Media & Investor Release

Roche's Tecentriq combined with lurbinectedin shows significant survival benefit in extensive-stage small cell lung cancer

- **46% reduction in the risk of disease progression or death, and 27% reduction in the risk of death, in an aggressive cancer type with limited survival and few treatment options[1]**
- **First Phase III study in ES-SCLC first-line maintenance to demonstrate clinically meaningful improvements in both progression-free and overall survival[2,3]**
- **Data were presented in an oral session at the 2025 ASCO Annual Meeting and simultaneously published in *The Lancet*[1,4]**

Basel, 3 June 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today positive results from the Phase III IMforte study of Tecentriq® (atezolizumab) in combination with lurbinectedin (Zepzelca®) as a first-line maintenance treatment for people with extensive-stage small cell lung cancer (ES-SCLC), following induction therapy with carboplatin, etoposide and Tecentriq. The data showed that this combination reduced the risk of disease progression or death by 46% and the risk of death by 27%, compared to Tecentriq maintenance therapy alone. Safety was consistent with the known safety profiles of Tecentriq and lurbinectedin. These data were presented in an oral session at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in *The Lancet*.[1,4]

"Small cell lung cancer is an aggressive and devastating disease. At the time of diagnosis, the large majority of patients have already progressed to extensive-stage disease and only one out of five survive longer than two years", said Luis Paz-Ares, MD, PhD, Head of Medical Oncology at the Hospital Universitario 12 de Octubre in Madrid, Spain, and IMforte trial principal investigator. "The IMforte results are very encouraging showing a potentially practice-changing option that could improve survival for patients with a very high unmet need."

"In the IMforte study, the Tecentriq and lurbinectedin maintenance regimen significantly extended survival for people living with extensive-stage small cell lung cancer," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "This study builds on Tecentriq's well-established safety and efficacy profile as the first immunotherapy for this cancer type and may provide another approach to help physicians and patients better manage this aggressive disease."

Patients in the IMforte study first completed four cycles of Tecentriq combined with chemotherapy, over the course of approximately three months, before being randomised into maintenance treatment. From the point of randomisation, 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). No new safety signals were observed.[1]

About the IMforte study

IMforte [NCT05091567] is a Phase III, open-label, randomised trial evaluating the efficacy and safety of Tecentriq® (atezolizumab) plus lurbinectedin 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.[1,5]

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

About Tecentriq

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.

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 injection.

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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