Media & Investor Release

FDA approves Roche's Tecentriq plus lurbinectedin as first-line maintenance therapy for extensive-stage small cell lung cancer

- **Combination reduced the risk of disease progression or death by 46% and risk of death by 27% in pivotal phase III IMforte study[1]**
- **First and only combination therapy for the first-line maintenance treatment of ES-SCLC, which is critical to help address the high rate of relapse in ES-SCLC[2]**
- **Regimen recommended in National Comprehensive Cancer Network® Guidelines for SCLC*[3]**

Basel, 3 October 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has approved Tecentriq® (atezolizumab) and Tecentriq Hybreza® (atezolizumab and hyaluronidase-tqjs) in combination with lurbinectedin (Zepzelca®) for the maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) whose disease has not progressed after first-line induction therapy with Tecentriq or Tecentriq Hybreza, carboplatin and etoposide (CE).[4] This approval marks the first and only combination therapy for the first-line maintenance treatment of ES-SCLC, a highly aggressive disease for which treatment options have been limited. The U.S. National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology (NCCN Guidelines®)* have been updated to include the regimen as a category 2A and preferred option for maintenance treatment of people with ES-SCLC, following induction therapy with Tecentriq and CE.[3]

"For people with extensive-stage small cell lung cancer and their families, the period after induction therapy is often filled with uncertainty, given the high risk of relapse," said Roy Herbst, M.D., Ph.D., deputy director and chief of medical oncology and haematology at Yale Cancer Center and Smilow Cancer Hospital. "The Tecentriq and Zepzelca combination provides a new option and a proactive approach in this setting shown to improve progression-free and overall survival in patients who haven't progressed after standard induction treatment with Tecentriq and chemotherapy. The approval may lead to a meaningful shift in how we manage this challenging disease and gives us a new tool to help to delay disease progression and extend survival."

"The Tecentriq and lurbinectedin combination reduced the risk of disease progression or death by nearly half," said Levi Garraway, Roche's Chief Medical Officer and Head of Global Product Development. "We are proud to deliver this advancement for the small cell lung cancer community in partnership with Jazz Pharmaceuticals, as it reflects our abiding commitment to improving outcomes in the hardest-to-treat cancers."

The FDA approval is based on results from the phase III IMforte study, which showed that the Tecentriq and lurbinectedin combination reduced the risk of disease progression or death by

46% and the risk of death by 27%, compared to Tecentriq maintenance therapy alone. Following 3.2 months of induction therapy, the median overall survival (OS) for the Tecentriq plus lurbinectedin regimen was 13.2 months versus 10.6 months for Tecentriq alone (stratified hazard ratio [HR]=0.73; 95% CI: 0.57–0.95; p=0.0174). Median progression-free survival (PFS) by independent assessment was 5.4 months versus 2.1 months, respectively (stratified HR=0.54; 95% CI: 0.43–0.67; p<0.0001). Safety was generally consistent with the known safety profiles of Tecentriq and lurbinectedin.[1]

Today's approval builds on Tecentriq's established role in ES-SCLC. In 2019, the FDA approved Tecentriq in combination with chemotherapy for the first-line treatment of adults with ES-SCLC, based on the IMpower133 study, which at the time was the first new treatment option in two decades for this patient population.[5]

About the IMforte study

IMforte [NCT05091567] is a phase III, open-label, randomised trial evaluating the efficacy and safety of Tecentriq® (atezolizumab) plus lurbinectedin (Zepzelca®) versus Tecentriq alone as first-line maintenance therapy for adults (≥18 years) with extensive-stage small-cell lung cancer (ES-SCLC). Patients first received induction therapy with Tecentriq, carboplatin and etoposide for four 21-day cycles. Those without disease progression were then randomised 1:1 to receive maintenance therapy with either Tecentriq plus lurbinectedin or Tecentriq alone until disease progression or unacceptable toxicity. The study enrolled 660 patients in the induction phase and randomised 483 patients in the maintenance phase. The study's primary endpoints were independent review facility (IRF)-assessed progression-free survival (PFS) and overall survival (OS) from randomisation into the maintenance phase.[1]

The trial is sponsored by Roche and co-funded by Jazz Pharmaceuticals.

About Tecentriq® (atezolizumab)

Tecentriq is a monoclonal antibody designed to bind with a protein called 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 re-activation of T cells. Tecentriq may also affect normal cells.

Tecentriq has been approved for some of the most aggressive and difficult-to-treat forms of cancer and is the first PD-(L)1 cancer immunotherapy available in both subcutaneous and intravenous formulations. 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.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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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[3] National Comprehensive Cancer Network (NCCN). NCCN Guidelines® small cell lung cancer version 2.2026. [Internet; cited September 2025]. Available from: https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1462.
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