Media & Investor Release

FDA accepts supplemental Biologics License Application for Roche's Polivy combination for people with previously untreated diffuse large B-cell lymphoma

- **First new treatment regimen in more than 20 years to significantly improve outcomes in people with this fast-growing type of lymphoma**
- **Application is based on pivotal data from the phase III POLARIX study showing Polivy plus R-CHP significantly reduced the risk of disease progression, relapse or death with comparable safety versus the standard of care, R-CHOP**
- **Various combination studies with Polivy and the company's CD20xCD3 bispecifics in diffuse large B-cell lymphoma are ongoing**

Basel, 16 August 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) for Polivy® (polatuzumab vedotin-piiq) in combination with Rituxan® (rituximab) plus cyclophosphamide, doxorubicin and prednisone (R-CHP) for the treatment of people with previously untreated diffuse large B-cell lymphoma (DLBCL). The FDA is expected to make a decision on approval by 2 April 2023.

"The POLARIX study results suggest that Polivy plus R-CHP could transform the treatment of this aggressive malignancy, and we are working with the FDA to bring this combination to newly diagnosed DLBCL patients as soon as possible," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We hope it will become the new standard of care for the first-line treatment of DLBCL, potentially reducing the need for subsequent treatments and limiting patient burden."

DLBCL is an aggressive blood cancer. Although DLBCL often responds to initial treatment, it is not cured with the current standard of care in four out of 10 people. Most relapses occur within two years of starting treatment and the majority of those who require subsequent lines of therapy have poor outcomes.

The sBLA is based on results from the pivotal phase III POLARIX trial, which is the first in two decades to show a clinically meaningful improvement in progression-free survival (PFS) compared to the current standard of care Rituxan plus cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP). The risk of disease progression, relapse or death was reduced by 27% with Polivy plus R-CHP compared with R-CHOP after a median follow-up of 28.2 months (hazard ratio [HR] 0.73; 95% confidence interval [CI]: 0.57–0.95; p<0.02). Safety outcomes were consistent with those seen in previous clinical trials, and the safety profile was comparable for Polivy plus R-CHP versus R-CHOP, including rates of Grade 3-4 adverse

events (AEs; 57.7% versus 57.5%), serious AEs (34.0% versus 30.6%), Grade 5 AEs (3.0% versus 2.3%), and AEs leading to dose reduction (9.2% versus 13.0%).

Based on pivotal data from the POLARIX study, the European Commission approved Polivy in combination with R-CHP in May 2022 for the treatment of adult patients with previously untreated DLBCL. Polivy is currently approved as a readily available, fixed-duration treatment option for relapsed or refractory (R/R) DLBCL in combination with bendamustine and Mabthera/Rituxan in more than 70 countries worldwide, including in the EU and in the United States.

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 the company's CD20xCD3 T-cell engaging bispecific antibodies Lunsumio® (mosunetuzumab) and glofitamab, and with 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-piiq) plus 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. 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. POLARIX is being conducted in collaboration with The Lymphoma Study Association (LYSA) and The Lymphoma Academic Research Organisation (LYSARC). Other clinical investigators from around the world also participated in the trial.

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.[1] DLBCL is an aggressive (fast-growing) type of NHL. [1] 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.[2,3] Approximately 150,000 people worldwide are estimated to be diagnosed with DLBCL each year.[4]

About Polivy® (polatuzumab vedotin-piiq)

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 hematological diseases. Our approved medicines include MabThera/Rituxan® (rituximab), Gazyvaro/Gazyva® (obinutuzumab), Polivy® (polatuzumab vedotin-piiq), Venclexta/Venclyxto® (venetoclax) in collaboration with AbbVie, and Hemlibra® (emicizumab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibodies, glofitamab and Lunsumio®(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

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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