New Phase III data support the benefit of Roche's Tecentriq in early-stage lung cancer

- **Data presented at the 2021 ESMO Virtual Congress and the IASLC 2021 WCLC add to the body of evidence supporting Tecentriq's role in treating early-stage lung cancer**
- **As published in The Lancet, Tecentriq is the first and only cancer immunotherapy to demonstrate positive Phase III results in the adjuvant lung cancer setting**
- **Tecentriq was granted Priority Review by the FDA and is currently being reviewed under the Real-Time Oncology Review pilot programme**

Basel, 20 September 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today presented new data from the Phase III IMpower010 study at the European Society for Medical Oncology (ESMO) Congress 2021 Presidential Symposium, reinforcing the significant disease-free survival (DFS) benefit offered by Tecentriq® (atezolizumab) for people with Stage II-IIIA non-small cell lung cancer (NSCLC) whose tumours express PD-L1≥1%. Data from the IMpower010 trial were published simultaneously in The Lancet. In IMpower010, treatment with Tecentriq, following surgery and chemotherapy, reduced the risk of disease recurrence or death (DFS) by 34% (hazard ratio [HR]=0.66, 95% CI: 0.50–0.88) in people with Stage II-IIIA NSCLC whose tumours express PD-L1≥1%, compared with best supportive care (BSC). Safety data for Tecentriq were consistent with its known safety profile and no new safety signals were identified.

"Today, more than half of all people with early-stage NSCLC experience recurrence following surgery," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "IMpower010 shows how, for the first time, a cancer immunotherapy may help many of these patients live longer without their disease returning. The data presented at ESMO and WCLC further contribute to our understanding of Tecentriq in this treatment setting."

At the 2021 ESMO Virtual Congress, new real-world data show that almost three-quarters of patients with early-stage NSCLC in the US did not receive adjuvant treatment, despite guideline recommendations.[1] Data presented from IMpower010 show that adjuvant Tecentriq offers a DFS benefit in the Stage II-IIIA patient population, irrespective of the stage of disease and across the main prior therapies.[2] Specifically, time to relapse appeared to be improved with Tecentriq, compared with BSC, among people with Stage II-IIIA NSCLC whose tumours express PD-L1 TC ≥1%, for both locoregional and distant sites. There was no clear difference in patterns of relapse. An extended analysis of PD-L1 subgroups in the Stage II-IIIA population shows there is a higher magnitude of benefit from adjuvant Tecentriq in people with PD-L1 expression ≥50%, compared with those with 1-49% PD-L1 expression. The exploratory nature of the analysis in patients with 1-49% PD-L1 expression prevents any firm conclusions, and these data will be further analysed and shared at a future medical congress.

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Additional IMpower010 data, recently presented at the International Association for the Study of Lung Cancer (IASLC) 2021 World Conference on Lung Cancer (WCLC) Presidential Symposium, showed that treatment with Tecentriq improved DFS in the PD-L1≥1% Stage II-IIIA NSCLC population, compared with BSC, regardless of most surgery types and adjuvant chemotherapy regimens.[3]

Based on the IMpower010 data, the US Food and Drug Administration (FDA) recently granted Priority Review to Tecentriq as an adjuvant treatment for certain people with early NSCLC and is reviewing the application under the Real-Time Oncology Review pilot programme, which aims to explore a more efficient review process to ensure safe and effective treatments are available to patients as early as possible. The FDA is expected to make a decision on approval by 1 December 2021.

Tecentriq has previously shown clinically meaningful benefit in various types of lung cancer, with five currently approved indications in markets around the world. It was the first approved cancer immunotherapy for front-line treatment of adults with extensive-stage small cell lung cancer (SCLC) in combination with carboplatin and etoposide (chemotherapy). Tecentriq also has four approved indications in advanced NSCLC as either a single agent or in combination with targeted therapies and/or chemotherapies. Tecentriq is available in three dosing options, providing the flexibility to choose administration every two, three or four weeks.

Roche has an extensive development programme for Tecentriq, including multiple ongoing and planned Phase III studies across different settings in 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 across various tumour types.

About the IMpower010 study
IMpower010 is a Phase III, global, multicentre, open-label, randomised study evaluating the efficacy and safety of Tecentriq compared with BSC, in participants with Stage IB-IIIA NSCLC (UICC 7th edition), following surgical resection and up to 4 cycles of adjuvant cisplatin-based chemotherapy. The study randomised 1,005 people with a ratio of 1:1 to receive either Tecentriq (up to 16 cycles) or BSC. The primary endpoint is investigator-determined DFS in the PD-L1-positive Stage II-IIIA, all randomised Stage II-IIIA and ITT Stage IB-IIIA populations. Key secondary endpoints include OS in the overall study population, ITT Stage IB-IIIA NSCLC.

About NSCLC
Lung cancer is one of the leading causes of cancer death globally.[4] Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day.[4] Lung cancer can be broadly divided into two major types: NSCLC and SCLC. NSCLC is the most prevalent type, accounting for around 85% of all cases.[5] 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.[5]

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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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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