US FDA Advisory Committee votes in favour of maintaining accelerated approval of Roche's Tecentriq for PD-L1-positive, metastatic triple-negative breast cancer

Basel, 28 April 2021 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) voted 7 to 2 in favour of maintaining accelerated approval of 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 an FDA-approved test. 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.

"People with triple-negative breast cancer have few treatment options, which is why today's committee decision to recognise the importance of this Tecentriq combination is significant," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We are grateful to the FDA and ODAC for the open dialogue and look forward to continued collaboration to improve the lives of people with breast cancer."

The FDA's Accelerated Approval Program allows for 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 March 2019 for the treatment of adults with PD-L1-positive, unresectable locally advanced or mTNBC based on the positive progression-free survival (PFS) results from the IMpassion130 study. Continued approval for this indication was contingent upon the results of IMpassion131, the PMR for the mTNBC indication. 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. As the clinically meaningful benefit demonstrated in the IMpassion130 study remains, Roche looks forward to continuing to work with the FDA to determine next steps with regard to Tecentriq in this indication.

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

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland
Group Communications Roche Group Media Relations
Tel. +41 61 688 88 88 www.roche.com

Tomorrow, on 28 April, the ODAC will discuss Tecentriq's accelerated approval for the treatment of people with locally advanced or metastatic urothelial carcinoma (mUC, bladder cancer) who are not eligible for cisplatin-containing chemotherapy.

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.[2-4] It is defined by the lack of expression and/or amplification of the targetable receptors for oestrogen, progesterone and HER2 amplification.[5] Patients with mTNBC generally experience rapid progression and shorter overall survival 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 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, Kadcyla 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 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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Roche Group Media Relations
Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Patrick Barth
Phone: +41 61 688 44 86

Dr. Daniel Grotzky
Phone: +41 61 688 31 10

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mählitz
Phone: +41 79 327 54 74

Nathalie Meetz
Phone: +41 61 687 43 05

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Roche Investor Relations

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Jon Kaspar Bayard
Phone: +41 61 68-83894
e-mail: jon_kaspar.bayard@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com

Dr. Lisa Tuomi
Phone: +1 650 467 8737
e-mail: tuomi.lisa@gene.com