Media & Investor Release

Ad hoc announcement pursuant to Art. 53 LR

Roche provides update on phase II/III SKYSCRAPER-06 study in metastatic non-squamous non-small cell lung cancer

- **SKYSCRAPER-06 evaluating tiragolumab plus Tecentriq and chemotherapy did not meet the primary endpoints of progression-free survival at primary analysis and overall survival at first interim analysis**
- **The combination of tiragolumab plus Tecentriq and chemotherapy showed reduced efficacy compared to the comparator arm**
- **Safety was consistent with previous studies, however we intend to halt the trial due to reduced efficacy compared to the comparator arm**

Basel, 04 July 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the phase II/III SKYSCRAPER-06 study, evaluating tiragolumab plus Tecentriq® (atezolizumab) and chemotherapy versus pembrolizumab and chemotherapy as an initial (first-line) treatment for people with previously untreated, locally advanced unresectable or metastatic non-squamous non-small cell lung cancer, did not meet its primary endpoints of progression-free survival (PFS) at its primary analysis with a hazard ratio (HR) of 1.27 [95% CI: 1.02,1.57] and overall survival (OS) at its first interim analysis with a HR of 1.33 [95% CI: 1.02, 1.73], which was immature. The combination of tiragolumab plus Tecentriq and chemotherapy showed reduced efficacy in both PFS and OS compared to the comparator arm in the intent-to-treat population, which includes the phase II and phase III cohorts. The overall safety profile remains consistent with the safety profile previously observed for the combination of tiragolumab plus Tecentriq and chemotherapy, and no new or unexpected findings were identified. Based on these results, patients and investigators will be unblinded and we intend to halt the study. A communication will be sent to the investigators and results will be shared with health authorities and subsequently presented at an upcoming medical meeting.

“These results are disappointing as it was our hope that this combination might yield improved outcomes for people living with metastatic non-squamous lung cancer,” said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. “We are thankful to all of the patients and healthcare professionals involved in the study, and we will leverage the learnings to inform our scientific understanding of the anti-TIGIT pathway and new avenues in cancer research.”

Ongoing phase III studies are investigating treatment settings and indications distinct from SKYSCRAPER-06. Based on today’s results, we will evaluate any relevant changes needed to the ongoing tiragolumab programme.

About SKYSCRAPER-06 study

SKYSCRAPER-06 is a global phase II/III, randomised, placebo-controlled and double-blinded study evaluating tiragolumab plus Tecentriq® (atezolizumab) and chemotherapy as an initial (first-line) treatment versus pembrolizumab and chemotherapy in 542 people with non-squamous non- small cell lung cancer. Primary endpoints are overall survival (OS) and progression-free survival (PFS).

About tiragolumab

Tiragolumab is an investigational 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. Based on preclinical research, tiragolumab is thought to work as an immune amplifier with other cancer immunotherapies such as Tecentriq® (atezolizumab). 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 cancer immunotherapy approved for some of the most aggressive and difficult-to-treat forms of cancer. Tecentriq was the first cancer immunotherapy approved for the treatment of a certain type of early-stage (adjuvant) non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC) and hepatocellular carcinoma (HCC). Tecentriq is also approved in countries around the world, either alone or in combination with targeted therapies and/or chemotherapies, for various forms of metastatic NSCLC, certain types of metastatic urothelial cancer (mUC), PD-L1-positive metastatic triple-negative breast cancer (TNBC), BRAF V600 mutation-positive advanced melanoma and alveolar soft part sarcoma (ASPS).

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 therapies and various chemotherapies across a broad range of cancers.

In addition to intravenous infusion, Tecentriq has been approved as a subcutaneous formulation in over 40 countries. The approved indications for Tecentriq SC mirror those of Tecentriq IV.

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 endeavour 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 fifteenth 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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