

FDA grants priority review to Roche's Tecentriq in combination with Abraxane for the initial treatment of people with PD-L1-positive, metastatic triple-negative breast cancer

- **Triple-negative breast cancer is an aggressive disease, with high unmet medical need**
- **If approved, this Tecentriq (atezolizumab) combination would be the first cancer immunotherapy regimen for the treatment of PD-L1-positive, metastatic triple-negative breast cancer**

Basel, 13 November 2018 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the US Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) and granted Priority Review for Tecentriq® (atezolizumab) plus chemotherapy (Abraxane® [albumin-bound paclitaxel; *nab*-paclitaxel]) for the initial (first-line) treatment of unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) in people whose disease expresses the PD-L1 protein, as determined by PD-L1 biomarker testing. The FDA is expected to make a decision on approval by 12 March 2019. A Priority Review designation is granted to medicines that the FDA has determined to have the potential to provide significant improvements in the treatment, prevention or diagnosis of a disease.

“Tecentriq in combination with *nab*-paclitaxel has the potential to meaningfully advance treatment for people with PD-L1-positive, metastatic triple-negative breast cancer. People need more options for this type of breast cancer, which is particularly difficult to treat,” said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. “We are working closely with the FDA to bring this Tecentriq combination to people with PD-L1-positive metastatic triple-negative breast cancer as soon as possible.”

The sBLA is based on data from the Phase III IMpassion130 study, which was presented at the European Society for Medical Oncology (ESMO) Congress and published in the *New England Journal of Medicine* in October 2018. Results demonstrate Tecentriq plus *nab*-paclitaxel as an initial (first-line) treatment for unresectable locally advanced or metastatic TNBC significantly reduced the risk of disease worsening or death (progression-free survival; PFS) compared with *nab*-paclitaxel alone in all randomised patients (intention-to-treat [ITT]) (median PFS=7.2 vs. 5.5 months; hazard ratio [HR]=0.80; 95% CI: 0.69-0.92, $p=0.0025$) and the PD-L1-positive population (median PFS=7.5 vs 5.0 months; HR=0.62; 95% CI: 0.49-0.78, $p<0.0001$), a subgroup determined by PD-L1 biomarker testing.^[1] At this interim analysis, statistical significance was not met for overall survival (OS) in the ITT population (median OS=21.3 vs 17.6 months; HR=0.84; 95% CI: 0.69-1.02, $p=0.0840$), but the combination showed a clinically meaningful OS improvement in the PD-L1-positive population (median OS=25.0 vs 15.5 months; HR=0.62; 95% CI: 0.45-0.86).^[1] Due to the hierarchical statistical design, results in the PD-L1-positive population were not formally tested for statistical significance. 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. Serious adverse events were reported in 23% of people who received Tecentriq plus *nab*-paclitaxel compared to 18% of people who received *nab*-paclitaxel alone.^[1]

Currently, Roche has seven ongoing Phase III studies investigating Tecentriq in TNBC, including early and advanced stages of the disease. If approved, this Tecentriq combination would be the first cancer immunotherapy regimen for the treatment of PD-L1-positive, metastatic TNBC.

About the IMpassion130 study

The IMpassion130 study is a Phase III, multicentre, randomised, double-blind study evaluating the efficacy, safety and pharmacokinetics of Tecentriq plus nab-paclitaxel compared with placebo plus nab-paclitaxel in people with unresectable locally advanced or metastatic TNBC who have not received prior systemic therapy for metastatic breast cancer. The study enrolled 902 people who were randomised equally (1:1). The co-primary endpoints are PFS per investigator assessment (RECIST 1.1) and OS. PFS and OS were assessed in all randomised patients (ITT) and in the PD-L1-positive population. Secondary endpoints include objective response rate, duration of response and time to deterioration in Global Health Status/Health-Related Quality of Life.

About TNBC

Breast cancer is the most common cancer among women with more than 2 million diagnosed worldwide each year.^[2] 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.^[3; 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.^[6]

About Tecentriq

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 80 countries for people with previously treated metastatic NSCLC and for certain types of untreated or previously treated metastatic urothelial carcinoma (mUC).

Abraxane is a registered trademark of Abraxis Bioscience, LLC, a wholly owned subsidiary of Celgene Corporation.

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 the HER2 -positive breast cancer. 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 and Kadcyła are continuing to transform the treatment of early and advanced HER2-positive breast cancer and, through our Tecentriq and ipatasertib clinical programmes, we hope to bring new treatment combinations to people with breast cancer, ultimately improving outcomes.

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. Moreover, for the tenth consecutive year, Roche has been recognised as the most sustainable company 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 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.

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References

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