# *Media Release*

## FDA grants priority review to Roche's Tecentriq monotherapy as first-line treatment of certain people with advanced non-small cell lung cancer

Basel, 19 February 2020 – 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) as a first-line (initial) monotherapy for people with advanced non-squamous and squamous non-small cell lung cancer (NSCLC) without EGFR or ALK mutations with high PD-L1 expression (TC3/IC3 wild-type [WT]), as determined by PD-L1 biomarker testing. The FDA is expected to make a decision on approval by June 19, 2020.

"In the IMpower110 study, Tecentriq alone demonstrated a significant improvement in overall survival compared with chemotherapy for people newly diagnosed with certain types of advanced non-small cell lung cancer," said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. "We are working closely with the FDA to bring this chemotherapy-free option to these patients as quickly as possible."

This sBLA is based on results 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]=0.595, 95% CI: 0.398–0.890; p=0.0106) in people with high PD-L1 expression (TC3/IC3-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]

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 to evaluate 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 advanced non-squamous or squamous NSCLC without ALK or EGFR mutations (WT). A total of 572 people (555 WT) were enrolled and were randomised 1:1 to receive:

- Tecentriq monotherapy, until 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.

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The primary efficacy endpoint is 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 include 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**
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 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 Organization: GLOBOCAN 2018 – Lung Cancer: Estimated cancer incidence, mortality and prevalence worldwide. [Internet; cited 2020 Feb] 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 Feb]: Available from: https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html.

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