Media & Investor Release

Ad hoc announcement pursuant to Art. 53 LR

Roche reports interim results for phase III SKYSCRAPER-01 study in PD-L1-high metastatic non-small cell lung cancer

- **The SKYSCRAPER-01 study evaluating tiragolumab plus Tecentriq did not meet its co-primary endpoint of progression-free survival**
- **The other co-primary endpoint of overall survival was immature and the study will continue until the next planned analysis**
- **The tiragolumab development programme continues as planned in non-small cell lung cancer and other cancer types**

Basel, 11 May 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced results from its phase III SKYSCRAPER-01 study, evaluating the investigational anti-TIGIT immunotherapy tiragolumab plus Tecentriq® (atezolizumab) versus Tecentriq alone as an initial (first-line) treatment for people with PD-L1-high locally advanced or metastatic non-small cell lung cancer (NSCLC). The study did not meet its co-primary endpoint of progression-free survival. At this first analysis, the other co-primary endpoint of overall survival (OS) was immature, and the study will continue until the next planned analysis. A numerical improvement was observed in both co-primary endpoints. Data suggest that tiragolumab plus Tecentriq was well-tolerated and no new safety signals were identified when adding tiragolumab. Further analyses of these results are ongoing and data will be presented at an upcoming medical meeting.

“While these results are not what we hoped for in our first analysis, we look forward to seeing mature overall survival for this study to determine next steps,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “We continue to believe that TIGIT may have a role in cancer treatment and we will share additional results from our tiragolumab programme as they emerge.”

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.

About the SKYSCRAPER-01 study

SKYSCRAPER-01 is a global phase III, randomised double-blinded study evaluating tiragolumab plus Tecentriq® (atezolizumab) versus Tecentriq alone in 534 patients with first-line PD-L1-high locally advanced, unresectable or metastatic non-small cell lung cancer. Patients were randomized 1:1 to receive either tiragolumab plus Tecentriq or placebo plus

Tecentriq, until disease progression, loss of clinical benefit or unacceptable toxicity. Co-primary endpoints are overall survival and progression-free survival.

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.[1] Based on preclinical research, tiragolumab is thought to work as an immune amplifier with other cancer immunotherapies such as Tecentriq® (atezolizumab).[2] 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.[1]

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. Tecentriq is also approved in the US, EU and 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, PD-L1-positive metastatic triple-negative breast cancer and BRAF V600 mutation-positive advanced melanoma.

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, the formulation of Tecentriq is also being investigated as subcutaneous injection to hopefully provide a faster and more convenient option for cancer patients.

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.

References

[1] Cho BC, Rodriguez-Abreu D, et al. Updated analysis and patient-reported outcomes from CITYSCAPE: a randomised, double-blind, Phase II study of the anti-TIGIT antibody tiragolumab + atezolizumab vs placebo + atezolizumab as first-line treatment for PD-L1+ NSCLC. Presented at the European Society for Medical Oncology (ESMO) Immuno-Oncology Congress 2021; 2021 December 8-11. Abstract #LBA2.
[2] Johnston RJ, Comps-Agrar L. Cancer Cell. 2014;26:923-937.

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 61 687 41 47

Sileia Urech
Phone: +41 79 935 81 48

Barbara von Schnurbein, PhD
Phone: +41 61 687 89 67

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mählitz
Phone: +41 79 327 54 74

Nathalie Meetz
Phone: +41 61 687 43 05

Roche Investor Relations

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com