Media & Investor Release

European Commission approves Roche's Tecentriq SC, the EU's first PD-(L)1 cancer immunotherapy subcutaneous injection for multiple cancer types

- **Subcutaneous (SC) injection offers the potential for a faster, more convenient alternative to intravenous (IV) infusion and is preferred by cancer patients, nurses and physicians[1-5]**
- **Tecentriq SC reduces treatment time by approximately 80%, compared with standard IV infusion[6]**
- **Roche is working closely with national health systems in Europe to ensure patients can access Tecentriq SC as quickly as possible**

Basel, 16 January 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission has granted marketing authorisation for Tecentriq® SC (atezolizumab), the European Union (EU)'s first PD-(L)1 cancer immunotherapy for subcutaneous (under the skin) injection. Last year, more than 38,000 people in the EU received Tecentriq to treat different types of lung, liver, bladder and breast cancer.[7] Until now, Tecentriq has been given directly into patients' veins by IV infusion which takes approximately 30-60 minutes.[6] The new subcutaneous injection will cut treatment time to approximately seven minutes, with most injections taking between four and eight minutes.[6] The marketing authorisation applies to all approved indications of Tecentriq IV.[7]

"We are pleased to introduce the first subcutaneous PD-L1 cancer immunotherapy in Europe," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Giving Tecentriq subcutaneously provides more flexibility to patients, while also helping to free up resources in constrained healthcare systems."

"Ensuring the best possible quality of life is crucial for people living with cancer," said Dr. Enriqueta Felip, Head of the Thoracic Cancer Unit of Vall d'Hebron Hospital, Spain. "The availability of a subcutaneous cancer immunotherapy option that can minimise the time receiving treatment and even allow for treatment outside of a hospital will undoubtedly make a significant difference to patients and their loved ones."

The approval 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.[6,8] 90% of healthcare professionals who were surveyed as part of the study agreed that the SC formulation is easy to administer and 75% said it could save time for healthcare teams compared with the IV formulation.[6]

In addition to offering shorter treatment time, Tecentriq SC may be administered by a healthcare professional outside of the hospital, in a community care setting or at a patient's home, depending on national regulations and health systems. Roche is in discussion with several providers in Europe to include Tecentriq SC in cancer homecare initiatives where possible.

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.

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, progression-free survival, overall survival and duration of response, 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.[6,8]

About Tecentriq SC (subcutaneous)

Tecentriq® (atezolizumab) in Tecentriq SC is the same monoclonal antibody as in Tecentriq IV. It has been 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 across a broad range of cancers.

Tecentriq SC combines Tecentriq with Halozyme Therapeutics' Enhanze® drug delivery technology. 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 SC was first approved in Great Britain in August 2023. The approved indications for Tecentriq SC mirror those of Tecentriq IV.

The standard IV formulation of Tecentriq is approved for some of the most aggressive and difficult-to-treat forms of cancer. Tecentriq IV 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 IV 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 fifteenth 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] 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.
[2] 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.
[3] 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.
[4] 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.
[5] 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.
[6] 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.
[7] European Medicines Agency. Tecentriq, INN-atezolizumab. SmPC. [Internet; last updated 25 July 2023; cited December 2023] Available from: https://www.ema.europa.eu/en/documents/product-information/tecentriq-epar-product-information_en.pdf.
[8] 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.

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