Media Release

Phase III IMpassion130 study showed Roche's Tecentriq plus Abraxane significantly reduced the risk of disease worsening or death in people with metastatic triple negative breast cancer

- **First Phase III immunotherapy study to demonstrate a statistically significant improvement in progression-free survival (PFS) in the intention-to-treat (ITT) and PD-L1 positive first-line metastatic triple negative breast cancer (TNBC) populations**
- **Encouraging overall survival (OS) benefit for PD-L1 positive population at interim analysis**
- **Data will be submitted to health authorities globally, including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA)**

Basel, 2 July 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMpassion130 study met its co-primary endpoint of progression-free survival (PFS). Results demonstrated that the combination of Tecentriq® (atezolizumab) plus chemotherapy (Abraxane® [albumin-bound paclitaxel; *nab*-paclitaxel]), as an initial (first-line) treatment, significantly reduced the risk of disease worsening or death (PFS) in the intention-to treat and PD-L1 positive population with metastatic or unresectable locally advanced triple negative breast cancer (TNBC). Overall survival (OS) is encouraging in the PD-L1 positive population at this interim analysis, and follow up will continue until the next planned analysis.

Safety in the Tecentriq plus *nab*-paclitaxel arm appeared consistent with the known safety profiles of the individual medicines, and no new safety signals were identified with the combination. Results will be presented at an upcoming medical meeting and will be submitted to health authorities globally, including the U.S. Food and Drug Administration FDA) and European Medicines Agency (EMA).

"IMpassion130 is the first positive Phase III immunotherapy study in triple negative breast cancer, an aggressive disease with limited treatment options," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "Highly encouraged by these results, we plan to submit to health authorities globally with the aim of bringing this combination to people with triple negative breast cancer as soon as possible."

This is the third positive Phase III study that includes Tecentriq and nab-paclitaxel as part of a treatment regimen. Currently, Roche has seven ongoing phase III studies investigating Tecentriq in TNBC.

About the IMpassion130 study
IMpassion130 study is a phase III multicentre, randomised, double-blind study evaluating the efficacy, safety, and pharmacokinetics of Tecentriq and *nab*-paclitaxel compared with placebo in combination with *nab*-paclitaxel in patients with locally advanced or metastatic TNBC who have not received prior systemic therapy for metastatic breast cancer (mBC). The study enrolled 902 patients who were randomised equally (1:1).

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The co-primary endpoints were progression-free survival (PFS) per investigator assessment (RECIST 1.1) and overall survival (OS). PFS and OS were assessed in all randomized participants [intention-to-treat (ITT)] and in those whose disease expressed the PD-L1 protein. Secondary endpoints included objective response rate, duration of response and time to deterioration in Global Health Status/Health-Related Quality of Life.

During the treatment duration, patients in:

- **ARM A** received Tecentriq at a fixed dose of 840 milligrams via intravenous (IV) infusion on Days 1 and 15 of each 28-day cycle and n*ab*-paclitaxel at a dose of 100 milligrams per square meter via IV infusion on Days 1, 8, and 15 of each 28-day cycle. *Nab*-paclitaxel was administered for a target of at least 6 cycles, with no maximum. Patients received both agents until unacceptable toxicity or disease progression.
- **ARM B** received *nab*-paclitaxel at a dose of 100 milligrams per square meter via IV infusion on Days 1, 8, and 15 of each 28-day cycle. *Nab*-paclitaxel was administered for a target of at least 6 cycles, with no maximum and placebo was administered via IV infusion on Days 1 and 15 of each 28-day cycle. Participants received both agents until unacceptable toxicity or disease progression

About triple negative breast cancer

Breast cancer is the most common cancer among women with more than 1.67 million diagnosed worldwide each year. [1] Triple negative breast cancer 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];[3] It is defined by the lack of expression and/or amplification of the targetable receptors for oestrogen, progesterone and HER2 amplification. [4];[5] Patients with metastatic triple negative breast cancer generally experience rapid progression and shorter overall survival compared to other subtypes of breast cancer. [6]

About Tecentriq® (atezolizumab)

Tecentriq is a monoclonal antibody designed to bind with a protein called PD-L1 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 has the potential to be used as a foundational combination partner with cancer immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers.

Tecentriq is already approved in the European Union, United States and more than 70 countries for people with previously treated metastatic NSCLC and for certain types of untreated or previously treated metastatic urothelial carcinoma (mUC).

About Roche in cancer immunotherapy

For more than 50 years, Roche has been developing medicines with the goal to redefine treatment in oncology. Today, we're investing more than ever in our effort to bring innovative treatment options that help a person's own immune system fight cancer.

By applying our seminal research in immune tumour profiling within the framework of the Roche-devised cancer immunity cycle, we are accelerating and expanding the transformative benefits with Tecentriq to a greater number of people living with cancer.

Our cancer immunotherapy development programme takes a comprehensive approach in pursuing the goal of restoring cancer immunity to improve outcomes for patients.

To learn more about the Roche 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. 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 nine 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 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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.

References
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