

Basel, 5 December 2017

TECENTRIQ GO29695 (NCT02431208) and BO29562 (NCT02631577) FDA partial clinical hold lifted

Roche (SIX: RO, ROG; OTCQX: RHHBY): today announced that following close consultation and agreement on study modifications with the U.S. Food and Drug Administration (FDA), the partial clinical holds placed on the Phase Ib and Phase Ib/II studies evaluating TECENTRIQ in combination with an immunomodulatory medicine (IMiD) in relapsed/refractory multiple myeloma and relapsed/refractory follicular lymphoma have been lifted. The studies will continue in accordance with the protocol amendments agreed upon by the FDA.

The studies had been placed on partial clinical hold as part of an FDA evaluation of all ongoing blood cancer trials, investigating PD-1/PD-L1 inhibitors in combination with an IMiD to determine if there was a class-wide (PD-1/PD-L1 inhibitor) concern in multiple myeloma/blood cancers, or a specific concern with certain combinations with IMiDs. The FDA evaluation was prompted by interim data from clinical trials evaluating pembrolizumab in combination with either lenalidomide or pomalidomide in multiple myeloma.

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

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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.

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