

Pivotal Phase III study shows Roche's Tecentriq helped people with early lung cancer live longer without their disease returning

- **First Phase III study to show that a cancer immunotherapy improves disease-free survival in people with resectable early stage lung cancer compared to best supportive care**
- **Treating lung cancer early, before it has spread, may help prevent the disease from returning and therefore provide the best opportunity for a cure**
- **Data will be submitted to health authorities globally as soon as possible, including the U.S. Food and Drug Administration and the European Medicines Agency, and presented at an upcoming medical meeting**

Basel, 22 March 2021 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMpower010 study evaluating Tecentriq® (atezolizumab), compared with best supportive care (BSC), met its primary endpoint of disease-free survival (DFS) at the interim analysis. Tecentriq showed a statistically significant improvement in DFS as adjuvant therapy following surgery and chemotherapy in all randomised Stage II-IIIa populations with non-small cell lung cancer (NSCLC). The magnitude of DFS benefit was particularly pronounced in the PD-L1-positive population.

Follow-up will continue with planned analyses of DFS in the overall intent-to-treat (ITT) population, which at the time of analysis did not cross the threshold, and overall survival (OS) data, which were immature at the time of interim analysis. Safety for Tecentriq was consistent with its known safety profile and no new safety signals were identified. Results from the IMpower010 study will be presented at an upcoming medical meeting and submitted to health authorities globally, including the U.S. Food and Drug Administration and the European Medicines Agency.

“With these landmark results, Tecentriq has become the first cancer immunotherapy to help many people with resectable early lung cancer live longer without their cancer returning,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “We’re excited by the clinical benefit adjuvant Tecentriq may bring to lung cancer patients, particularly in the PD-L1-positive population. We will submit these data to regulatory authorities as soon as possible.”

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 NSCLC as either a single agent or in combination with targeted therapies and/or chemotherapies.

Furthermore, Roche has an extensive development programme for Tecentriq, including multiple ongoing and planned Phase III studies across different lung, genitourinary, skin, breast, gastrointestinal, gynecological, 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 tumor 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-III A 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 at most 16 cycles of Tecentriq or BSC. The primary endpoint is investigator-determined DFS in the PD-L1-positive Stage II-III A, all randomised Stage II-III A and ITT Stage IB-III A populations. Key secondary endpoints include OS in the overall study population, ITT Stage IB-III A NSCLC.

About NSCLC

Lung cancer is the one of the leading causes of cancer death globally.¹ Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day.¹ 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 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.²

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 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 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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References

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- [2] American Cancer Society: What Is Lung Cancer? [Internet; cited March 2021]: Available from: <https://www.cancer.org/cancer/lung-cancer/about/what-is.html>.

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