 chronic lymphocytic leukaemia (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 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, AML and MM. 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 leukaemia (AML) ineligible for intensive chemotherapy, and in combination with low-dose cytarabine (LDAC) for people with untreated AML ineligible for intensive chemotherapy.

About polatuzumab vedotin

Polatuzumab vedotin is a first-in-class anti-CD79b antibody drug conjugate (ADC) currently being investigated for the treatment of several subtypes of non-Hodgkin lymphoma (NHL). The CD79b protein is highly specific and expressed in the majority of types of B-cell NHL, making it a promising target for the development of new therapies.[2] Polatuzumab vedotin is thought to bind to CD79b, triggering internalisation of the drug into the cells. This targets the chemotherapy (which is attached to the monoclonal antibody) to these B-cells. This process is thought to maximise tumour cell death while potentially minimising the effects on normal healthy cells.[3,4] Polatuzumab vedotin is being developed by Roche utilising Seattle Genetics ADC technology.

About Chronic Lymphocytic Leukaemia

Chronic lymphocytic leukaemia (CLL) is the most common type of leukaemia in the Western world.[5] CLL mainly affects men and the median age at diagnosis is about 70 years.[6] Worldwide, the incidence of all leukaemias is estimated to be over 350,000 and CLL is estimated to affect around one-third of all people newly diagnosed with leukaemia.[7]

About Acute Myeloid Leukaemia

Acute myeloid leukaemia (AML) is an aggressive form of leukaemia that starts in immature forms of blood-forming cells, known as myeloid cells, found in the bone marrow.[8] AML is the most common type of aggressive leukaemia in adults.[9] It has one of the lowest survival rates of all types of leukaemia.[1] Even with the best available therapies, older patients aged 65 and over have survival rates comparable to patients with advanced lung cancer, with a five year overall survival rate of <5%.[10,11] Approximately 20,000 people in the United States and 18,000 in Europe are diagnosed with AML each year.[12,13]

About diffuse large B-cell lymphoma

Diffuse large B-cell lymphoma (DLBCL) is the most common subtype of non-Hodgkin lymphoma (NHL), accounting for about one in three cases of NHL.[14] DLBCL is an aggressive (fast-growing) type of NHL, which is generally responsive to treatment in the frontline.[15] However, as many as 40% of patients will relapse, at which time salvage therapy options are limited and survival is short.[13] Approximately 123,000 people worldwide are estimated to be diagnosed with DLBCL each year.[16]

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 Hemlibra® (emicizumab), a bispecific monoclonal antibody for the treatment of haemophilia A.

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 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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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References

[1] Leukemia & Lymphoma Society: Facts and statistics overview – Leukemia. Available at: http://www.lls.org/http%3A/llsorg.prod.acquia-sites.com/facts-and-statistics/facts-and-statistics-overview/facts-and-statistics#Leukemia.

[2] Dornan D, et al. Therapeutic potential of an anti-CD79b antibody-drug conjugate, anti-CD79b-vc-MMAE, for the treatment of non-Hodgkin lymphoma. Blood 2009; 114:2721–2729

[3] Ducry L, Stump B. Antibody-drug conjugates: linking cytotoxic payloads to monoclonal antibodies. Bioconjug Chem. 2010;21:5-13.

[4] ADC Review. What are antibody-drug conjugates? [Internet; cited 2016 Jan 12]. Available from: https://adcreview.com/adc-university/adcs-101/antibody-drug-conjugates-adcs/

[5] Union for International Cancer Control. 2014 Review of Cancer Medicines on the WHO List of Essential Medicines: Chronic lymphocytic leukemia [Internet; cited 2014]. Available from: http://www.who.int/selection_medicines/committees/expert/20/applications/CLL.pdf?ua=1

[6] SEER Stat Fact Sheets: Chronic Lymphocytic Leukemia (CLL) [Internet; cited 2018 May]. Available from: http://seer.cancer.gov/statfacts/html/clyl.html

[7] Wendtner CM, et al. Chronic lymphocytic leukemia. Onkopedia guidelines 2012 [Internet; cited 2018 May]. Available from: https://www.onkopedia-guidelines.info/en/onkopedia/guidelines/chronic-lymphocytic-leukemia-cll/@@view/html/index.html

[8] American Cancer Society: What is acute myeloid leukemia? Available at: http://www.cancer.org/cancer/leukemia-acutemyeloidaml/detailedguide/leukemia-acute-myeloid-myelogenous-what-is-aml

[9] National Cancer Institute: Adult Acute Myeloid Leukemia Treatment (PDQ®)–Patient Version. Available at: https://www.cancer.gov/types/leukemia/patient/adult-aml-treatment-pdq#link/_1.

[10] Sekeres MA. Treatment Of Older Adults With Acute Myeloid Leukemia: State Of The Art And Current Perspectives. Haematologica 2008; 93: 1769-1772

[11] Cancer Research UK: Survival statistics for acute myeloid leukaemia (AML). [Internet; cited 2018 May] Available at: http://www.cancerresearchuk.org/about-cancer/acute-myeloid-leukaemia-aml/survival?_ga=2.239561667.1384102361.1500450925-993068745.1500450925.

[12] National Cancer Institute. Adult Acute Myeloid Leukemia Treatment (PDQ®)–Health Professional Version [Internet; cited 2018 May]. Available from: https://www.cancer.gov/types/leukemia/hp/adult-aml-treatment-pdq

[13] Visser O, et al. (RARECARE Working Group). Incidence, survival and prevalence of myeloid malignancies in Europe. Eur J Cancer. 2012;48:3257-3266.

[14] Lyon, France. World Health Organization Classification of Tumors of Haematopoietic and Lymphoid Tissues. IARC Press;2008.

[15] Maurer, JM et al.. Event-free survival at 24 months is a robust end point for disease-related outcome in diffuse large B-cell lymphoma treated with immunochemotherapy. J Clin Oncol 2014; 32: 1066-73.

[16] Numbers derived from GLOBOCAN 2012: Estimated cancer incidence, mortality and prevalence worldwide in 2012. [Internet; cited 2018 May]. Available from: http://globocan.iarc.fr.