

**Ad hoc announcement pursuant to Art. 53 LR**

## **Roche provides update on Phase III Skyscraper-01 study in PD-L1-high metastatic non-small cell lung cancer**

Basel, 23 August 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has been made aware of an inadvertent disclosure of the second interim analysis of the 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).

SKYSCRAPER-01 is ongoing and the study remains blinded to patients and investigators. We are continuing the study until the final analysis for overall survival. All other studies in the tiragolumab programme will continue as planned.

The interim results for the primary endpoint of overall survival were not mature at the time of the second interim analysis, with median overall survival estimates of 22.9 months [95% CI: 17.5, NE] in the tiragolumab plus Tecentriq arm, and 16.7 months [95% CI: 14.6, 20.2] in the Tecentriq monotherapy arm, yielding a hazard ratio (HR) of 0.81 [95% CI: 0.63, 1.03]. This second interim analysis took place in February 2023 and was based on a data cut-off in November 2022, with a median follow-up of 15.5 months. The data showed that tiragolumab plus Tecentriq was well-tolerated and no new safety signals were identified when adding tiragolumab to Tecentriq.

### **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 randomised 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 (OS) and progression-free survival (PFS) in the primary analysis set.

### **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. 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 monoclonal antibody designed to bind with a protein called PD-L1. Tecentriq is designed to bind to PD-L1 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 re-activation of T cells. Tecentriq may also affect normal cells.

## 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 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.

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## Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: [media.relations@roche.com](mailto:media.relations@roche.com)

### Hans Trees, PhD

Phone: +41 79 407 72 58

### Nathalie Altermatt

Phone: +41 79 771 05 25

### Karsten Kleine

Phone: +41 79 461 86 83

### Nina Mähltitz

Phone: +41 79 327 54 74

**Kirti Pandey**

Phone: +49 172 6367262

**Sileia Urech**

Phone: +41 79 935 81 48

**Rebekka Schnell**

Phone: +41 79 205 27 03

**Roche Investor Relations****Dr. Bruno Eschli**

Phone: +41 61 68-75284

e-mail: [bruno.eschli@roche.com](mailto:bruno.eschli@roche.com)

**Dr. Sabine Borngräber**

Phone: +41 61 68-88027

e-mail: [sabine.borngraeber@roche.com](mailto:sabine.borngraeber@roche.com)

**Dr. Birgit Masjost**

Phone: +41 61 68-84814

e-mail: [birgit.masjost@roche.com](mailto:birgit.masjost@roche.com)

**Dr. Gerard Tobin**

Phone: +41 61 68-72942

e-mail: [gerard.tobin@roche.com](mailto:gerard.tobin@roche.com)

**Investor Relations North America****Loren Kalm**

Phone: +1 650 225 3217

e-mail: [kalm.loren@gene.com](mailto:kalm.loren@gene.com)