US FDA approves Roche's Tecentriq as adjuvant treatment for certain people with early non-small cell lung cancer

- **Tecentriq is the first and only cancer immunotherapy approved for NSCLC in the adjuvant setting**
- **Approval is based on the Phase III IMpower010 study showing adjuvant Tecentriq improved disease-free survival by more than one-third in PD-L1-positive Stage II-IIIA lung cancer, compared with best supportive care**

Basel, 15 October 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) has approved Tecentriq® (atezolizumab) as adjuvant treatment, following surgery and platinum-based chemotherapy, for adults with Stage II-IIIA non-small cell lung cancer (NSCLC) whose tumours express PD-L1≥1%, as determined by an FDA-approved test.

"Tecentriq is now the first and only cancer immunotherapy available for adjuvant treatment of NSCLC, introducing a new era where people diagnosed with early lung cancer may have the opportunity to receive immunotherapy to increase their chances for cure," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Today's landmark approval gives physicians and patients a new way to treat early lung cancer that has the potential to significantly reduce risk of cancer recurrence, after more than a decade with limited treatment advances in this setting."

"Too many patients with early-stage lung cancer experience disease recurrence following surgery. Now, the availability of immunotherapy following surgery and chemotherapy offers many patients new hope and a powerful new tool to reduce their risk of cancer relapse," said Bonnie Addario, Co-founder and Chair, GO2 Foundation for Lung Cancer. "With this approval, it is more important than ever to screen for lung cancer early and test for PD-L1 at diagnosis to help bring this advance to the people who can benefit."

The approval is based on results from an interim analysis of the Phase III IMpower010 study. The results showed treatment with Tecentriq, following surgery and platinum-based chemotherapy, reduced the risk of disease recurrence or death by 34% (hazard ratio [HR]=0.66, 95% CI: 0.50-0.88) in people with Stage II-IIIA NSCLC (UICC/AJCC 7th edition) 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. Fatal and serious adverse reactions occurred in 1.8% and 18%, respectively, of patients receiving Tecentriq. The most frequent serious adverse reactions (>1%) were pneumonia (1.8%), pneumonitis (1.6%), and pyrexia (1.2%).

The review of this application was conducted under the FDA's Project Orbis initiative, which provides a framework for concurrent submission and review of oncology medicines among international partners. According to the FDA, collaboration among international regulators may allow people with cancer to receive earlier access to products in other countries where there may be significant delays in regulatory submissions.

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Simultaneous applications were submitted to regulators in Switzerland, the UK, Canada, Brazil and Australia under Project Orbis. Additionally, the FDA reviewed and approved the application under its 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 IMpower010 data have also been submitted as the basis of marketing applications to the European Medicines Agency (EMA) and other global health authorities.

Tecentriq has previously shown clinically meaningful benefit in various types of lung cancer, with six currently approved indications in the US. In addition to becoming the first approved cancer immunotherapy for adjuvant NSCLC, Tecentriq was also 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/AJCC 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 intention-to-treat (ITT) Stage IB-IIIA populations. Key secondary endpoints include overall survival (OS) in the overall study population, ITT Stage IB-IIIA NSCLC.

About lung cancer

Lung cancer is 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 SCLC. NSCLC is the most prevalent type, accounting for around 85% of all cases.[2] Approximately 50% of patients with NSCLC are diagnosed with early-stage (Stages I and II) or locally advanced (Stage III) disease.[3] Today, about half of all people with early lung cancer still experience a cancer recurrence following surgery.[4] Treating lung cancer early, before it has spread, may help prevent the disease from returning and provide people with the best opportunity for a cure.

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 has shown clinically meaningful benefit in advanced NSCLC and SCLC, with five currently approved indications in the EU. 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.

References

[1] World Health Organization: GLOBOCAN 2020 – Lung Cancer: Estimated cancer incidence, mortality and prevalence worldwide. [Internet; cited September 2021] Available from: https://gco.iarc.fr/today/data/factsheets/cancers/15-Lung-fact-sheet.pdf
[2] American Cancer Society: What Is Lung Cancer? [Internet; cited September 2021] Available from: https://www.cancer.org/cancer/lung-cancer/about/what-is.html
[3] EpiCast report: NSCLC Epidemiology Forecast to 2025. GlobalData. 2016. [Internet; cited September 2021] Available from: https://store.globaldata.com/report/gdhcer132-16--epicast-report-non-small-cell-lung-cancer-nsclc-epidemiology-forecast-to-2025/
[4] Yano T, et al. Therapeutic strategy for postoperative recurrence in patients with non-small cell lung cancer. World J Clin Oncol. 2014;5(5):1048-54.

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