Basel, 30 June 2017

Roche’s polatuzumab vedotin receives priority medicines scheme (PRIME) designation for treatment of the most common form of aggressive lymphoma

- European Medicines Agency PRIME (PRIority MEdicines) status is granted to medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options
- First PRIME designation for a Roche medicine

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the European Medicines Agency (EMA) has granted PRIME (PRIority MEdicines) designation for the company’s investigational medicine polatuzumab vedotin in combination with MabThera® (rituximab) and bendamustine for the treatment of people with relapsed or refractory diffuse large B cell lymphoma (DLBCL), the most common aggressive form of non-Hodgkin lymphoma. It is estimated that as many as 40% of patients with DLBCL relapse following initial treatment, at which time salvage therapy options are limited and survival is short.1

“We are very pleased that by granting PRIME designation the agency has recognised the early promise of polatuzumab vedotin for patients with relapsed or refractory diffuse large B cell lymphoma,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “We look forward to working closely with the EMA to bring this medicine to patients as quickly as possible.”

PRIME is a new designation implemented by the EMA to support data generation and development plans for promising medicines, provide a pathway for accelerated evaluation by the agency, and thus potentially enable them to reach patients earlier. PRIME designation for polatuzumab vedotin is primarily based on results from the randomized phase II component of the GO29365 study in people with relapsed or refractory DLBCL that compared treatment with polatuzumab vedotin plus bendamustine and MabThera®/Rituxan® (rituximab) to bendamustine plus MabThera/Rituxan.
About the GO29365 study

GO29365 is a Roche-sponsored, 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 follicular or diffuse large B cell lymphoma. The phase II stage randomised patients to receive either MabThera/Rituxan plus bendamustine, or MabThera/Rituxan plus bendamustine in combination with polatuzumab vedotin. The primary objective was to evaluate responses to polatuzumab vedotin in combination with MabThera/Rituxan and bendamustine at the time of the primary response assessment (6–8 weeks after Cycle 6, Day 1 or the last dose of the study medication) and as defined by an independent review committee. The secondary efficacy objectives included best objective response (CR and OR) by investigator assessment with positron emission tomography and/or computed tomography scans and objective response (CR and PR) at the time of primary response assessment.

About Polatuzumab vedotin

Polatuzumab vedotin is an anti-CD79b antibody drug conjugate (ADC) consisting of an anti-CD79b monoclonal antibody that is linked to a potent microtubule-disrupting agent. 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. DLBCL is an aggressive (fast-growing) type of NHL, which is generally responsive to treatment in the frontline. However, as many as 40% of patients will relapse, at which time salvage therapy options are limited and survival is short. Approximately 123,000 people worldwide are estimated to be diagnosed with DLBCL each year.

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 VenclextaTM/VenclyxtoTM (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 antagonist of MDM2 (idasanutlin/RG7388). Roche’s dedication to developing novel molecules in haematology expands
beyond malignancy, with the development of the investigational haemophilia A treatment emicizumab.

**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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry eight years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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 Investor Relations**

Dr. Karl Mahler  
Phone: +41 61 68-78503  
e-mail: karl.mahler@roche.com

Dr. Sabine Borngräber  
Phone: +41 61 68-88027  
e-mail: sabine.borngraebere@roche.com

Dr. Bruno Eschli  
Phone: +41 61 68-75284  
e-mail: bruno.eschli@roche.com

Dr. Tamer Farhan  
Phone: +41 61 68-82552  
e-mail: tamer.farhan@roche.com
References