

## Roche provides update on Tecentriq US indication for PD-L1-positive, metastatic triple-negative breast cancer

Basel, 27 August 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the company has made the decision to voluntarily withdraw the US accelerated approval for Tecentriq® (atezolizumab) in combination with chemotherapy (Abraxane®, albumin-bound paclitaxel; nab-paclitaxel) for the treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) whose tumours express PD-L1, as determined by a US Food and Drug Administration (FDA)-approved test. Roche made this decision following consultation with the US FDA, based on the agency's assessment of the current mTNBC treatment landscape and in accordance with the requirements of the accelerated approval programme. This decision only impacts the mTNBC indication in the US. It does not affect other approved indications for Tecentriq in the US and outside the US, including mTNBC. This is not related to any changes in either the efficacy or safety associated with Tecentriq.

“TNBC remains the most challenging type of breast cancer to treat, which makes the decision to withdraw so difficult for us, as patients have had this medicine as an important option for more than two years,” said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. “We appreciate the opportunity to have been able to help people with mTNBC in the US with Tecentriq through the accelerated approval process, which has brought many significant and novel therapies to patients. We remain dedicated to finding meaningful treatments for people living with this aggressive disease and will continue to study Tecentriq in mTNBC.”

Tecentriq was granted accelerated approval by the FDA for the mTNBC indication in March 2019, making it the first immunotherapy agent to be approved in this setting. Approval was based on the progression-free survival (PFS) results of the Phase III IMpassion130 study for people with mTNBC whose tumours express PD-L1 ( $\geq 1\%$ ). Continued approval for this indication was contingent upon the results of IMpassion131, the postmarketing requirement (PMR). This study did not meet its primary endpoint of PFS for the initial (first-line) treatment of people with mTNBC in the PD-L1-positive population. The results of both studies were discussed at the FDA Oncology Drugs Advisory Committee (ODAC), which voted 7 to 2 on 27 April 2021 in favour of maintaining the accelerated approval of Tecentriq in combination with nab-paclitaxel for the treatment of people with PD-L1-positive mTNBC. Since then, Roche has been working diligently with the FDA on a possible alternative PMR. However, due to the recent changes in the treatment landscape, the FDA no longer considers it appropriate to maintain the accelerated approval. This led to the difficult decision to voluntarily withdraw the US mTNBC indication.

Roche will work with the FDA over the coming weeks to complete the withdrawal process. Roche is notifying healthcare professionals in the US about this withdrawal. Patients in the US being treated with Tecentriq for PD-L1-positive mTNBC should discuss their care with their healthcare provider.

Roche is committed to following the science to better understand cancer, including which patients may benefit most from immunotherapy treatment. Tecentriq has already demonstrated its transformational role in areas of high medical need and is a first-in-class medicine approved for particularly difficult-to-treat cancers. Tecentriq's extensive development programme includes multiple ongoing and planned Phase III studies across different lung, genitourinary, skin, breast, gastrointestinal, gynaecological, and head and neck cancers. This includes studies evaluating Tecentriq both alone and in combination with other medicines, as well as studies in metastatic, adjuvant and neoadjuvant settings.

### **About triple-negative breast cancer**

Breast cancer is the most common cancer among women with more than 2 million diagnosed worldwide each year.<sup>1</sup> 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.<sup>2-4</sup> It is defined by the lack of expression and/or amplification of the targetable receptors for oestrogen, progesterone and HER2 amplification.<sup>5</sup> Patients with mTNBC generally experience rapid progression and shorter overall survival compared to other subtypes of breast cancer.<sup>3</sup>

### **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, Phesgo, Kadcyra and Tecentriq are continuing to transform the treatment of early and advanced HER2-positive and triple-negative breast cancers and, through our 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 Programmed Death Ligand-1 (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 lung cancer (NSCLC), small cell lung cancer (SCLC), certain types of metastatic urothelial cancer, in PD-L1-positive metastatic triple-negative breast cancer and for hepatocellular carcinoma. In the US, Tecentriq is also approved in combination with Cotellic® (cobimetinib) and Zelboraf® (vemurafenib) for the treatment of people with BRAF V600 mutation-positive advanced melanoma.

### **About Roche in cancer immunotherapy**

Roche's rigorous pursuit of ground-breaking 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, 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](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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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 twelfth 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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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](http://www.roche.com).

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## References

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