Media Release

Roche's subcutaneous formulation of Tecentriq demonstrates positive Phase III results

- **IMscin001 study showed non-inferior levels of cancer immunotherapy Tecentriq in the blood, when injected subcutaneously, compared to intravenous infusion, in people with advanced non-small cell lung cancer**
- **Administered under the skin, the subcutaneous formulation reduces time spent receiving treatment to just minutes, compared with up to an hour for IV infusion**
- **Data will be submitted to health authorities globally, including the US Food and Drug Administration and European Medicines Agency**

Basel, 2 August 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMscin001 study evaluating a subcutaneous formulation of Tecentriq® (atezolizumab) met its co-primary endpoints. The study showed non-inferior levels of Tecentriq in the blood (pharmacokinetics), when injected subcutaneously, compared with intravenous (IV) infusion, in cancer immunotherapy-naïve patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) for whom prior platinum therapy has failed. The safety profile of the subcutaneous formulation was consistent with that of IV Tecentriq.

Administering Tecentriq subcutaneously (injecting the medicine under the skin) reduces the treatment time to 3-8 minutes per injection, compared with 30-60 minutes for standard IV infusion.[1]

"By reducing the administration time, this new Tecentriq formulation could help save time for patients and healthcare systems," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We are excited by the potential of bringing a subcutaneous cancer immunotherapy to patients globally, delivering on our commitment to improve the treatment experience for patients."

Multiple oncology studies suggest that the majority of cancer patients generally prefer to receive treatment subcutaneously due to reduced pain and discomfort, ease of administration and shorter duration of treatment, compared to IV infusion.[2-6]

Roche will share detailed findings of the IMscin001 study at an upcoming medical meeting and submit them for regulatory approval to health authorities globally, including the US Food and Drug Administration (FDA) and European Medicines Agency (EMA).

About the IMscin001 study

IMscin001 is a Phase Ib/III, global, multicentre, randomised study evaluating the pharmacokinetics, safety and efficacy of the subcutaneous formulation of Tecentriq, compared with IV Tecentriq, in patients with previously treated locally advanced or metastatic NSCLC for whom prior platinum therapy has failed. The study enrolled 371

patients. The co-primary endpoints of the study are minimum levels of Tecentriq in the blood during a given dosing interval on the basis of established pharmacokinetic measurements; observed serum C_{trough} and model-predicted area under the curve (AUC). Secondary endpoints include safety, immunogenicity, patient-reported outcomes and efficacy.

About the subcutaneous formulation of Tecentriq

The investigational subcutaneous formulation combines Tecentriq with Halozyme Therapeutics' Enhanze® drug delivery technology.

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 Enhanze drug delivery technology is based on a proprietary recombinant human hyaluronidase PH20 (rHuPH20), an enzyme that locally and temporarily degrades hyaluronan – a glycosaminoglycan or chain of natural sugars in the body – in the subcutaneous space. This increases the permeability of the tissue under the skin, allowing space for Tecentriq to enter, and enables the subcutaneous formulation to be rapidly dispersed and absorbed into the bloodstream.

IV Tecentriq is approved for some of the most aggressive and difficult-to-treat forms of cancer. IV Tecentriq was the first cancer immunotherapy approved for the treatment of a certain type of early-stage NSCLC, small cell lung cancer (SCLC) and hepatocellular carcinoma (HCC). IV 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, PD-L1-positive metastatic triple-negative breast cancer and 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 an 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 recognizing 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.

For more information, please visit www.roche.com.

References

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

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

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mählitz
Phone: +41 79 327 54 74

Nathalie Altermatt
Phone: +41 79 771 05 25

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Sileia Urech
Phone: +41 79 935 81 48