

FDA grants Roche's Tecentriq in combination with Abraxane accelerated approval for people with PD-L1-positive, metastatic triple-negative breast cancer

- **This Tecentriq combination is the first cancer immunotherapy regimen approved for breast cancer**
- **Triple-negative breast cancer is an aggressive disease, with high unmet medical need**

Basel, 11 March 2019 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) has granted accelerated approval to Tecentriq® (atezolizumab) plus chemotherapy (Abraxane® [paclitaxel protein-bound particles for injectable suspension (albumin-bound); *nab*-paclitaxel]) for the treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) in people whose tumours express PD-L1, as determined by an FDA-approved test. This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). The FDA's Accelerated Approval Programme allows conditional approval of a medicine that fills an unmet medical need for a serious or life-threatening disease or condition.

“The FDA approval of this Tecentriq combination is an important treatment advance for people with PD-L1-positive, metastatic triple-negative breast cancer, a disease with high unmet medical need,” said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. “This Tecentriq combination is the first cancer immunotherapy regimen to be approved in breast cancer, representing a meaningful step forward in the understanding of this disease.”

This accelerated approval is based on data from the Phase III IMpassion130 study, which demonstrated that Tecentriq plus *nab*-paclitaxel significantly reduced the risk of disease worsening or death (PFS) by 40% compared with *nab*-paclitaxel alone (median PFS=7.4 vs. 4.8 months; HR=0.60, 95% CI: 0.48-0.77, p<0.0001) in PD-L1-positive patients with unresectable locally advanced or metastatic TNBC who had not received prior chemotherapy for metastatic disease. Overall survival (OS) results were immature with 43% of events in all randomised patients (intent-to-treat; ITT), and further data will be shared with the FDA and presented at an upcoming medical meeting. 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. The most common Grade 3-4 side effects (≥2%) with Tecentriq plus *nab*-paclitaxel were low white blood cells, tingling or numbness in the hands and feet, neutrophil count decreased, feeling tired, low red blood cells, low blood potassium level, pneumonia and increased blood level of a liver enzyme (AST). The most common side effects (≥20 %) were hair loss, feeling tired, tingling or numbness in the hands and feet, nausea, diarrhoea, low red blood cells, constipation, cough, headache, low white blood cells, decreased appetite and vomiting.

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) in the ITT population and in the PD-L1-positive population and OS in the ITT population. OS results were immature in the ITT population. Secondary endpoints include objective response rate and duration of response.

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.^{2,3,4} 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.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 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 Kadcyla 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 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 85 countries for people with previously treated metastatic non-small cell lung cancer (NSCLC) and for certain types of untreated or previously treated metastatic urothelial carcinoma (mUC). Tecentriq was also recently approved in the United States for the initial treatment of people with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumour aberrations.

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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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.

All trademarks used or mentioned in this release are protected by law.

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

References

- [1] Breast Cancer Factsheet. World Health Organization. Available from: <http://gco.iarc.fr/today/data/factsheets/cancers/20-Breast-fact-sheet.pdf> Accessed February 2019.
- [2] Yao H et al. Triple-negative breast cancer: is there a treatment on the horizon? *Oncotarget*. 2017;8(1):1913-1924.
- [3] What is Triple-Negative Breast Cancer? BreastCancer.org. Available from: https://www.breastcancer.org/symptoms/diagnosis/trip_neg?what Accessed February 2019.
- [4] Triple negative breast cancer risk factors. Cancer Treatment Centers of America. Available from: <https://www.cancercenter.com/breast-cancer/risk-factors/tab/triple-negative-breast-cancer-risk-factors/> Accessed February 2019.
- [5] Pal SK et al. Triple negative breast cancer: unmet medical needs. *Breast Cancer Res Treat*. 2011;125(3):627–636.

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

- Nicolas Dunant (Head)
- Patrick Barth
- Ulrike Engels-Lange
- Simone Oeschger
- Anja von Treskow