Media Release

Roche's Tecentriq in combination with chemotherapy (including Abraxane) meets primary endpoint of improved pathological complete response, regardless of PD-L1 status, as initial treatment for people with early triple-negative breast cancer

- **IMpassion031 data will be discussed with health authorities globally, including the US Food and Drug Administration and the European Medicines Agency**
- **Tecentriq is the only approved cancer immunotherapy for the treatment of metastatic triple-negative breast cancer, a very aggressive and difficult-to-treat form of breast cancer**

Basel, 18 June 2020 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMpassion031 study, evaluating Tecentriq® (atezolizumab) in combination with chemotherapy (Abraxane®, albumin-bound paclitaxel; nab-paclitaxel; followed by doxorubicin and cyclophosphamide) in comparison to placebo plus chemotherapy (including Abraxane), met its primary endpoint by demonstrating a statistically significant and clinically meaningful improvement in pathological complete response (pCR) for the treatment of people with early triple-negative breast cancer (TNBC), regardless of PD-L1 expression.

"Triple-negative breast cancer remains an aggressive disease with high rates of recurrence," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Our goal in treating TNBC at its earliest stages is to provide people with the best chance for a future cure. Adding Tecentriq to chemotherapy now has the potential to help women with TNBC at multiple different stages of the disease."

In the study, fewer patients who received the Tecentriq combination as a neoadjuvant (before surgery) treatment had evidence of tumour tissue detectable at the time of surgery (known as pCR), regardless of PD-L1 expression, in comparison to the control arm. Neoadjuvant treatment may allow a doctor to quickly assess whether a medicine is working and may also reduce a tumour's size so it is easier to surgically remove. pCR is a common measure of neoadjuvant treatment effect and can be assessed more quickly than traditional endpoints in early stage breast cancer.

Safety for the Tecentriq combination appeared to be consistent with the known safety profiles of the individual medicines and no new safety signals were identified. Results of the IMpassion031 study will be presented at an upcoming medical meeting and will be discussed with global health authorities including the US Food and Drug Administration (FDA) and European Medicines Agency (EMA).

The IMpassion031 study is the second positive Phase III study from Roche demonstrating the benefit of Tecentriq in TNBC, and the first Tecentriq study to demonstrate benefit in early TNBC. Tecentriq in combination with nab-paclitaxel is currently approved in more than 70 countries worldwide, including the US and across Europe, for the treatment of adults with unresectable locally advanced or metastatic TNBC in people whose tumours express PD-L1 (IC≥1%).

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Roche has an extensive development programme for Tecentriq, including multiple ongoing and planned Phase III studies across lung, genitourinary, skin, breast, gastrointestinal, gynaecological, and head and neck cancers. This includes studies evaluating Tecentriq both alone and in combination with other medicines.

About the IMpassion031 study
The IMpassion031 study is a Phase III, multicentre, randomised, double-blind study evaluating the efficacy and safety of Tecentriq in combination with chemotherapy (nab-paclitaxel; followed by doxorubicin and cyclophosphamide) in comparison to placebo plus chemotherapy, in people with previously untreated, early TNBC. The study enrolled 333 people who were randomised in a 1:1 ratio to receive Tecentriq or placebo plus chemotherapy in the neoadjuvant (before surgery) setting. Treatment with Tecentriq continued adjuvantly (after surgery) for those in the Tecentriq arm of the study. The primary endpoint is pCR using the American Joint Committee on Cancer (AJCC) staging system in the intention-to-treat (ITT) population and in the PD-L1-positive population. Secondary endpoints include overall survival (OS), event-free survival, disease-free survival and quality of life measures.

About triple-negative breast cancer
Breast cancer is the most common cancer among women with more than 2 million diagnosed worldwide each year.[1] TNBC represents ~15% of all breast cancers and is more common in women under the age of 50, compared with other forms of breast cancer.[2-4] It is defined by the lack of expression and/or amplification of the targetable receptors for oestrogen, progesterone and HER2 amplification.[5] Patients with metastatic TNBC generally experience rapid progression and shorter OS compared to other subtypes of breast cancer.[3]

About Roche in breast cancer
Roche has been advancing breast cancer research for more than 30 years with the goal of helping as many people with the disease as possible. Our medicines, along with companion diagnostic tests, have contributed to bringing breakthrough innovations in HER2-positive and triple-negative breast cancers. As our understanding of breast cancer biology rapidly improves, we are working to identify new biomarkers and approaches to treatment for all forms of early and advanced breast cancer, including triple-negative and hormone receptor-positive.

Our targeted medicines Herceptin, Perjeta, Kadcyla and Tecentriq are continuing to transform the treatment of early and advanced HER2-postive and triple-negative breast cancers and, through our Tecentriq and ipatasertib clinical programmes, we hope to bring new treatment combinations to people with breast cancer, ultimately improving outcomes.

About Tecentriq
Tecentriq is a monoclonal antibody designed to bind with a protein called PD-L1, which is expressed on tumour cells and tumour-infiltrating immune cells, blocking its interactions with both PD-1 and B7.1 receptors. By inhibiting PD-L1, Tecentriq may enable the activation of T-cells. Tecentriq is a cancer immunotherapy that has the potential to be used as a foundational combination partner with other immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers. The development of Tecentriq and its clinical programme is based on our greater understanding of how the immune system interacts with tumours and how harnessing a person's immune system combats cancer more

effectively.

Tecentriq is approved in the US, EU and countries around the world, either alone or in combination with targeted therapies and/or chemotherapies in various forms of non-small cell and small cell lung cancer, certain types of metastatic urothelial cancer and in PD-L1-positive metastatic triple-negative breast cancer. In the US, Tecentriq in combination with Avastin is approved for people with unresectable or metastatic hepatocellular carcinoma.

About Roche in cancer immunotherapy
Roche's rigorous pursuit of groundbreaking science has contributed to major therapeutic and diagnostic advances in oncology over the last 50 years, and today, realising the full potential of cancer immunotherapy is a major area of focus. With over 20 molecules in development, Roche is investigating the potential benefits of immunotherapy alone, and in combination with chemotherapy, targeted therapies or other immunotherapies with the goal of providing each person with a treatment tailored to harness their own unique immune system to attack their cancer. Our scientific expertise, coupled with innovative pipeline and extensive partnerships, gives us the confidence to continue pursuing the vision of finding a cure for cancer by ensuring the right treatment for the right patient at the right time.

In addition to Roche's approved PD-L1 checkpoint inhibitor, Tecentriq® (atezolizumab), Roche's broad cancer immunotherapy pipeline includes other checkpoint inhibitors, such as tiragolumab, a novel cancer immunotherapy designed to bind to TIGIT, individualised neoantigen therapies and T-cell bispecific antibodies. To learn more about Roche's scientific-led approach to cancer immunotherapy, please follow this link:
http://www.roche.com/research_and_development/what_we_are_working_on/oncology/cancer-immunotherapy.htm

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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