

## **FDA grants Roche's Polivy accelerated approval for people with previously treated aggressive lymphoma**

- **New targeted medicine shown to improve clinical outcomes in people with relapsed or refractory diffuse large B-cell lymphoma compared to a commonly used regimen**
- **First-in-class antibody-drug conjugate that specifically targets CD79b, a protein expressed in the majority of B-cells**
- **Ninth indication with Breakthrough Therapy Designation in Roche's haematology portfolio to receive FDA approval**

Basel, 11 June 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) has granted accelerated approval to Polivy™ (polatuzumab vedotin-piiq) in combination with bendamustine plus Rituxan® (rituximab) (BR) for the treatment of adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), who have received at least two prior therapies. Accelerated approval was granted for this indication based on complete response rates observed in a randomised, controlled clinical trial. The FDA's Accelerated Approval Program allows conditional approval of a medicine that fills an unmet medical need for a serious condition. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

“Despite meaningful progress in the treatment of diffuse large B-cell lymphoma, treatment options are very limited when the disease is refractory to or recurrent after multiple regimens,” said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. “Today's approval of this Polivy combination will provide a novel treatment that is both immediately available and very much needed for people with this aggressive disease.”

The accelerated approval of Polivy was based on the results from the phase Ib/II GO29365 study. This is the first and only randomised pivotal clinical trial to show higher response rates over BR, a commonly used regimen, in people with R/R DLBCL who are ineligible 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; 95% CI: 25-57), meaning no cancer could be detected at the time of assessment, compared to 18% with BR alone (n=7/40; 95% CI: 7-33). Complete response rates were assessed by independent review committee. The study also showed that 45% of people on Polivy plus BR achieved an objective response at the end of treatment (n=18/40; 95% CI: 29-62), compared to 18% of people treated with BR alone (n=7/40; 95% CI: 7-33). Of the people treated with Polivy plus BR who achieved a complete or partial response, 64% (n=16/25) had a duration of response (DOR) lasting at least six months as compared to 30% (n=3/10) of people treated with BR alone. Additionally, 48% (n=12/25) of people treated with Polivy plus BR had a DOR lasting at least a year as compared to 20% (n=2/10) of people treated with BR alone. Adverse reactions occurring in at least 20% of patients, and at least 5% more frequently in patients treated with Polivy plus BR compared to BR alone, included low white blood cell count, low platelet levels, low red blood cell count, numbness, tingling or pain in the hands and feet, diarrhoea, fever, decreased appetite and pneumonia.

The US FDA granted Priority Review for the company's Biologics License Application for Polivy in February 2019. Priority Review designation is granted to medicines that the FDA considers to have the potential to provide significant improvements in the safety and effectiveness of the treatment, prevention or diagnosis of a serious disease. In addition, Polivy was granted Breakthrough Therapy Designation by the FDA and PRIME (PRiority MEDicines) designation by the European Medicines Agency for the treatment of people with R/R DLBCL in 2017. Breakthrough Therapy Designation is designed to expedite the development and review of medicines intended to treat a serious condition with preliminary evidence that indicates they may demonstrate substantial improvement over existing therapies.

### **About the GO29365 study**

GO29365 is a global, phase Ib/II randomised study evaluating the safety, tolerability and activity of Polivy (polatuzumab vedotin-piiq) in combination with bendamustine and Rituxan (rituximab) (BR) or Gazyva (obinutuzumab) in relapsed or refractory (R/R) follicular lymphoma or diffuse large B-cell lymphoma (DLBCL). Eligible patients were not candidates for 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. Patients enrolled had received a median of two prior therapies (a range of 1-7 prior therapies in the Polivy arm and range of 1-5 prior therapies in the BR alone arm). 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 (DOR), progression-free survival, event-free survival and overall survival.

### **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.<sup>1,2</sup> 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.<sup>3,4</sup> Polivy is being developed by Roche using Seattle Genetics ADC technology and is currently being investigated for the treatment of several types 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.<sup>5</sup> DLBCL is an aggressive (fast-growing) type of NHL, which is generally responsive to treatment in the frontline.<sup>6</sup> However, as many as 40% of patients will relapse, at which time salvage therapy options are limited and survival is short.<sup>1,4</sup> Approximately 150,000 people worldwide are estimated to be diagnosed with DLBCL each year.<sup>7</sup>

### **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-piiq), 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, and Tecentriq® (atezolizumab), a monoclonal antibody designed to bind with PD-L1. 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. 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 tenth consecutive year, Roche has been recognised as the most sustainable company 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](http://www.roche.com).

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### **Roche Group Media Relations**

Phone: +41 61 688 8888 / e-mail: [media.relations@roche.com](mailto:media.relations@roche.com)

- Nicolas Dunant (Head)
- Patrick Barth
- Ulrike Engels-Lange
- Simone Oeschger
- Anja von Treskow