

Ad hoc announcement pursuant to Art. 53 LR

Phase III study shows Roche's Polivy plus R-CHP is the first regimen in 20 years to significantly improve outcomes in previously untreated aggressive form of lymphoma compared to standard of care

- **Pivotal phase III POLARIX trial comparing Polivy in combination with chemotherapy regimen R-CHP versus the standard of care R-CHOP in treatment of first-line diffuse large B-cell lymphoma (DLBCL) met its primary endpoint of investigator-assessed progression-free survival**
- **Prolonging survival without disease advancement could be transformative for newly diagnosed DLBCL patients as currently 40% of patients relapse after disease progression**
- **Data will be submitted to health authorities globally as soon as possible and presented at an upcoming medical meeting**

Basel, 9 August 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the pivotal phase III POLARIX trial investigating Polivy® (polatuzumab vedotin) in combination with MabThera®/Rituxan® (rituximab) plus cyclophosphamide, doxorubicin and prednisone (R-CHP) versus MabThera/Rituxan plus cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP), met its primary endpoint by demonstrating significantly improved and clinically meaningful progression-free survival in people with previously untreated diffuse large B-cell lymphoma (DLBCL). Safety outcomes were consistent with those seen in previous trials.

“Since 40% of people with DLBCL relapse after initial therapy, achieving meaningful treatment effects in the front-line setting has the potential to be transformative,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “This Polivy regimen is the first in two decades to improve progression-free survival in DLBCL compared to the standard of care, and we look forward to sharing these results with health authorities to bring this important potential new treatment option to patients as soon as possible.”

Today’s POLARIX results will be presented at an upcoming medical meeting and submitted to health authorities as part of Roche’s commitment to transforming the treatment of DLBCL by providing options tailored to patient and healthcare professional needs. Roche would like to thank all investigators, academic partners and people with DLBCL who participated in the study.

Currently, Polivy is used as an off-the-shelf, fixed-duration treatment option in the relapsed or refractory (R/R) DLBCL setting, and is approved in combination with bendamustine and MabThera/Rituxan for the treatment of R/R DLBCL in more than 60 countries worldwide, including in the EU and in the US. Roche continues to explore areas of unmet need where Polivy has the potential to deliver benefit, with ongoing studies investigating combinations of Polivy with the CD20xCD3 T-cell engaging bispecific antibodies

mosunetuzumab and glofitamab, with Venclexta®/Venclxyto® (venetoclax), which is being developed by AbbVie and Roche, and with MabThera/Rituxan in combination with gemcitabine and oxaliplatin in the phase III POLARGO study.

About the POLARIX study

POLARIX [[NCT03274492](https://clinicaltrials.gov/ct2/show/study/NCT03274492)] is an international phase III, randomised, double-blind, placebo-controlled study evaluating the efficacy, safety and pharmacokinetics of Polivy® (polatuzumab vedotin) plus MabThera®/Rituxan® (rituximab), cyclophosphamide, doxorubicin and prednisone (R-CHP) versus MabThera/Rituxan, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) in people with previously untreated diffuse large B-cell lymphoma (DLBCL). Eight-hundred and seventy-nine patients were randomised 1:1 to receive either Polivy plus R-CHP plus a vincristine placebo for six cycles, followed by MabThera/Rituxan for two cycles; or R-CHOP plus a Polivy placebo for six cycles, followed by two cycles of MabThera/Rituxan. The primary outcome measure is progression-free survival as assessed by the investigator using the Lugano Response Criteria for malignant lymphoma. POLARIX is being conducted in collaboration with The Lymphoma Study Association (LYSA) and The Lymphoma Academic Research Organisation (LYSARC).

About the LYSA and the LYSARC

The Lymphoma Study Association, or LYSA, is the internationally leading cooperative group for lymphoma research in Europe, conducting clinical studies ranging from the first tests of new medicines in humans to the establishment of reference therapeutic strategies. LYSA includes in its network more than 120 care centres distributed throughout four countries (France, Belgium, Portugal, Israel), and collaborates with many scientific teams at the international level.

The Lymphoma Academic Research Organisation, or LYSARC, is the LYSA operational structure that conducts clinical research projects on lymphomas at the international level.

About Polivy® (polatuzumab vedotin)

Polivy is a first-in-class anti-CD79b antibody-drug conjugate (ADC). The CD79b protein is expressed specifically in the majority of B-cells, an immune cell impacted in some types of non-Hodgkin lymphoma (NHL), making it a promising target for the development of new therapies.^{1,2} Polivy binds to cancer cells such as CD79b and kills these B-cells through the delivery of an anti-cancer agent, which is thought to minimise the effects on normal cells.^{3,4} Polivy is being developed by Roche using Seagen ADC technology and is currently being investigated for the treatment of several types of NHL. Polivy is marketed in the US by Genentech as Polivy (polatuzumab vedotin-piiq), with piiq as the suffix designated in accordance with Nonproprietary Naming of Biological Products Guidance for Industry issued by the U.S. Food and Drug Administration.

About diffuse large B-cell lymphoma (DLBCL)

DLBCL is the most common form of non-Hodgkin lymphoma (NHL), accounting for about one in three cases of NHL.⁵ DLBCL is an aggressive (fast-growing) type of NHL.⁶ While it is generally responsive to treatment in the frontline, as many as 40% of patients will relapse or have refractory disease, at which time salvage therapy options are limited and survival is short.^[6] Approximately 150,000 people worldwide are estimated to be diagnosed with DLBCL each year.⁷

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 T-cell engaging bispecific antibodies, glofitamab and mosunetuzumab, targeting both CD20 and CD3, and cevostamab, targeting both FcRH5 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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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 twelfth 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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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.

All trademarks used or mentioned in this release are protected by law.

References

- [1] 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;114:2721-29.
- [2] Pfeifer M, et al. Anti-CD22 and anti-CD79B antibody drug conjugates are active in different molecular diffuse large B-cell lymphoma subtypes. *Leukemia* 2015;29:1578-86.
- [3] Ducry L, et al. 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 2021 July]. Available from: <https://adcreview.com/adc-university/adcs-101/antibody-drug-conjugates-adcs/>.
- [5] World Health Organization Classification of Tumours of Haematopoietic and Lymphoid Tissues. IARC Press; 2008.
- [6] 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.
- [7] Globocan 2020. World Fact Sheet. [Internet; cited 2021 July]. Available from: <http://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf>

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Patrick Barth
Phone: +41 61 688 44 86

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mähltitz
Phone: +41 79 327 54 74

Nathalie Meetz
Phone: +41 61 687 43 05

Roche Investor Relations

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Jon Kaspar Bayard
Phone: +41 61 68-83894
e-mail: jon_kaspar.bayard@roche.com

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com