New data presented at ASH 2020 reinforces the benefit/risk profile of fixed-duration Polivy plus bendamustine and MabThera/Rituxan in patients with relapsed or refractory diffuse large B-cell lymphoma

- **Longer-term data from the GO29365 study and results from 106 additional patients show continued survival benefit of this fixed-duration, off-the-shelf, Polivy combination**
- **Polivy is already approved in more than 40 countries worldwide, including in the US and in the EU**
- **Polivy is currently being investigated in untreated diffuse large B-cell lymphoma, with results expected in 2021**

Basel, 07 December 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced longer-term data from the pivotal phase Ib/II GO29365 study, including data from a single-arm extension cohort of 106 additional patients, which show the benefit of Polivy® (polatuzumab vedotin) plus bendamustine and MabThera®/Rituxan® (rituximab) (BR) in people with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), who are not eligible for stem cell transplant. Updated data from the randomised cohort (n=80) show that with longer follow-up (48.9 months) a complete response (CR) rate of 42.5% (n=17/40) was maintained in patients following completion of treatment with Polivy plus BR, compared to 17.5% (n=7/40) with BR alone, indicating responses to the Polivy regimen were durable. No new or delayed safety signals were reported. Furthermore, new data from an extension cohort showed a CR rate of 38.7% (n=41/106) with Polivy plus BR. These results, which were presented as a poster (Abstract #3020) at the all-virtual 62nd American Society of Hematology (ASH) Annual Meeting and Exposition on 5-8 December 2020, further support the clinical benefit this Polivy-based combination brings to patients with this aggressive disease.

“Despite recent advances, treatment options are needed that can improve survival outcomes, enhance convenience, and support a good quality of life for patients with relapsed or refractory diffuse large B-cell lymphoma,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “We are encouraged by the continued survival benefit seen with this Polivy combination across a broad range of patients, which reinforces the positive impact that this off-the-shelf treatment option could have for people with this aggressive disease.”

Additional data from the randomised cohort also show that the survival benefit with Polivy plus BR persisted with longer follow-up. After 48.9 months, median progression-free survival (PFS) was 9.2 months with Polivy plus BR, versus 3.7 months for BR alone, as assessed by an independent review committee. Median overall survival (OS) was also sustained at 12.4 months for Polivy plus BR compared to 4.7 months for BR alone. New data from the extension cohort, which included 37 patients with second-line DLBCL were consistent with previously reported results from the GO29365 study, and show Polivy plus BR is effective in a broad range of patients. The median PFS was 6.6 months and median OS was 12.5 months with the Polivy combination. Sub-group analyses of this cohort also show that Polivy plus BR was effective in different

patient populations, including high-risk patients, regardless of prior lines of therapy, with results from the pooled Polivy plus BR arms achieving a median OS of 7.6 months in primary refractory patients (n=55), and 32.0 months in non-primary refractory patients (n=97).

Based on initial results from the GO29365 study, in January 2020 Polivy was granted conditional marketing authorisation by the European Commission in combination with bendamustine and MabThera for the treatment of adult patients with R/R DLBCL, who are not candidates for a haematopoietic stem cell transplant. Prior to this, the U.S. Food and Drug Administration granted accelerated approval of Polivy in combination with BR for the treatment of adult patients with R/R DLBCL, who have received at least two prior therapies. Beyond R/R disease, Polivy is also being investigated in first-line DLBCL, with results from the phase III POLARIX trial anticipated in 2021. Other ongoing studies include combinations of Polivy with Gazyva®/Gazyvaro® (obinutuzumab), Venclexta®/Venclyxto® (venetoclax) and CD20xCD3 bispecific antibodies mosunetuzumab and glofitamab to identify areas where Polivy has the potential to deliver benefit in areas of unmet need.

About the GO29365 study
GO29365 [NCT02257567] is a global, phase Ib/II study evaluating the safety, tolerability and activity of Polivy® (polatuzumab vedotin) in combination with bendamustine and MabThera®/Rituxan® (rituximab) (BR) or Gazyva®/Gazyvaro® (obinutuzumab) in relapsed or refractory (R/R) follicular lymphoma or diffuse large B-cell lymphoma (DLBCL). Eligible patients were not candidates for a haematopoietic stem cell transplant at study entry. The phase II part of the study randomised 80 patients with heavily pre-treated R/R DLBCL to receive either BR, or BR in combination with Polivy for a fixed duration of six 21-day cycles. Of the patients enrolled, 80% had refractory disease. The primary endpoint was complete response (CR) at the end of treatment, as measured by positron emission tomography and assessed by an independent review committee (IRC). Secondary endpoints included overall response rate (ORR; CR and partial response) by investigator assessment and best ORR at the end of treatment by investigator and IRC assessment. Exploratory endpoints included duration of response, progression-free survival, event-free survival and overall survival. In addition to the randomised cohort of the study, an additional 106 patients were treated with Polivy plus BR in a single-arm extension cohort, also with CR as the primary endpoint.

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 CD79b and destroys 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 Seattle Genetics ADC technology and is currently being investigated for the treatment 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, which is generally responsive to treatment in the frontline.[6] However, as many as 40% of patients will relapse, 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 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 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 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.

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