Media Release

CHMP recommends conditional EU approval of Roche's Polivy for people with previously treated aggressive lymphoma

- **First-in-class antibody-drug conjugate that specifically targets CD79b, a protein expressed in the majority of B-cells**
- **Targeted off-the-shelf treatment represents potential new option for people with relapsed or refractory diffuse large B-cell lymphoma, an aggressive type of non-Hodgkin lymphoma**

Basel, 15 November 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the EU Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Polivy® (polatuzumab vedotin) in combination with bendamustine plus MabThera® (rituximab) (BR) for the treatment of adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), who are not candidates for a haematopoietic stem cell transplant. Based on this positive CHMP recommendation, a final decision regarding the conditional marketing authorisation of Polivy is expected from the European Commission in the near future.

"People with relapsed or refractory diffuse large B-cell lymphoma have limited treatment options – especially those who are not candidates for haematopoietic stem cell transplant," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "We are pleased the CHMP has recognised the potential of Polivy to provide a much needed new treatment option for patients with this aggressive disease."

The positive CHMP opinion is based on the results from the phase Ib/II GO29365 study, 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 R/R DLBCL 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 Polivy plus BR more than doubled OS, with a median OS of 12.4 months in the Polivy arm, versus 4.7 months in the BR alone arm (HR=0.42). The most commonly reported adverse events in people treated with Polivy in combination with BR include anaemia, thrombocytopenia, neutropenia, fatigue, diarrhoea, nausea, and pyrexia.

Polivy was granted PRIME (PRIority MEdicines) designation by the European Medicines Agency (EMA) for the treatment of people with R/R DLBCL in 2017, the first PRIME designation for a Roche medicine. We will continue to work with the EMA and local health providers to make Polivy available to patients as quickly as possible. In addition, Polivy plus BR was granted accelerated approval by the US Food and Drug Administration for people with R/R DLBCL who have received at least two prior therapies, in June 2019.

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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. 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..

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 several types 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 US Food and Drug Administration.

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.[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 idasanutlin, a small molecule which inhibits the interaction of MDM2 with p53; T-cell engaging bispecific antibodies targeting both CD20 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 eleventh 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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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