Media Release

FDA approves Roche's Tecentriq plus chemotherapy (Abraxane and carboplatin) for the initial treatment of metastatic non-squamous non-small cell lung cancer

- **Approval based on the Phase III IMpower130 study showing the Tecentriq plus chemotherapy combination demonstrated a significant overall survival and progression-free survival benefit**

Basel, 4 December 2019 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) approved Tecentriq® (atezolizumab) in combination with chemotherapy (Abraxane® [paclitaxel protein-bound; nab-paclitaxel] and carboplatin) for the initial (first-line) treatment of adults with metastatic non-squamous non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumour aberrations.

"We are pleased to offer this Tecentriq-based combination as a new treatment option that can provide a clinically meaningful survival benefit for people with non-squamous non-small cell lung cancer," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Today's approval offers another opportunity to help prolong the lives of people with this type of the disease."

This approval is based on results from the Phase III IMpower130 study, which showed Tecentriq in combination with chemotherapy helped people live significantly longer compared to chemotherapy alone (median overall survival [OS]=18.6 versus 13.9 months; hazard ratio [HR]=0.80; 95% CI: 0.64–0.99; p=0.0384) in the intention-to-treat wild-type (ITT-WT) population.[1] The Tecentriq-based combination also significantly reduced the risk of disease worsening or death (progression-free survival [PFS]) compared with chemotherapy alone (median PFS=7.2 versus 6.5 months; HR=0.75; 95% CI: 0.63–0.91; p=0.0024) in the ITT-WT population.[1]

Safety for the Tecentriq plus chemotherapy combination appeared consistent with the known safety profiles of the individual medicines, and no new safety signals were identified with the combination. Grade 3-4 treatment-related adverse events were reported in 73.2% of people receiving Tecentriq plus chemotherapy compared with 60.3% of people receiving chemotherapy alone.

In lung cancer, Tecentriq is also approved in the US in combination with Avastin® (bevacizumab), paclitaxel and carboplatin (chemotherapy), for the initial (first-line) treatment of adults with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumour aberrations. Additionally, Tecentriq is approved by the FDA to treat adults with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have disease progression on FDA-approved therapy for NSCLC harbouring these aberrations prior to receiving Tecentriq. Tecentriq is also approved in the US in combination with carboplatin and etoposide (chemotherapy) for the initial (first-line) treatment of adults with extensive-stage small cell lung cancer (ES-SCLC).

Roche has an extensive development programme for Tecentriq, including nine Phase III studies underway across different types of lung cancer, and multiple ongoing and planned Phase III studies across

genitourinary, skin, breast, gastrointestinal, gynaecological and head and neck cancers. This includes studies evaluating Tecentriq both alone and in combination with other medicines.

About the IMpower130 study
IMpower130 is a Phase III, multicentre, open-label, randomised study evaluating the efficacy and safety of Tecentriq in combination with nab-paclitaxel and carboplatin versus chemotherapy (nab-paclitaxel and carboplatin) alone for chemotherapy-naïve patients with stage IV non-squamous NSCLC. The study enrolled 724 people, of whom 681 were in the ITT-WT population and were randomised (2:1) to receive:

- Tecentriq plus nab-paclitaxel and carboplatin (Arm A), or
- Nab-paclitaxel and carboplatin (Arm B, control arm)

During the treatment-induction phase, people in Arm A received Tecentriq and carboplatin on day 1 of each 21-day cycle, and nab-paclitaxel on days 1, 8 and 15 of each 21-day cycle for 4 or 6 cycles or until loss of clinical benefit, whichever occurred first. People in Arm A received Tecentriq during the maintenance treatment phase until loss of clinical benefit was observed.

During the treatment-induction phase, people in Arm B received carboplatin on day 1 and nab-paclitaxel on days 1, 8 and 15 of each 21-day cycle for 4 or 6 cycles or until disease progression, whichever occurred first. People in Arm B received best supportive care during the maintenance treatment phase. Switch maintenance to pemetrexed was also permitted. People who were consented prior to a protocol revision were given the option to crossover to receive Tecentriq as monotherapy until further disease progression.

The co-primary endpoints were:

- PFS, as determined by the investigator using RECIST v1.1 in people without EGFR or ALK mutations (the ITT-WT population)
- OS in the ITT-WT population

About NSCLC
Lung cancer is the leading cause of cancer death globally.[2] Each year 1.76 million people die as a result of the disease; this translates into more than 4,800 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.[3] NSCLC comprises non-squamous and squamous-cell lung cancer, the squamous form of which is characterised by flat cells covering the airway surface when viewed under a microscope.[3]

About Tecentriq (atezolizumab)
Tecentriq is a monoclonal antibody designed to bind with a protein called 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 and small cell lung cancer, certain types of metastatic urothelial cancer, and in PD-L1-positive metastatic triple-negative breast cancer.

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. 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 eleventh 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF

56.8 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.

References

[1] Capuzzo F et al. IMpower130: Progression-free survival (PFS) and safety analysis from a randomised phase 3 study of carboplatin + nab-paclitaxel (CnP) with or without atezolizumab (atezo) as first-line (1L) therapy in advanced non-squamous NSCLC. Presented at: European Society for Medical Oncology (ESMO) 2018 Conference, 22 October 2018, Munich, Germany. Abstract #LBA53.
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[3] American Cancer Society. What Is Non-Small Cell Lung Cancer? [Internet]: Available from: https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html Accessed November 2019.

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