Media & Investor Release

Ad hoc announcement pursuant to Art. 53 LR

Roche provides update on phase III SKYSCRAPER-02 study in extensive-stage small cell lung cancer

- **SKYSCRAPER-02, the first randomized study of tiragolumab in extensive stage small-cell lung cancer (ES-SCLC), did not meet its co-primary endpoint of progression-free survival**
- **ES-SCLC is a hard-to-treat disease and Tecentriq plus chemotherapy remains a standard of care**
- **Tiragolumab continues to be evaluated in non-small cell lung cancer (NSCLC) and other cancer types through additional phase III trials as planned**

Basel, 30 March 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the phase III SKYSCRAPER-02 study, evaluating the investigational anti-TIGIT immunotherapy tiragolumab plus Tecentriq® (atezolizumab) and chemotherapy (carboplatin and etoposide) as an initial (first-line) treatment for people with extensive-stage small cell lung cancer (ES-SCLC), did not meet its co-primary endpoint of progression-free survival. The co-primary endpoint of overall survival was not met at its interim analysis and is unlikely to reach statistical significance at the planned final analysis. Data suggest tiragolumab plus Tecentriq and chemotherapy was well-tolerated and no new safety signals were identified when adding tiragolumab. Data will be presented at an upcoming medical meeting.

“Today’s outcome is disappointing as we had hoped to continue building on the advances of Tecentriq in extensive stage small-cell lung cancer, which remains difficult to treat. We are thankful to all the patients and healthcare professionals involved in the study,” said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. “We look forward to seeing additional data from the upcoming phase III trial in PD-L1-high non-small cell lung cancer based on the encouraging results from the CITYSCAPE study.”

SCLC is the most aggressive form of any lung cancer and is characterised by rapid progression and poor survival.[1,2] Tecentriq was the first cancer immunotherapy to show a survival benefit in ES-SCLC (phase III IMpower133 study), and was the first approved treatment option in 20 years.[3] More options are needed, particularly for hard-to-treat cancers like SCLC, and Roche is committed to exploring innovative medicines to improve outcomes for people with lung cancer.

The tiragolumab programme continues to explore advances in multiple clinical trials to build on Tecentriq, expand into earlier stages of disease, and seeks to provide new treatment options in advanced and difficult-to-treat cancers with high unmet medical need. Tiragolumab was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration in 2021 for the initial treatment of PD-L1-high metastatic non-small cell lung cancer, based on the results of the phase II CITYSCAPE study – representing the only

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investigational anti-TIGIT therapy to be granted this designation.[4,6] The phase III SKYSCRAPER-01 trial is currently ongoing to confirm the CITYSCAPE results. Since 2020, Roche has initiated five phase III trials, including NSCLC (SKYSCRAPER-01, SKYSCRAPER-03), ES- SCLC (SKYSCRAPER-02), oesophageal cancers (SKYSCRAPER-07, SKYSCRAPER-08), and multiple early trials in various tumour types.[5]

About small cell lung cancer (SCLC)

SCLC has the most aggressive course of any lung cancer and is characterised by rapid progression and poor survival.[1,2] Due to its fast-growing nature, two-thirds of patients are diagnosed with extensive-stage SCLC (ES-SCLC), when the cancer has already spread to other parts of the body.[1]

Tecentriq® (atezolizumab) was the first cancer immunotherapy to show a survival benefit in ES-SCLC (phase III IMpower133 study), offering new hope to patients and laying the groundwork for a new era of novel therapeutic approaches to improve patients' experience.[3]

About the SKYSCRAPER-02 study

SKYSCRAPER-02 is a global phase III, randomised, placebo-controlled and double-blinded study evaluating tiragolumab plus Tecentriq® (atezolizumab) and chemotherapy as an initial (first-line) treatment versus Tecentriq and chemotherapy alone in 490 people with extensive-stage small cell lung cancer. Co-primary endpoints are overall survival (OS) and progression-free survival (PFS) in the primary analysis set (all randomised patients whose cancer had not spread to the brain). Key secondary endpoints include OS and PFS in all randomised patients, and safety.

About tiragolumab

Tiragolumab is a novel immune checkpoint inhibitor with an intact Fc region. Tiragolumab selectively binds to TIGIT, a novel inhibitory immune checkpoint, which suppresses the immune response to cancer.[6] Based on preclinical research, tiragolumab is thought to work as an immune amplifier with other cancer immunotherapies such as Tecentriq® (atezolizumab).[7] The TIGIT pathway is distinct but complementary to the PD-L1/PD-1 pathway. Dual blockade with tiragolumab and Tecentriq may help overcome immune suppression and restore the immune response.

About Tecentriq® (atezolizumab)

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 non-small cell lung cancer (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

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.
In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we

work.

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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