Media Release

Roche's Tecentriq approved by Swissmedic as adjuvant treatment for certain people with early non-small cell lung cancer

- **Tecentriq is the first cancer immunotherapy available for treatment after surgery and chemotherapy (as adjuvant treatment) in certain patients with early non-small cell lung cancer (NSCLC)[1]**
- **The approval is based on the Phase III IMpower010 study showing that adjuvant Tecentriq improved disease-free survival and reduced the risk of recurrence by 57% in PD-L1 ≥ 50% Stage II-IIIA NSCLC patients, compared with best supportive care (BSC)[2]**

Basel, 10 January 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Swiss agency for therapeutic products (Swissmedic) has approved Tecentriq® (atezolizumab) as adjuvant monotherapy treatment, following surgery and a cisplatin-based chemotherapy, for adults with Stage II-IIIA (according to the 7th Edition of the UICC/AJCC Staging System) non-small cell lung cancer (NSCLC) whose tumors express PD-L1 ≥ 50%.[1]

In Switzerland, lung cancer still affects around 4500 people every year.[3] The current standard of care for patients diagnosed at early stages of non-small cell lung cancer with resectable tumors is surgery followed by adjuvant chemotherapy but more than half of all patients will still incur a relapse at some point in time.[2,4,5,6]

"With today's approval, patients will be able to benefit from this immunotherapy option in earlier non-small cell lung cancer stages by reducing their risk of cancer recurrence and increasing their chances to remain disease-free as long as possible" said Jean-Marc Häusler, M.D., Country Medical Director, Roche Pharma Switzerland.

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 cisplatin-based chemotherapy, reduced the risk of disease recurrence or death by 57% (hazard ratio [HR]=0.43, 95% CI: 0.27-0.68) in people with Stage II-IIIA NSCLC (UICC/AJCC 7th edition) whose tumors express PD-L1 ≥ 50%, compared with best supportive care (BSC). Safety data for Tecentriq were consistent with its known safety profile and no new safety signals were identified.[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.

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Simultaneous applications were submitted to regulators in Switzerland, the UK, Canada, Brazil and Australia under Project Orbis.

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.[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 tumor cells and tumor-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.[7,8]

Tecentriq has shown clinically meaningful benefit in advanced NSCLC and SCLC, with four currently approved indications in Switzerland. It is also approved 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 as well as in combination with Cotellic® (cobimetinib) and Zelboraf® (vemurafenib) for the treatment of people with BRAF V600 mutation-positive advanced melanoma.[1]

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, realizing 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, the company 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 thirteenth consecutive year, Roche has been recognised as one of the most sustainable companies in the pharmaceutical 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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