Media Release

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FDA grants priority review to Roche's cancer immunotherapy TECENTRIQ (atezolizumab) for initial treatment of people with a specific type of metastatic lung cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) and granted Priority Review for TECENTRIQ® (atezolizumab), in combination with Avastin® (bevacizumab), paclitaxel and carboplatin (chemotherapy), for the initial (first-line) treatment of people with metastatic non-squamous non-small cell lung cancer (NSCLC). The FDA is expected to make a decision on approval by 5 September 2018. A Priority Review designation is granted to medicines that the FDA has determined to have the potential to provide significant improvements in the treatment, prevention or diagnosis of a disease.

"Our phase III results showed TECENTRIQ in combination with Avastin, paclitaxel and carboplatin has the potential to provide a significant survival benefit in the initial treatment of metastatic non-squamous non-small cell lung cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We are working closely with the FDA to bring this treatment regimen to people with this type of lung cancer as soon as possible."

This sBLA is based on results from the Phase III IMpower150 study, which met its co-primary endpoints of overall survival (OS) and progression-free survival (PFS) in the initial treatment of people with advanced non-squamous NSCLC. The safety profile of the combination was consistent with the safety profiles of the individual medicines, and no new safety signals were identified.

TECENTRIQ is currently approved by the FDA to treat people with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy, and have progressed on an appropriate FDA-approved targeted therapy if their tumour has ALK and EGFR mutations.

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About the IMpower150 study

IMpower150 is a multicentre, open-label, randomised, controlled Phase III study evaluating the efficacy and safety of TECENTRIQ in combination with carboplatin and paclitaxel with or without Avastin in people with stage IV non-squamous NSCLC who had not been treated with chemotherapy for their advanced disease. It enrolled 1,202 people, of which those with ALK and EGFR mutations were excluded from the primary intention-to-treat (ITT) analysis. People were randomised (1:1:1) to receive:

- TECENTRIQ plus carboplatin and paclitaxel (Arm A), or
- TECENTRIQ and Avastin plus carboplatin and paclitaxel (Arm B), or
- Avastin plus carboplatin and paclitaxel (Arm C, control arm)

The co-primary endpoints were OS and PFS, as determined by the investigator using Response Evaluation Criteria in Solid Tumours Version 1.1 (RECIST v1.1). The primary analysis of the co-primary PFS endpoint in IMpower150 was assessed in two populations: all randomised people without an ALK or EGFR genetic mutation (intention-to-treat wild-type) and in a subgroup of people who had a specific biomarker (T-effector "Teff" gene signature expression). The co-primary OS endpoint was assessed in all randomised people without an ALK or EGFR genetic mutation (intention-to-treat wild-type). Key secondary endpoints included investigator-assessed PFS and OS, safety in the ITT population and in EGFR and ALK mutation subgroups.

About NSCLC

Lung cancer is the leading cause of cancer death globally[1]. Each year 1.59 million people die as a result of the disease; this translates into more than 4,350 deaths worldwide every day[2]. Lung cancer can be broadly divided into two major types: NSCLC and small cell lung cancer. NSCLC is the most prevalent type, accounting for around 85% of all cases[2].

About the TECENTRIQ and Avastin combination

There is a strong scientific rationale to support further investigation of TECENTRIQ plus Avastin in combination. We are investigating this combination in a broad range of cancers, including first-line advanced NSCLC. Avastin, in addition to its anti-angiogenic effects, may further enhance TECENTRIQ's ability to restore anti-cancer immunity by inhibiting VEGF-related immunosuppression, promoting T cell tumour infiltration and enabling priming and activation of T cell responses against tumour antigens.

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.

Currently, Roche has eight Phase III lung cancer studies underway, evaluating TECENTRIQ alone or in combination with other medicines.

TECENTRIQ is already approved in the European Union, United States and more than 60 countries for people with previously treated metastatic NSCLC and for people with locally advanced or metastatic urothelial cancer (mUC) who are not eligible for cisplatin chemotherapy, or who have had disease progression during or following platinum-containing therapy.

About Avastin

Avastin is a prescription-only medicine that is a solution for intravenous infusion. It is a biologic antibody designed to specifically bind to a protein called vascular endothelial growth factor (VEGF) that plays an important role throughout the lifecycle of the tumour to develop and maintain blood vessels, a process known as angiogenesis. Avastin is designed to interfere with the tumour blood supply by directly binding to the VEGF protein to prevent interactions with receptors on blood vessel cells. The tumour blood supply is thought to be critical to a tumour's ability to grow and spread in the body (metastasise).

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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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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