Media & Investor Release

FDA approves Roche's Tecentriq Hybreza, the first and only subcutaneous anti-PD-(L)1 cancer immunotherapy

- **Tecentriq Hybreza provides patients and physicians with greater flexibility of treatment options while showing safety and efficacy consistent with intravenous (IV) Tecentriq[1,2]**
- **New subcutaneous (SC) option reduces treatment time to approximately seven minutes, compared with 30-60 minutes for IV infusion[2]**

Basel, 13 September 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has approved Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs), the first and only PD-(L)1 inhibitor for subcutaneous (SC), under the skin injection for patients in the United States. Tecentriq Hybreza can be injected subcutaneously over approximately seven minutes, compared with 30-60 minutes for standard intravenous (IV) infusion of Tecentriq (atezolizumab).[2] It will be available for all IV indications of Tecentriq approved for adults in the U.S., including certain types of lung, liver, skin and soft tissue cancer.[3]

"By enabling subcutaneous administration for a cancer immunotherapy, Tecentriq Hybreza now offers patients with multiple cancer types and their physicians greater flexibility and choice of treatment administration," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We are pleased to introduce this new subcutaneous formulation that builds on the established safety and efficacy profile of intravenous Tecentriq and can treat patients faster and in more accessible settings."

"This approval represents a significant option to improve the patient experience," said Ann Fish-Steagall, RN, senior vice president of Patient Services at the LUNGevity Foundation. "When patients have options, they feel empowered to be vital participants in their own care and choose their preferred treatment option."

The FDA 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.[1,2] The Phase II IMscin002 study showed that 71% of patients preferred Tecentriq Hybreza over intravenous atezolizumab, and the most common reasons were less time in the clinic, increased comfort during treatment and reduced emotional distress.[4] 4 out of 5 patients (79%) chose Tecentriq Hybreza to continue their treatment, after experiencing both formulations.[4]

Developing new formulations of our medicines is part of our commitment to improve the patient experience and support people living with different illnesses at every step of their treatment journey. With Tecentriq Hybreza and Roche's 13 other subcutaneous therapies – available across various diseases – we offer additional administration options to meet the diverse preferences of patients.

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

The subcutaneous formulation of Tecentriq received its first worldwide approval in Great Britain in August 2023 and is now approved in 50 countries (outside the U.S. marketed as Tecentriq SC).[5] Regulatory reviews in other countries and regions are ongoing.

About the IMscin001 study

IMscin001 is a Phase IB/III, global, multicentre, randomised study evaluating the pharmacokinetics, safety and efficacy of Tecentriq Hybreza, 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 objective 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 Hybreza was also consistent with that of Tecentriq IV.[1,2]

About the IMscin002 study

IMscin002 is a Phase II, global crossover study evaluating patient preference between the SC and IV formulations of Tecentriq. The study enrolled 179 patients, including people with PD-L1- positive resected Stage II-IIIB NSCLC who have completed adjuvant platinum-based chemo- therapy without evidence of disease recurrence, and untreated patients with PD-L1-high Stage IV NSCLC. The study met its primary endpoint, showing that 71% of participants preferred the SC formulation (21% preferred IV and 8% stated no preference); 79% opted for Tecentriq Hybreza to complete their treatment, after experiencing both formulations of Tecentriq. The study confirmed that switching between Tecentriq Hybreza and Tecentriq IV was well tolerated, with no new safety signals.[4]

About Tecentriq Hybreza

Tecentriq Hybreza combines Tecentriq with Halozyme Therapeutics' Enhanze® drug delivery technology.

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.

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.

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
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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). In addition to intravenous infusion, Tecentriq has been approved as a subcutaneous formulation in 50 countries (outside the U.S. marketed as Tecentriq SC). The approved indications for Tecentriq Hybreza and Tecentriq SC mirror those of Tecentriq IV.

About Roche in cancer immunotherapy

To learn more about Roche's scientific-led approach to cancer immunotherapy, please follow this link.

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

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F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

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[2] Burotto M, et al. IMscin001 Part 2 updated results: Efficacy, safety, immunogenicity and patient-reported outcomes (PROs) from the randomised Phase III study comparing atezolizumab (atezo) subcutaneous (SC) vs intravenous (IV) in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). Presented at ESMO 2023 Congress. Poster #1447P, on display 23 October 2023.
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F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

Roche Global 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

Simon Goldsborough
Phone: +44 797 32 72 915

Nina Mählitz
Phone: +41 79 327 54 74

Yvette Petillon
Phone: +41 79 961 92 50

Sileia Urech
Phone: +41 79 935 81 48

Lorena Corfas
Phone: +34 620 29 25 51

Karsten Kleine
Phone: +41 79 461 86 83

Kirti Pandey
Phone: +49 172 6367262

Dr. 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

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com