Media & Investor Release

Ad hoc announcement pursuant to Art. 53 LR

FDA approves Roche's Polivy in combination with R-CHP for people with certain types of previously untreated diffuse large B-cell lymphoma

- **Polivy combination is the first FDA-approved therapy in nearly 20 years for the first-line treatment of diffuse large B-cell lymphoma, an aggressive disease and the most common form of non-Hodgkin lymphoma in the US**
- **POLARIX trial showed the Polivy combination reduced the risk of disease progression, relapse or death by 27% compared to the standard of care, R-CHOP, with a comparable safety profile**
- **First-line treatment with Polivy plus R-CHP has the potential to reduce the burden on patients and healthcare systems, associated with disease progression**

Basel, 19 April 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has approved Polivy® (polatuzumab vedotin-piiq) in combination with Rituxan® (rituximab), cyclophosphamide, doxorubicin and prednisone (R-CHP) for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index (IPI) score of two or greater. This FDA decision converts the accelerated approval of Polivy in combination with bendamustine and Rituxan for relapsed or refractory (R/R) DLBCL after at least two prior therapies to regular approval.

DLBCL is an aggressive, hard-to-treat disease and is the most common form of non-Hodgkin lymphoma in the United States. Approximately 31,000 people in the US are projected to be diagnosed with DLBCL in 2023. Limited progress has been made in improving patient outcomes in previously untreated DLBCL over the last two decades. While many patients are responsive to initial treatment, as many as four in 10 people with DLBCL do not respond or relapse. For people who undergo initial treatment with the standard of care, MabThera/Rituxan plus cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP), most relapses occur within two years of starting treatment, and the majority of those who require subsequent lines of therapy have poor outcomes.

"It has been nearly 20 years since a new treatment option has become available to people newly diagnosed with diffuse large B-cell lymphoma," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Today's decision from the

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FDA to approve Polivy in combination with R-CHP in this setting brings a much-needed new treatment option which may improve outcomes and bring other benefits to many patients with this aggressive lymphoma."

The FDA approval of Polivy plus R-CHP for the first-line treatment of DLBCL is based on pivotal data from POLARIX, an international phase III, randomised, double-blind, placebo-controlled study that demonstrated a statistically significant and clinically meaningful improvement in PFS compared to R-CHOP. The risk of disease progression, relapse or death was reduced by 27% with Polivy plus R-CHP (n=440) compared with R-CHOP (n=439; hazard ratio [HR] 0.73; 95% confidence interval [CI]: 0.57–0.95; p<0.02). 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%). The most common AEs were peripheral neuropathy, nausea, fatigue, diarrhoea, constipation, alopecia, and mucositis. The most common Grade 3-4 AEs were lymphopenia and neutropenia.

This approval follows the FDA Oncologic Drugs Advisory Committee (ODAC) vote of 11 to 2 in favour of Polivy in combination with R-CHP for previously untreated DLBCL. More than 70 countries have approved this Polivy combination for the treatment of adult patients with previously untreated DLBCL, including in the EU, UK, Japan, Canada and China. Polivy in combination with R-CHP was recently added to the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a category 1, preferred regimen for first-line DLBCL. Polivy in combination with bendamustine and MabThera/Rituxan is currently approved in more than 80 countries worldwide for the treatment of adults with relapsed or refractory (R/R) DLBCL after one or more prior therapies, including in the US.

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) or Columvi® (glofitamab). Trials include the phase III SUNMO study in combination with Lunsumio in patients with R/R DLBCL and the phase III POLARGO study with MabThera/Rituxan in combination with gemcitabine and oxaliplatin in patients with R/R DLBCL.

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 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 and The Lymphoma Academic Research Organisation.

About Diffuse Large B-Cell Lymphoma

Diffuse large B-cell lymphoma (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 160,000 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.

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-piiq), Venclexta®/Venclyxto® (venetoclax) in collaboration with AbbVie, Hemlibra® (emicizumab), Lunsumio® (mosunetuzumab) and Columvi® (glofitamab). Our pipeline of investigational haematology medicines includes a T-cell engaging bispecific antibody 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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