Media & Investor Release

Roche presents new and updated data for Polivy in previously untreated diffuse large B-cell lymphoma at ASH 2022

- **Updated data from the phase III POLARIX study continue to demonstrate a statistically significant reduction in the risk of disease worsening or death for people with previously untreated diffuse large B-cell lymphoma (DLBCL)[1]**

- **Patients receiving Polivy plus R-CHP for DLBCL reported similar health-related quality of life outcomes, during and after fixed-duration treatment, to those receiving the current standard-of-care, with superior progression-free survival[2]**

Basel, 12 December 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new and updated data for its first-in-class anti-CD79b antibody-drug conjugate Polivy® (polatuzumab vedotin) were presented at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition, 10-13 December. Data from the POLARIX study support the potential benefit of Polivy in combination with MabThera®/Rituxan® (rituximab), cyclophosphamide, doxorubicin and prednisone (R-CHP) to improve outcomes for people with previously untreated diffuse large B-cell lymphoma (DLBCL).[1]

“Too many patients with diffuse large B-cell lymphoma see their cancer relapse or progress after initial treatment. This highlights the need to improve on a standard-of-care that has remained unchanged for the last two decades,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “These updated POLARIX data indicate the potential benefits that this Polivy based-regimen could bring to people living with this aggressive type of lymphoma, and demonstrate our commitment to developing new treatment options.”

After a median follow up of three years, progression-free survival (PFS) data continued to show a statistically significant reduction in the risk of disease worsening or death with Polivy plus R-CHP compared with rituximab plus cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP; [hazard ratio (HR) 0.76; 95% confidence interval (CI): 0.60-0.97]). After a median follow-up of 39.7 months, overall survival (OS) data was immature with few events in each arm and remained similar between Polivy plus R-CHP and R-CHOP (HR 0.94; 95% CI: 0.67-1.33; p=0.73). In the longer follow-up analysis, no new safety signals were identified.[1]

Health-related quality of life (HRQoL) data from the POLARIX study were also presented, showing that most patients with previously untreated DLBCL receiving Polivy plus R-CHP or R-CHOP reported clinically meaningful improvements in lymphoma symptoms after the first cycle of treatment across both arms (82.3% and 81.3% of patients, respectively). Improvements in fatigue and physical functioning were similar with Polivy plus R-CHP versus

R-CHOP, with 74.8% versus 68.2% of patients reporting improvements in fatigue and 42.4% versus 39.6% of patients reporting clinically meaningful improvements in physical functioning at any time point. Reported improvements were sustained during and after first-line therapy, up to the 24-month follow-up. This HRQoL analysis of the POLARIX study demonstrates that these patient-reported outcomes are not compromised with improved PFS, highlighting the potential of Polivy to help manage the burden of DLBCL.[2]

The need for more effective treatments for patients with previously untreated DLBCL was underscored in an economic analysis of the total cost of care in relapsed or refractory (R/R) DLBCL. The study evaluated healthcare costs and resources in the second-line setting and beyond, and found that total healthcare costs increased with each additional line of treatment.[3] Separately, an analysis of the POLARIX study also presented at ASH showed that over the next ten years, Polivy plus R-CHP has the potential to reduce the number of patients receiving second-line treatment by 27% compared to R-CHOP, potentially improving the chance of a positive outcome for more patients and significantly reducing the overall treatment burden of DLBCL.[4]

Based on the pivotal data from the POLARIX study, more than 50 countries have approved Polivy in combination with R-CHP for the treatment of adult patients with previously untreated DLBCL, including the EU, Japan and, most recently, Canada. The company's supplemental Biologics License Application was accepted by the U.S. Food and Drug Administration, and a decision is expected by 2 April, 2023. Polivy is currently approved in more than 80 countries and regions worldwide, including in the U.S. and Europe, as a readily available, fixed-duration treatment option for R/R DLBCL in combination with bendamustine and MabThera/Rituxan, after at least two prior therapies.

Roche continues to explore areas of unmet need where Polivy has the potential to deliver additional benefit, including in ongoing studies investigating combinations of Polivy with CD20xCD3 T-cell engaging bispecific antibodies, Lunsumio® (mosunetuzumab) and glofitamab, including the phase III SUNMO study in combination with Lunsumio, and with MabThera/Rituxan in combination with gemcitabine and oxaliplatin in the phase III POLARGO study.

About the POLARIX study

POLARIX [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 rituximab, 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 rituximab for two

cycles; or R-CHOP plus a Polivy placebo for six cycles, followed by two cycles of rituximab. The primary outcome measure is progression-free survival (PFS) as assessed by the investigator using the Lugano Response Criteria for malignant lymphoma. PFS is a clinically meaningful disease-related outcome for patients with previously untreated DLBCL as it represents the goal of first-line therapy: decreasing the risk of disease worsening.

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. DLBCL is an aggressive (fast-growing) type of NHL.[5] While it is generally responsive to treatment in the frontline, as many as 40% of people will relapse or have refractory disease, at which time salvage therapy options are limited and survival is short.[6,7] Approximately 150,000 people worldwide are estimated to be diagnosed with DLBCL each year.[8]

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. Polivy binds to cancer cells such as CD79b and destroys these B-cells through the delivery of an anti-cancer agent, which is thought to minimise the effects on normal cells. 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 currently marketed in the EU for the treatment of relapsed or refractory diffuse large B-cell lymphoma.

About Roche in haematology

Roche has been developing medicines for people with malignant and non-malignant blood diseases for more than 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, Hemlibra® (emicizumab) and Lunsumio® (mosunetuzumab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibodies glofitamab, 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

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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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