Media Release

FDA approves Roche's Tecentriq as a first-line monotherapy for certain people with metastatic non-small cell lung cancer

- **Tecentriq's fourth indication in metastatic non-small cell lung cancer and fifth indication in lung cancer overall in the US**
- **Approval based on the Phase III IMpower110 study showing Tecentriq demonstrated a significant overall survival benefit in people with high PD-L1 expression compared with chemotherapy**

Basel, 19 May 2020 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) has approved Tecentriq® (atezolizumab) as a first-line (initial) treatment for adults with metastatic non-small cell lung cancer (NSCLC) whose tumours have high PD-L1 expression (PD-L1 stained ≥ 50% of tumour cells [TC ≥ 50%] or PD-L1 stained tumour-infiltrating [IC] covering ≥ 10% of the tumour area [IC ≥ 10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumour aberrations.

"We are pleased to offer people with certain types of lung cancer a new chemotherapy-free option that can help prolong their lives and be administered on a flexible dosing schedule, including an option for once-a-month Tecentriq infusions," said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. "Today marks the fifth approval of Tecentriq in lung cancer, as we remain committed to providing an effective and tailored treatment option for every person diagnosed with this disease."

This approval is based on an interim analysis from the Phase III IMpower110 study, which showed that Tecentriq monotherapy improved overall survival (OS) by 7.1 months compared with chemotherapy (median OS=20.2 versus 13.1 months; hazard ratio [HR]=0.59, 95% CI: 0.40–0.89; p=0.0106) in people with high PD-L1 expression (TC3/IC3-wild-type [WT]). Safety for Tecentriq appeared to be consistent with its known safety profile, and no new safety signals were identified. Grade 3–4 treatment-related adverse events (AEs) were reported in 12.9% of people receiving Tecentriq compared with 44.1% of people receiving chemotherapy.[1]

Tecentriq is the first and only single-agent cancer immunotherapy with three dosing options, allowing administration every two, three or four weeks. The supplemental Biologics License Application for the Tecentriq monotherapy was granted Priority Review, a designation given to medicines the FDA has determined to have the potential to provide significant improvements in the treatment, prevention or diagnosis of a disease.

In the US, Tecentriq has received four approvals across NSCLC, including as a single agent or in combination with targeted therapies and/or chemotherapies. It is also approved in combination with carboplatin and etoposide (chemotherapy) for the first-line treatment of adults with extensive-stage small cell lung cancer.

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Roche has an extensive development programme for Tecentriq, including multiple ongoing and planned Phase III studies across lung, 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 IMpower110 study
IMpower110 is a Phase III, randomised, open-label study evaluating the efficacy and safety of Tecentriq monotherapy compared with cisplatin or carboplatin and pemetrexed or gemcitabine (chemotherapy) in PD-L1-selected, chemotherapy-naïve participants with Stage IV non-squamous or squamous NSCLC. The study enrolled 572 people, of whom 554 were in the intention-to-treat WT population, which excluded people with EGFR or ALK genomic tumour aberrations, and were randomised 1:1 to receive:

- Tecentriq monotherapy, until disease progression (or loss of clinical benefit, as assessed by the investigator), unacceptable toxicity or death; or
- Cisplatin or carboplatin (per investigator discretion) combined with either pemetrexed (non-squamous) or gemcitabine (squamous), followed by maintenance therapy with pemetrexed alone (non-squamous) or best supportive care (squamous) until disease progression, unacceptable toxicity or death.

The primary efficacy endpoint was OS by PD-L1 subgroup (TC3/IC3-WT; TC2/3/IC2/3-WT; and TC1,2,3/IC1,2,3-WT), as determined by the SP142 assay test. Key secondary endpoints included investigator-assessed progression-free survival (PFS), objective response rate (ORR) and duration of response (DoR).

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
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
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 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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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] Spigel D et al. IMpower110: Interim OS Analysis of a Phase III Study of Atezolizumab (atezo) vs Platinum-Based Chemotherapy (chemo) as 1L Treatment (tx) in PD-L1–selected NSCLC [ESMO 2019 Abstract LBA78].
[2] World Health Organisation: GLOBOCAN 2018 – Lung Cancer: Estimated cancer incidence, mortality and prevalence worldwide. [Internet; cited 2020 May] Available from: http://gco.iarc.fr/today/data/factsheets/cancers/15-Lung-fact-sheet.pdf.
[3] American Cancer Society: What Is Lung Cancer? [Internet; cited 2020 May]: Available from: https://www.cancer.org/cancer/lung-cancer/about/what-is.html.

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