US FDA Advisory Committee votes in favour of maintaining accelerated approval of Roche's Tecentriq for previously untreated metastatic bladder cancer

Basel, 28 April 2021 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the US Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) voted 10 to 1 in favour of maintaining accelerated approval of Tecentriq® (atezolizumab) for the treatment of adults with locally advanced or metastatic urothelial carcinoma (mUC, bladder cancer) 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 percent 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. Today's ODAC meeting is 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 approvals. The advisory committee provides the FDA with independent opinions and recommendations from outside medical experts though the recommendations are not binding. The FDA has not announced when it will make its final decision for Tecentriq in this indication.

"Today's positive vote reaffirms that Tecentriq fills a significant unmet need for people with previously untreated metastatic bladder cancer, many of whom cannot tolerate standard of care chemotherapy and need additional options," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Having now received positive ODAC recommendations in both bladder cancer and triple-negative breast cancer, we will continue to work with the FDA on next steps for Tecentriq in these indications."

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 (PMRs) to confirm the clinical benefit and convert to regular approval.

Tecentriq was granted accelerated approval in 2017 for the treatment of adults with locally advanced or mUC who are not eligible for cisplatin-containing chemotherapy based on the positive overall response rate and duration of response results from the IMvigor210 study. Tecentriq's indication was subsequently focused on PD-L1 high patients, who would benefit the most based on findings from the IMvigor130 study in 2018. This Phase III trial is the designated PMR for the first-line mUC indication and met its co-primary endpoint of progression-free survival. IMvigor130 continues for overall survival (OS). Roche looks forward to sharing the final OS results once available.

Roche remains 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

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cancers. This includes studies evaluating Tecentriq both alone and in combination with other medicines, as well as studies in metastatic, adjuvant and neoadjuvant settings.

Yesterday, on 27 April, the ODAC voted 7 to 2 in favour of maintaining the accelerated approval of Tecentriq in combination with nab-paclitaxel for the treatment of people with PD-L1-positive, metastatic triple-negative breast cancer.

About bladder cancer
In 2020, there were over half a million new cases of bladder cancer diagnosed globally, with around 212,500 deaths from the disease.[1] Urothelial carcinoma, which develops in the cells of the bladder lining, is the most common type of bladder cancer, accounting for about 90% of all cases.[2] In total, 30% of cases are considered advanced based on muscle-invasive or metastatic disease.[3] There remains a high unmet need for people facing previously untreated advanced bladder cancer. Despite improvements in tolerability, there have been no efficacy improvements for more than 30 years with chemotherapy as standard of care, and patients continue to experience poor outcomes.[4,5]

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 NSCLC, 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 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 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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