

Roche provides update on Phase III study of Tecentriq in combination with paclitaxel for people with metastatic triple-negative breast cancer

Basel, 06 August 2020 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMpassion131 study, evaluating Tecentriq® (atezolizumab) in combination with paclitaxel (chemotherapy), in comparison to placebo plus paclitaxel, did not meet statistical significance on its primary endpoint of progression-free survival (PFS) for the initial (first-line) treatment of people with metastatic triple-negative breast cancer (TNBC), in the PD-L1-positive population.

The data for the secondary endpoint of overall survival (OS) showed a negative trend, however, the study was not powered for the secondary endpoint of OS and data were immature at time of analysis. OS follow-up is planned to continue until final analysis. Safety for the Tecentriq combination appeared to be consistent with the known safety profile of the individual medicines, and no new safety signals were identified.

In the previous IMpassion130 study, Tecentriq (atezolizumab) in combination with Abraxane® (paclitaxel protein-bound particles for injectable suspension (albumin-bound); nab-paclitaxel) demonstrated a statistically significant PFS benefit and, while not formally tested, showed clinically meaningful improvements in OS for people with metastatic TNBC whose tumours express PD-L1 ($\geq 1\%$). Tecentriq in combination with nab-paclitaxel is approved in over 70 countries for the treatment of adults with unresectable locally advanced or metastatic TNBC whose tumours express PD-L1 ($\geq 1\%$).

“While we are disappointed by the results from the IMpassion131 study, we are grateful for all the patients, families and physicians who were involved in the study,” said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. “Today's results underscore the need to better understand the cancer and immune system interactions, including the chemotherapy backbone and associated regimens. We remain committed to finding optimal treatments for all people living with this aggressive disease.”

Full results from IMpassion131 are being discussed with global health authorities and will be presented at a future medical meeting. The insights will also be used to inform existing and future studies in triple-negative breast cancer with Tecentriq in combination with paclitaxel.

Roche has an extensive development programme for Tecentriq, including multiple ongoing and planned Phase III studies across several types of 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 IMpassion131 study

The IMpassion131 study is a Phase III, multicentre, randomised, double-blind study evaluating the efficacy and safety of Tecentriq in combination with paclitaxel, in comparison to placebo plus paclitaxel, in people with previously untreated, inoperable, locally advanced or metastatic TNBC. The study enrolled 651 people who were randomised in a 2:1 ratio to receive Tecentriq or placebo plus paclitaxel. The primary endpoint is PFS per investigator assessment (RECIST 1.1) in the PD-L1-positive population followed by intention-to-treat (ITT) populations. Secondary endpoints include OS, objective response rate and duration of response in the PD-L1-positive and ITT populations.

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, Kadcyra and Tecentriq are continuing to transform the treatment of early and advanced HER2-positive 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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