TOLREMO therapeutics Completes Phase I Study of TT125-802 and Presents Final Clinical Data at World Conference on Lung Cancer 2026

- Final Phase 1 data provide clinical validation of CBP/p300 as a novel therapeutic target for overcoming transcriptional resistance in NSCLC
- TT125-802 demonstrates monotherapy anti-tumor activity across biologically distinct resistance settings. 42% of NSCLC patients experienced tumor shrinkage, including durable partial responses in primary resistance to EGFR inhibition, acquired resistance to KRAS G12C inhibition, and SOX2-amplified squamous NSCLC
- The final 45-patient dataset establishes 60 mg once daily as the recommended dose, confirms a differentiated safety profile without thrombocytopenia and supports advancement into resistance-targeted combination studies

Basel, September 15, 2026 – TOLREMO therapeutics AG (TOLREMO), a clinical-stage biotechnology company pioneering therapies targeting non-oncogene addiction in cancer, today announced the completion of its Phase I study of monotherapy TT125-802 (NCT06403436) and the presentation of final clinical data from the study at the 2026 World Conference on Lung Cancer (WCLC) in Seoul, South Korea. The data highlights TT125-802's confirmed clinical activity as monotherapy in drug-resistant NSCLC and supports CBP/p300 inhibition as a novel therapeutic strategy to address transcriptional drug resistance in solid tumors.

The completed study enrolled 45 patients with advanced solid tumors, including 24 patients with NSCLC. 10 of 24 patients (42%) experienced tumor shrinkage, including three confirmed partial responses observed in distinct resistance settings: primary resistance to first-line EGFR inhibition (osimertinib), acquired resistance to KRAS-G12C inhibition (elironrasib), and in SOX2-amplified squamous NSCLC following progression on chemo-immunotherapy.

“The completion of our Phase I marks an important milestone for TOLREMO and provides strong clinical evidence supporting our strategy of targeting non-oncogene addiction and transcriptional resistance mechanisms in cancer,” said Stefanie Flückiger-Mangual, Ph.D., Chief Executive Officer and Co-founder of TOLREMO therapeutics. “The final data show durable monotherapy anti-tumor activity across biologically distinct forms of drug resistance in NSCLC. This validates our core scientific platform and positions TT125-802 as a foundational therapy capable of extending the reach and durability of existing targeted regimens."

TT125-802 demonstrated a favorable and differentiated safety profile without thrombocytopenia across the 45-patient study population. 98% of treatment-related adverse events were Grade 1 or Grade 2, reversible and manageable. The most frequently reported treatment-related adverse events included dysgeusia and low grade hyperglycemia.

“The recommended dose of 60 mg once a day without food restriction delivers continuous target coverage and anti-tumor activity in drug-resistant NSCLC, while the favorable safety profile and absence of thrombocytopenia support the development of TT125-802 as a combination partner for targeted therapies,” said Alessandra Cesano, MD, Ph.D., CMO of TOLREMO therapeutics. “We are now positioned to evaluate whether simultaneously inhibiting oncogenic signaling and CBP/p300-dependent transcriptional escape can generate deeper and more durable therapeutic responses in our next study.”

The final Phase 1 monotherapy dataset was presented at WCLC in the poster “TT125-802, a Selective Clinical Bromodomain Inhibitor of CBP/p300, Targeting Transcriptional Resistance Mechanisms in NSCLC.” First author Martina Imbimbo, M.D., Medical Oncologist at the Oncology Institute of Southern Switzerland (IOSI) in Bellinzona, provides expert commentary on the findings and the emerging role of CBP/p300 inhibition in drug-resistant NSCLC in a video discussion available on the TOLREMO website.

About TOLREMO

TOLREMO therapeutics is pioneering a comprehensive new approach to tackle non-oncogene addiction in cancer by blocking transcriptional escape pathways that operate parallel to the primary oncogene signaling axis. Leveraging our proprietary phenotypic screening platform, we have uncovered a novel role for CBP/p300 as an epigenetic master regulator of transcriptional resistance. Our clinical compound, TT125-802, is an orally available small molecule inhibitor of the bromodomain of CBP/p300 with a differentiated safety profile and activity as a single agent in solid tumors. Targeting non-oncogene addiction represents a differentiated strategy to address a major challenge in cancer treatment, with significant therapeutic potential both as a monotherapy and in combination with targeted therapies in solid tumors and hematological malignancies.

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