Roche announces new data on novel CD20-CD3 bispecific cancer immunotherapies in people with difficult-to-treat lymphomas

- **Mosunetuzumab data to be presented at the American Society of Hematology 2019 Annual Meeting Plenary Scientific Session demonstrate durable complete responses in people with relapsed or refractory non-Hodgkin lymphoma**
- **Preliminary safety and efficacy data for CD20-TCB support potential of combination approaches with anti-CD20 therapies**

Basel, 7 December 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced new data on two investigational CD20-CD3 T-cell engaging bispecific antibodies, mosunetuzumab and CD20-TCB, in people with relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (NHL). Results from the phase I/Ib GO29781 study of mosunetuzumab, including data from people previously treated with chimeric antigen receptor (CAR) T-cell therapy, will be presented at the 61st American Society of Hematology (ASH) 2019 Annual Meeting during the Plenary Scientific Session. The Plenary Scientific Session highlights the top six abstracts submitted to the meeting, as determined by the ASH Program Committee. Additionally, results from the phase I/Ib NP30179 study evaluating CD20-TCB as a combination therapy with Gazyva®/Gazyvaro® (obinutuzumab) for people with R/R NHL, will be presented.

"Despite recent treatment advancements, slow-growing and aggressive non-Hodgkin lymphomas present increasingly difficult management challenges with each subsequent relapse," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We're encouraged by these early results, which suggest that our novel bispecific cancer immunotherapies may help people with relapsed or treatment-refractory disease who need more options."

The GO29781 study evaluated mosunetuzumab in patients with R/R NHL, including patients who have relapsed following, or are resistant to, CAR T-cell therapy – a patient population with limited treatment options. Results from this dose-escalation study showed encouraging efficacy with an objective response rate (ORR) of 62.7% (n=42/67) in slow-growing NHL and 37.1% (n=46/124) in aggressive NHL. Additionally, data demonstrated a complete response (CR) rate of 43.3% (n=29/67) in slow-growing NHL and 19.4% (n=24/124) in aggressive NHL. CRs showed durability, with 82.8% (n=24/29) of patients with slow-growing NHL remaining in remission up to 26 months off initial treatment and 70.8% (n=17/24) of patients with aggressive NHL remaining in remission up to 16 months off initial treatment. Of the participants who received prior CAR T-cell therapy, the ORR was 38.9% (n=7/18), and 22.2% (n=4/18) achieved a CR. Adverse reactions included cytokine release syndrome (CRS) in 28.9% of patients with 20.0% at Grade 1 and 1.1% at Grade 3. Grade 3 neurological adverse events occurred in 3.7% of patients.

Results from the phase I/Ib dose-escalation NP30179 study, evaluating CD20-TCB at doses ranging from 0.6 mg to 16 mg plus Gazyva/Gazyvaro in people with R/R B-cell NHL, showed an ORR of 54% (n=15/28) and a CR rate of 46% (n=13/28). This included an ORR and CR of 66.7% (n=4/6) in people with follicular

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland
Investor Relations email: investor.relations@roche.com
Tel. +41 61 68-88880 Fax +41 61 69-10014 www.roche.com

lymphoma and an ORR of 50.0% (n=11/22) and a CR of 40.9% (n=9/22) in aggressive NHL. The most frequently observed adverse event across all treatment doses was CRS, occurring in 67.9% of patients (n=19/28), with the majority of events being low grade (Grade 1-2).

Both mosunetuzumab and CD20-TCB continue to be evaluated in a robust clinical development programme, investigating the treatments as monotherapies and in combination with other therapies, in people with slow-growing and aggressive forms of NHL.

About Roche's investigational bispecifics in haematology
Roche is currently developing two T-cell engaging bispecific antibodies, mosunetuzumab and CD20-TCB, 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 and CD20-TCB differ in their structures, and both are being developed by Roche as part of our ongoing strategy to explore multiple bispecific formats, to identify those that maximise potential clinical benefits for patients. 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' region targets CD3. CD20-TCB is based on a novel structural format which we call '2:1', which refers to the structure of the antibody. It is engineered to have two 'Fab' regions which bind to CD20, and one 'Fab' region which binds to CD3. The clinical development programmes for mosunetuzumab and CD20-TCB include ongoing investigations of these molecules as monotherapies and in combination with other medicines, for the treatment of people with CD20-positive B-cell non-Hodgkin lymphomas, including diffuse large B-cell lymphoma and follicular lymphoma.

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 the NP30179 study
The NP30179 study [NCT03075696] is a phase I/Ib, multicentre, open-label, dose-escalation study, evaluating the efficacy, safety, tolerability and pharmacokinetics of CD20-TCB. In this study, CD20-TCB is assessed as a single agent and in combination with Gazyva/Gazyvaro (obinutuzumab), following pre-treatment with a one-time, fixed dose of Gazyva/Gazyvaro, in people with relapsed or refractory B-cell non-Hodgkin lymphoma. Outcome measures include overall response rate, complete response rate per Lugano 2014 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 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.

Roche Investor Relations

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

Jon Kaspar Bayard
Phone: +41 61 68-83894
e-mail: jon_kaspar.bayard@roche.com

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

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

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com

Dr. Lisa Tuomi
Phone: +1 650 467 8737
e-mail: tuomi.lisa@gene.com