FDA grants Breakthrough Therapy Designation for Roche's CD20xCD3 bispecific cancer immunotherapy mosunetuzumab recognising its potential in follicular lymphoma

- **This designation is based on results from the phase I/Ib GO29781 study that showed mosunetuzumab demonstrated high response rates and durable complete remissions in people with relapsed or refractory non-Hodgkin lymphoma**
- **Tenth Breakthrough Therapy Designation awarded for Roche's haematology medicines**

Basel, 14 July 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that its investigational CD20xCD3 T-cell engaging bispecific mosunetuzumab has been granted Breakthrough Therapy Designation (BTD) by the US Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma who have received at least two prior systemic therapies.

"We are pleased that the FDA has granted Breakthrough Therapy Designation to mosunetuzumab, recognising the promising early efficacy data for this molecule and the remaining unmet need in follicular lymphoma," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Indeed, we are excited by the potential of both our CD20xCD3 bispecific antibodies – mosunetuzumab and glofitamab – in development for difficult-to-treat lymphomas, and remain committed to developing innovative therapies to improve outcomes for patients."

This designation was granted based on encouraging efficacy results observed in the phase I/Ib GO29781 study [NCT02500407] investigating mosunetuzumab in R/R non-Hodgkin lymphoma (NHL). The safety profile of this T-cell engaging bispecific was consistent with its mechanism of action. Results from this study were previously presented at the American Society of Hematology 2019 Annual Meeting.

BTD is designed to accelerate the development and review of medicines intended to treat serious or life-threatening conditions with preliminary evidence that indicates they may demonstrate a substantial improvement over existing therapies. This is the 34th BTD for Roche's portfolio of medicines, and the 10th designation for its haematology portfolio.

A robust clinical development programme for mosunetuzumab is ongoing across a number of lymphoma indications and earlier lines of treatment, investigating the molecule alone and in combination to identify where mosunetuzumab may be able to provide benefit over current treatment options. This includes further investigation of mosunetuzumab in combination with Roche's Polivy® (polatuzumab vedotin) and Tecentriq® (atezolizumab) as well as with chemotherapy regimens and non-Roche molecules.

About mosunetuzumab
Mosunetuzumab is an investigational CD20xCD3 T-cell engaging bispecific designed to target CD20 on the surface of B-cells and CD3 on the surface of T-cells. This dual targeting activates and redirects a patient's existing T-cells to engage and eliminate target B-cells by releasing cytotoxic proteins into the B-cells. Mosunetuzumab has a structure similar to that of a natural human antibody in that it has two 'Fab' regions, but is different from naturally-occurring antibodies in that one 'Fab' region targets CD20 and the other 'Fab'

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region targets CD3. A robust clinical development programme for mosunetuzumab is ongoing, investigating the molecule as a monotherapy and in combination with other medicines, for the treatment of people with CD20-positive B-cell non-Hodgkin lymphomas, including follicular lymphoma and diffuse large B-cell lymphoma, and other blood cancers.

About the GO29781 study
The GO29781 study [NCT02500407] is a phase I/Ib, multicentre, open-label, dose-escalation study evaluating the safety and pharmacokinetics of mosunetuzumab in people with relapsed or refractory B-cell non-Hodgkin lymphoma. Outcome measures include best objective response rate by revised International Working Group criteria, maximum tolerated dose, and tolerability.

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, glofitamab and mosunetuzumab, 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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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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