Media Release

Swissmedic approved Roche's Polivy for people with previously treated aggressive lymphoma

- **Polivy provides a new off-the-shelf treatment option for people with relapsed or refractory diffuse large B-cell lymphoma, an aggressive lymphoid disease**
- **Polivy approval is based on a phase Ib/II study including two extension cohorts, the first and only study showing improved response rates and overall survival in patients with this aggressive lymphoma who are not candidates for a haematopoietic stem cell transplant, compared to a commonly used regimen**

Basel, 20 July 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced that the Swiss agency for therapeutic products (Swissmedic) has approved Polivy® (polatuzumab vedotin), in combination with bendamustine plus MabThera® (rituximab) (BR), for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) who are not candidates for a hematopoietic stem cell transplant.

"Diffuse large B-cell lymphoma is the most common type of aggressive lymphoma, a group of blood cancers. At the relapsed or refractory stage, the prognosis is very poor and few treatments are available," said Jean-Marc Häusler, M.D., Roche's Country Medical Director in Switzerland. "With this approval, we are proud to bring this first-in-class treatment option to those who need it most."

The approval is based on the results from the phase Ib/II GO29365 study[1] and its extension cohort[2], the first and only clinical trial to show higher response rates and improved overall survival (OS) compared to BR, a commonly used regimen, in people with relapsed or refractory diffuse large B-cell lymphoma who are not candidates for a haematopoietic stem cell transplant. Results of the study showed that 40% of people treated with Polivy plus BR achieved a complete response (n=16/40), meaning no cancer could be detected at the time of assessment, compared to 17.5% (n=7/40) with BR alone. Complete response rates were assessed by an independent review committee. The study also showed that OS more than doubled, with a median of 12.4 months in the Polivy arm vs. 4.7 months in the BR alone arm (HR=0.42).

This full Swissmedic approval follows the conditional EU approval in early 2020 and US Food and Drug Administration's (FDA) accelerated approval in 2019 of Polivy in combination with BR for the treatment of people with R/R DLBCL.

About the GO29365 study
GO29365 is a global, phase Ib/II study evaluating the safety, tolerability and activity of Polivy (polatuzumab vedotin) in combination with bendamustine and MabThera® (rituximab) (BR) or 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.

This data was confirmed in the extension cohort of 106 additional patients treated with Polivy with BR and reached a median OS of 12.5 months. Furthermore, patients treated with Polivy plus BR showed a longer time between first response to treatment and disease worsening than those receiving BR alone (investigator assessed median duration of response: 10.3 months vs. 4.1 months; HR=0.44). The most commonly reported adverse events in people treated with Polivy in combination with BR included anaemia, thrombocytopenia, neutropenia, fatigue, diarrhoea, nausea, and pyrexia.

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.[3,4] 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.[5,6] Polivy is being developed by Roche using Seagen ADC technology and is currently being investigated for the treatment of NHL.

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.[7] DLBCL is an aggressive (fast-growing) type of NHL, which is generally responsive to treatment in the frontline.[8] However, as many as 40% of patients will relapse, at which time salvage therapy options are limited and survival is short.[9] Approximately 150,000 people worldwide are estimated to be diagnosed with DLBCL each year.

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, Gazyva/Gazyvaro, Polivy, 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 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.

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