Longer-term follow-up data demonstrate sustained benefit of polatuzumab vedotin-based treatment in relapsed or refractory diffuse large B-cell lymphoma

- Polatuzumab vedotin in combination with MabThera/Rituxan (rituximab) plus bendamustine more than doubled overall survival, compared to MabThera/Rituxan plus bendamustine alone in the phase Ib/II GO29365 study
- Polatuzumab vedotin has the potential to provide a promising new treatment option at first relapse
- Results from the GO29365 study, the first and only randomised study to suggest a survival benefit for patients not eligible for a haematopoietic stem cell transplant, will be submitted to health authorities around the world for approval consideration

Basel, 3 December 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced longer-term data from the phase Ib/II GO29365 study showing that polatuzumab vedotin, an investigational anti-CD79b antibody drug conjugate (ADC), in combination with MabThera*/Rituxan* (rituximab) plus bendamustine (BR), demonstrated a median overall survival (OS) of over one year compared to the BR arm (12.4 vs. 4.7 months, HR 0.42; 95% CI 0.24, 0.75), in people with R/R DLBCL not eligible for a haematopoietic stem cell transplant. OS was an exploratory endpoint. Adverse events (AEs) were consistent with those seen in previous studies of polatuzumab vedotin, and of BR, with no new safety signals observed. These data were presented at the 60th American Society of Hematology (ASH) Annual Meeting on Saturday 1 December 2018, at 18:15-20:15 PT (Sunday 2 December 2018, 03:15-05:15 CET; abstract #1683).

Treatment with polatuzumab vedotin plus BR resulted in a 66% reduction in risk of disease progression or death (as measured by investigator-assessed progression free survival; PFS; HR=0.34; 95% CI 0.2-0.570; p<0.0001), with 40% achieving a complete response (CR) compared to 18% in the BR arm (primary endpoint, as measured by positron emission tomography (PET); CR rates assessed by independent review committee; p=0.026). Furthermore, patients treated with polatuzumab vedotin plus BR achieved higher CR rates and longer PFS and OS compared with BR in all subgroups tested, including patients from cell-of-origin groups, germinal centre B-cell-like and activated B-cell-like, which are associated with a worse prognosis in DLBCL.

“There is a significant need for new and more effective treatment options for the approximately 40% of people with diffuse large B-cell lymphoma whose disease either does not respond to initial treatment or returns – a situation that is associated with a very poor prognosis that worsens after each relapse,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “We are delighted that polatuzumab vedotin has demonstrated sustained clinical benefits and has the potential to hopefully improve survival rates in this population. We are working with health authorities to make this novel regimen available to patients worldwide.”
The phase Ib/II GO29365 study is the first and only randomised study to suggest a survival benefit for R/R DLBCL patients who are ineligible for haematopoietic stem cell transplant. Results were presented at the 60th ASH, and the data for the polatuzumab vedotin plus BR arm of the GO29365 study in R/R DLBCL will be submitted to health authorities around the world for approval consideration.

Polatuzumab vedotin is a first-of-its-kind anti-CD79b ADC currently being investigated for the treatment of several types of non-Hodgkin lymphoma. It is the only ADC targeted to CD79b, a protein that is highly specific, expressed in the majority of types of B-cell malignancies. Polatuzumab vedotin in combination with BR has been granted Breakthrough Therapy Designation and orphan drug designation by the US Food and Drug Administration, as well as PRIority MEdicines designation and orphan drug designation by the European Medicines Agency, for the treatment of adult patients with R/R DLBCL who are not candidates for haematopoietic stem cell transplantation.

About the GO29365 study
GO29365 is a global, phase Ib/II study evaluating the safety, tolerability and activity of polatuzumab vedotin in combination with MabThera/Rituxan (rituximab) or Gazyva/Gazyvaro (obinutuzumab) plus bendamustine in relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) or follicular lymphoma. The phase II stage randomised 80 patients with previously treated R/R DLBCL to receive either bendamustine plus MabThera/Rituxan (BR), or BR in combination with polatuzumab vedotin. Patients enrolled had received a median of two prior therapies (a range of 1-7 prior therapies in the polatuzumab vedotin arm and a 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 (PET) and assessed by an independent review committee (IRC). Other key endpoints included objective response (OR; CR and partial response, PR) by investigator and IRC assessment, best objective response at the end of treatment by investigator assessment, duration of response (DOR), progression-free survival (PFS), event-free survival (EFS) and overall survival (OS).

About polatuzumab vedotin
Polatuzumab vedotin is a first-of-its-kind anti-CD79b antibody drug conjugate (ADC) currently being investigated for the treatment of several subtypes of non-Hodgkin lymphoma (NHL). The CD79b protein is highly specific and expressed in the majority of types of B-cell NHL, making it a promising target for the development of new therapies.[1;2] Polatuzumab vedotin is thought to bind to CD79b, triggering internalisation of the drug into the cells. This targets the chemotherapy (which is attached to the monoclonal antibody) to these B-cells. This process is thought to maximise tumour cell death while potentially minimising the effects on normal healthy cells.[3;4] Polatuzumab vedotin is being developed by Roche utilising Seattle Genetics ADC technology.

About diffuse large B-cell lymphoma
Diffuse large B-cell lymphoma (DLBCL) is the most common subtype 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.[1;4] Approximately 150,000 people worldwide are estimated to be diagnosed with DLBCL each year.[7]
About Roche in haematology
For more than 20 years, Roche has been developing medicines that redefine treatment in haematology. Today, we are investing more than ever in our effort to bring innovative treatment options to people with diseases of the blood. In addition to approved medicines MabThera®/Rituxan® (rituximab), Gazyva®/Gazyvaro® (obinutuzumab), and Venclexta®/Venclyxto® (venetoclax) in collaboration with AbbVie, Roche’s pipeline of investigational haematology medicines includes Tecentriq® (atezolizumab), an anti-CD79b antibody drug conjugate (polatuzumab vedotin/RG7596) and a small molecule which inhibits the interaction of MDM2 with p53 (idasanutlin/RG7388). Roche’s dedication to developing novel molecules in haematology expands beyond malignancy, with the development of Hemlibra® (emicizumab), a bispecific monoclonal antibody for the treatment of haemophilia A.

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 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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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References


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