Statement

Roche statement on FDA Oncologic Drug Advisory Meetings on 27–29 April 2021

Basel, 12 March 2021

Roche will participate in the US Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) meetings on 27–29 April 2021, as part of an industry-wide review of accelerated approvals with confirmatory trials that have not met their primary endpoint(s) and have yet to gain regular approval. The ODAC meetings include Tecentriq® (atezolizumab) indications in certain people with metastatic triple-negative breast cancer (mTNBC), and in first-line metastatic urothelial carcinoma (mUC, bladder cancer). The FDA's Accelerated Approval Program allows conditional approval of a medicine that fills an unmet medical need for a serious condition, with specific postmarketing requirements to confirm the clinical benefit and convert to regular approval.

Cancer immunotherapy has fundamentally changed the way certain cancers are treated, especially difficult-to-treat types of cancer where the unmet need is particularly high. Checkpoint inhibitors, like Tecentriq, continue to demonstrate benefits across multiple cancer types and have provided a novel treatment option for many patients. We remain committed to following the science to better understand cancer, including which patients may benefit most from immunotherapy treatment. We look forward to continued collaboration with the FDA and discussions with the advisory committees.

About Tecentriq ODAC Meetings
On 27 April 2021, the advisory committee will discuss the accelerated approval for Tecentriq plus chemotherapy (Abraxane® [paclitaxel protein-bound particles for injectable suspension (albumin-bound); nab-paclitaxel]) for the treatment of adults with unresectable locally advanced or mTNBC in people whose tumours express PD-L1, as determined by an FDA-approved test. On 28 April 2021, the advisory committee will discuss the accelerated approval for Tecentriq for the treatment of adults with locally advanced or mUC who are not eligible for cisplatin-containing chemotherapy and whose tumours express high levels of PD-L1 (PD-L1–stained tumour-infiltrating immune cells covering ≥5% of the tumour area), as determined by an FDA-approved test, or are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

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

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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 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.

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