Media & Investor Release

Roche's subcutaneous injection of Tecentriq recommended by the EU's CHMP for multiple cancer types

- **If approved, Tecentriq subcutaneous (SC) would be the first injectable PD-(L)1 cancer immunotherapy in the EU, cutting treatment time by approx. 80%[1]**
- **The CHMP recommended Tecentriq SC for all indications of intravenous (IV) Tecentriq, including certain types of lung, liver, bladder and breast cancer[2]**
- **A majority of healthcare professionals surveyed in the IMscin001 study found that the SC formulation is easy to administer and could save time compared with IV[1]**

Basel, 14 November 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of subcutaneous (SC, or under the skin) Tecentriq® (atezolizumab). Tecentriq SC can be injected in approximately seven minutes, with most injections taking between four and eight minutes compared with 30-60 minutes for intravenous (IV) infusion, which can free up time for patients, healthcare teams and caregivers.[1] The CHMP recommended Tecentriq SC for all indications in which Tecentriq IV has been previously approved, including certain types of lung, liver, bladder and breast cancer.[2] A final decision on its approval is expected from the European Commission in the near future.

"Tecentriq has helped to treat more than 430,000 people diagnosed with some of the most aggressive forms of cancer," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Subcutaneous administration offers a faster and more convenient alternative to IV infusion. The CHMP's recommendation brings us a step closer to offering the first subcutaneous PD-L1 cancer immunotherapy treatment to patients in the EU."

The CHMP's positive opinion 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.[3] Roche recently presented mature overall survival (OS) data with a median follow-up of 9.5 months at the European Society for Medical Oncology (ESMO) Congress 2023. The updated analysis confirmed the earlier results and showed that OS and other efficacy endpoints were consistent between the SC and IV treatment arms.[1] A majority of healthcare professionals who were surveyed as part of the study agreed that the SC formulation is easy to administer (90%) and that it could save time for healthcare teams compared with the IV formulation (75%).[1]

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Tecentriq SC, which recently received its first marketing authorisation in Great Britain, was developed to provide patients with an alternative to the IV administration of Tecentriq and the potential for treatment outside of the hospital setting. It is Roche's fourth subcutaneous cancer therapy.[4-6] 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.[7-11]

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 non-small cell lung cancer (NSCLC) for whom prior platinum therapy has failed. The study enrolled 371 patients.

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 progression-free survival (PFS), objective response rates (ORR) and OS, 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.

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) 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] Burotto M, Zvirbule Z, Alvarez R, et al. IMscin001 Part 2 updated results: Efficacy, safety, immunogenicity, healthcare provider perspectives and patient-reported outcomes from the randomised Phase III study of atezolizumab subcutaneous vs intravenous in patients with locally advanced or metastatic non-small cell lung cancer. Presented at ESMO; 23 October 2023. Poster #1447P.
[2] European Medicines Agency. Tecentriq, INN-atezolizumab. SmPC. [Internet; last updated 25 July 2023; cited October 2023] Available from: https://www.ema.europa.eu/en/documents/product-information/tecentriq-epar-product-information_en.pdf.
[3] Burotto M, Zvirbule Z, Mochalova A, et al. IMscin001 Part 2: a randomised phase III, open-label, multicentre study examining the pharmacokinetics, efficacy, immunogenicity, and safety of atezolizumab subcutaneous versus intravenous administration in previously treated locally advanced or metastatic non-small-cell lung cancer and pharmacokinetics comparison with other approved indications. *Ann Oncol.* 2023;34(8):693-702.

[4] Phesgo, INN-pertuzumab/trastuzumab. SmPC. [Internet; last updated 02 March 2023; cited October 2023] Available from: https://www.ema.europa.eu/en/documents/product-information/phesgo-epar-product-information_en.pdf.
[5] European Medicines Agency. Herceptin, INN-trastuzumab. SmPC. [Internet; last updated 17 March 2023; cited October 2023] Available from: https://www.ema.europa.eu/en/documents/product-information/herceptin-epar-product-information_en.pdf.
[6] European Medicines Agency. MabThera, INN-rituximab. SmPC. [Internet; last updated 22 March 2023; cited October 2023] Available from: https://www.ema.europa.eu/en/documents/product-information/mabthera-epar-product-information_en.pdf.
[7] 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.
[8] 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.
[9] 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.
[10] 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.
[11] 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.

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