Media & Investor Release

Roche's Tecentriq becomes the first subcutaneous anti-PD-(L)1 cancer immunotherapy available to patients in Great Britain, reducing treatment time to just minutes

- **Tecentriq subcutaneous (SC) is now approved in Great Britain for all indications of intravenous Tecentriq, including certain types of lung, bladder, breast and liver cancer, offering a faster, more convenient option to receive treatment**
- **Administered under the skin within approx. seven minutes, Tecentriq SC saves time for patients and helps conserve resources in healthcare systems[1]**
- **Evaluations by the FDA, EMA and other health authorities globally are ongoing**

Basel, 29 August 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that Tecentriq® SC (atezolizumab) has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain. It will be provided by the National Health Service (NHS) England. Injecting Tecentriq subcutaneously (under the skin) takes approximately seven minutes, compared with 30-60 minutes for intravenous (IV) infusion. Tecentriq SC will be available to patients in Great Britain for all indications in which the IV formulation of Tecentriq has been previously approved, including certain types of lung, bladder, breast and liver cancer.[2]

Tecentriq SC is Roche's fourth subcutaneous cancer therapy.[3-5] Multiple oncology studies suggest that the majority of cancer patients generally prefer SC over IV administration due to reduced discomfort, ease of administration and shorter duration of treatment.[6-10]

"Cancer immunotherapy has transformed the way we treat cancer. Giving Tecentriq subcutaneously now offers patients a faster and more flexible treatment option and can free up resources for healthcare systems, while maintaining its established safety profile," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We are working with health authorities globally to bring this option to many more patients around the world."

The MHRA regulatory approval is the first for Tecentriq SC worldwide. It is based on pivotal data from the Phase IB/III IMscin001 study, which showed comparable levels of Tecentriq in the blood, when administered subcutaneously, and a safety and efficacy profile consistent with the IV formulation.[11] While the IMscin001 trial was conducted within the hospital setting, Tecentriq SC may be suitable for out of hospital administration by a healthcare professional.

For Northern Ireland, the Tecentriq SC marketing authorisation application is currently under assessment by the European Medicines Agency (EMA). Evaluations by the US Food and Drug Administration (FDA) and other health authorities globally are also ongoing.

About the IMscin001 study

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

In August 2022, part 2 of the study met its primary endpoints, demonstrating comparable 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. Efficacy, as measured by the overall response rate and progression-free survival, was similar between the SC and IV treatment arms and consistent with the known profile of Tecentriq IV. The safety profile of Tecentriq SC was also consistent with that of Tecentriq IV.[11]

About Tecentriq SC (subcutaneous)

Tecentriq SC 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, enabling it to be rapidly dispersed and absorbed into the bloodstream.

Tecentriq is 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).

About Roche in cancer immunotherapy

To learn more about Roche's scientific-led approach to cancer immunotherapy, please follow this link: https://www.roche.com/solutions/focus-areas/oncology/cancer-immunotherapy

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.

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

References

[1] Anderson, K C, et al. Humanistic and economic impact of subcutaneous versus intravenous administration of oncology biologics. Future Oncol. 2019;15(28):3267-3281.
[2] UK Electronic Medicines Compendium (EMC). Tecentriq: package leaflet. Last updated 5 July 2022. https://www.medicines.org.uk/emc/files/pil.8442.pdf Accessed April 2023.
[3]. UK EMC. Phesgo SC: package leaflet. Last updated 16 March 2022. https://www.medicines.org.uk/emc/files/pil.11989.pdf Accessed April 2023.
[4] UK EMC. Herceptin SC: package leaflet. Last updated 28 September 2021. https://www.medicines.org.uk/emc/files/pil.1227.pdf Accessed April 2023.
[5] UK EMC. MabThera: package leaflet. Last updated 24 January 2022. https://www.medicines.org.uk/emc/files/pil.5333.pdf Accessed April 2023.
[6] De Cock E, et al. A time and motion study of subcutaneous versus intravenous trastuzumab in patients with HER2-positive early breast cancer. Cancer Med. 2016;5(3):389-97.

[7] O'Shaugnessy, J. Patient (pt) preference for the pertuzumab-trastuzumab fixed-dose combination for subcutaneous use (PH FDC SC) in HER2-positive early breast cancer (EBC): Primary analysis of the open-label, randomised crossover PHranceSCa study. Presented at ESMO; 19-21 Sept 2020. Abstract #165MO.
[8] Pivot X, et al. Efficacy and safety of subcutaneous trastuzumab and intravenous trastuzumab as part of adjuvant therapy for HER2-positive early breast cancer: final analysis of the randomised, two-cohort PrefHer study. Eur J Cancer. 2017;86:82-90
[9] Rummel M, et al. Preference for subcutaneous or intravenous administration of rituximab among patients with untreated CD20+ diffuse large B-cell lymphoma or follicular lymphoma: results from a prospective, randomized, open-label, crossover study (PrefMab). Ann Oncol. 2017;28(4):836-842.
[10] Denys H, et al. Safety and tolerability of subcutaneous trastuzumab at home administration, results of the phase IIIb open-label BELIS study in HER2-positive early breast cancer. Breast Cancer Res Treat. 2020;181(1):97-105.
[11] Burotto M, Zvirbule Z, Mochalova A, et al. IMscin001 (Part 2: Randomized Phase III): Pharmacokinetics (PK), efficacy and safety of atezolizumab subcutaneous (SC) vs intravenous (IV) in previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC). Presented at ESMO IO; 7-9 Dec 2022. Abstract #61MO.

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: 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 Mählitz
Phone: +41 79 327 54 74

Kirti Pandey
Phone: +49 172 6367262

Rebekka Schnell
Phone: +41 79 205 27 03

Sileia Urech
Phone: +41 79 935 81 48

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