# *Media Release*

## Roche announces Venclexta/Venclyxto combination improved overall survival in people with previously untreated acute myeloid leukaemia

- **Phase III VIALE-A study showed Venclexta/Venclyxto plus azacitidine helped people with the most common type of aggressive leukaemia in adults live longer compared to azacitidine alone**
- **Data will be shared with global health authorities and presented at an upcoming medical meeting**

Basel, 23 March 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the phase III VIALE-A study met its dual primary endpoints of overall survival and composite complete remission rate (CR + CRi). Venclexta®/Venclyxto® (venetoclax) in combination with azacitidine, a hypomethylating agent, showed a statistically significant improvement in overall survival in people with previously untreated acute myeloid leukaemia (AML) who were ineligible for intensive induction chemotherapy, compared to azacitidine alone. Safety for Venclexta/Venclyxto plus azacitidine appeared consistent with the known safety profile of these medicines.

"Acute myeloid leukaemia remains a challenging blood cancer, with particularly low median survival rates in patients who cannot tolerate intensive chemotherapy given their age or underlying health," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "These data validate the benefit that this Venclexta/Venclyxto-based combination can bring to patients and we look forward to discussing the results with health authorities."

Data from the VIALE-A study will be shared with global health authorities and presented at an upcoming medical meeting. Venclexta has previously been granted accelerated approval by the US Food and Drug Administration (FDA) in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of people with newly-diagnosed AML who are aged 75 years or older, or for those ineligible for intensive induction chemotherapy due to coexisting medical conditions, based on response rates from the M14-358 and M14-387 studies. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory studies. Venclexta has also been granted five Breakthrough Therapy Designations by the FDA, including two for previously untreated AML.

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 US, and commercialised by AbbVie outside of the US.

**About the VIALE-A study**
VIALE-A (NCT02993523) is a phase III, randomised, double-blind, placebo-controlled multicentre study evaluating the efficacy and safety of Venclexta/Venclyxto plus azacitidine, a hypomethylating agent, compared to placebo plus azacitidine, in 431 people with previously untreated acute myeloid leukaemia who are ineligible for intensive chemotherapy. Two-thirds of patients received 400 mg Venclexta/Venclyxto daily, in combination with azacitidine, and the remaining patients received placebo tablets in combination with azacitidine. The primary endpoints of the study are overall survival, and rate of complete remission (CR) and CR with incomplete blood count recovery (CRi). Secondary endpoints include event free survival, CR and

**F. Hoffmann-La Roche Ltd** 4070 Basel Switzerland
Group Communications Roche Group Media Relations
Tel. +41 61 688 88 88 www.roche.com

CR with partial haematologic recovery (CRh), transfusion independence and patient-reported outcomes.

**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.[1] AML is the most common type of aggressive leukaemia in adults.[2] It has the lowest survival rate of all types of leukaemia.[2] 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%.[3,4] Approximately 20,000 people in the US and 18,000 in Europe are diagnosed with AML each year.[5,6]

**About Venclexta/Venclyxto (venetoclax)**
Venclexta/Venclyxto is a first-in-class targeted medicine designed to selectively bind and inhibit the B-cell lymphoma-2 (BCL-2) protein. In some blood cancers and other tumours, BCL-2 builds up and prevents cancer cells from dying or self-destructing, a process called apoptosis. Venclexta/Venclyxto blocks the BCL-2 protein and works to restore the process of apoptosis.

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 US, and commercialised by AbbVie outside of the US. Together, the companies are committed to research with Venclexta/Venclyxto, which is currently being studied in clinical trials across several types of blood and other cancers.

In the US, Venclexta has been granted five Breakthrough Therapy Designations by the US Food and Drug Administration: one for previously untreated chronic lymphocytic leukaemia (CLL), two for relapsed or refractory CLL and two for previously untreated acute myeloid leukaemia.

**About Roche in haematology**
Roche has been developing medicines for people with malignant and non-malignant blood diseases for over 20 years; our experience and knowledge in this therapeutic area runs deep. Today, we are investing more than ever in our effort to bring innovative treatment options to patients across a wide range of haematologic diseases. Our approved medicines include MabThera®/Rituxan® (rituximab), Gazyva®/Gazyvaro® (obinutuzumab), Polivy® (polatuzumab vedotin), Venclexta/Venclyxto (venetoclax) in collaboration with AbbVie, and Hemlibra® (emicizumab). Our pipeline of investigational haematology medicines includes idasanutlin, a small molecule which inhibits the interaction of MDM2 with p53; T-cell engaging bispecific antibodies targeting both CD20 and CD3, Tecentriq® (atezolizumab), a monoclonal antibody designed to bind with PD-L1; and crovalimab, an anti-C5 antibody engineered to optimise complement inhibition. Our scientific expertise, combined with the breadth of our portfolio and pipeline, also provides a unique opportunity to develop combination regimens that aim to improve the lives of patients even further.

**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. More than 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. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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.



**References**

[1] American Cancer Society. What is acute myeloid leukemia? [Internet; cited March 2020]. Available from: http://www.cancer.org/cancer/leukemia-acutemyeloidaml/detailedguide/leukemia-acute-myeloid-myelogenous-what-is-aml.
[2] Leukemia & Lymphoma Society: Facts and statistics overview – Leukemia. [Internet; cited March 2020]. Available from: https://www.lls.org/facts-and-statistics/facts-and-statistics-overview/facts-and-statistics#Leukemia.
[3] Sekeres MA. Treatment Of Older Adults With Acute Myeloid Leukemia: State Of The Art And Current Perspectives. Haematologica 2008;93:1769-1772.
[4] Cancer Research UK: Survival statistics for acute myeloid leukaemia (AML). [Internet; cited March 2020]. Available from: https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/leukaemia-aml/survival.
[5] National Cancer Institute. Adult Acute Myeloid Leukemia Treatment (PDQ®)–Health Professional Version. [Internet; cited March 2020]. Available from: https://www.cancer.gov/types/leukemia/hp/adult-aml-treatment-pdq.
[6] Visser, et al. Incidence, survival and prevalence of myeloid malignancies in Europe. Eur J Cancer. 2012; 48(17): 3257-66.

**Roche Group Media Relations**

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com
- Nicolas Dunant (Head)
- Patrick Barth
- Daniel Grotzky
- Karsten Kleine
- Nathalie Meetz
- Barbara von Schnurbein