TOLREMO therapeutics Completes First In Human Dose Escalation for TT125-802 and Presents Solid Tumor Monotherapy Results at ESMO 2025

- Monotherapy shows deep and durable responses in NSCLC and a best-in-class safety profile without thrombocytopenia

- Completion of monotherapy dose escalation part of the study will be followed by the start of combination studies in EGFRmut, KRAS-G12Cmut and squamous NSCLC

Basel, October 17, 2025 – TOLREMO therapeutics AG (TOLREMO) today announced encouraging clinical data from 34 patients with advanced solid tumors treated with TT125-802 in the dose escalation part of an ongoing first-in-human study (NCT06403436). The data will be presented on October 19 at the European Society of Medical Oncology (ESMO) Congress 2025 in Berlin, Germany, and highlights TT125-802's confirmed clinical activity and favorable safety profile.

TT125-802 is an orally available small-molecule inhibitor that selectively blocks the bromodomains of CBP/p300, transcriptional co-activators implicated in non-oncogene addiction - a key driver of cancer and drug resistance that functions in parallel to oncogenic pathways. This update expands on initial data presented at ASCO earlier this year, establishing TT125-802 as the first CBP/p300 bromodomain inhibitor to report clinical activity across a variety of solid tumors, including durable confirmed responses in non-small cell lung cancer (NSCLC).

In the now completed dose escalation part of the study, 34 heavily pre-treated solid tumor patients received TT125-802 across 5 dose escalation cohorts (15 mg QD – 60 mg BID) and 2 cohorts examining the role of food on exposures. No MTD was reached and TT125-802 was safe and well tolerated. The most common drug-related AEs were dysgeusia and hyperglycemia. No thrombocytopenia was observed. The recommended dose was selected at 60 mg once a day a on a continuous basis, without food restriction.

Suppression of CBP/p300 target pathways was confirmed in patient hair follicles by RNA-seq.

Anti-tumor activity was observed across all dose levels in this heavily pre-treated population. 4 patients stayed on study for over one year, including 3 patients with adenoid cystic carcinoma and one patient with a bulky dedifferentiated liposarcoma. 3 patients (EGFR exon 19 delta, KRAS-G12C, squamous NSCLC) achieved a deep confirmed partial response (PR). The EGFRmut and KRAS-G12Cmut patients had progressed on an EGFR inhibitor and KRAS-G12C inhibitor, respectively, in a prior line of therapy. Both had a rapid PR after 6 weeks of TT125-802 monotherapy and remained progression-free for almost 7 months. The squamous NSCLC patient had progressed on standard-of-care therapy and had a PR after 12 weeks of TT125-802. The patient was on study for 5.5 months until progression.

Dr. Omar Saavedra Santa Gadea at NEXT Oncology Hospital Quirónsalud in Barcelona, an investigator on the study said, "It is remarkable to see such rapid, deep and durable responses in NSCLC patients who had exhausted all prior treatments. TT125-802's mechanism targeting non-oncogene addiction offers a novel approach to improving clinical outcomes for patients in this high-need setting."

"These results validate our approach to target epigenetic mechanisms driving cancer and drug resistance and support the continued clinical development of TT125-802 in patients with solid tumors and hematological malignancies," said **Florian Vogl, CMO at TOLREMO.** "The absence of thrombocytopenia, a common toxicity with bromodomain inhibitors, sets TT125-802 apart. The wide therapeutic window opens up clinical opportunities for TT125-802 which have so far been unattainable for this class of drugs. "

"We will now initiate a combination study investigating the efficacy of TT125-802 in combination with an EGFR inhibitor and a KRAS-G12C inhibitor in the respective oncogene-driven NSCLC populations, and

with docetaxel in squamous NSCLC patients. We look forward to demonstrating the full therapeutic potential of TT125-802 for patients in need," said **Stefanie Flückiger-Mangual, Ph.D., CEO and co-founder of TOLREMO**.

Details of the poster presentations are:

Abstract Title: Clinical activity of TT125-802, a highly selective bromodomain inhibitor of CBP/p300, in advanced solid tumors: update on the ongoing phase I study

Authors: O. Saavedra, E. Garralda, V. Boni, J. Fuentes Antrás, I. Colombo, M. Imbimbo, G. Molina, I. Braña, K. Homicsko, F.D. Vogl, D. Gruber, S. Costanzo, A. Cesano, S. Flückiger-Mangual

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TOLREMO is assessing TT125-802 in a first-in-human, multicenter Phase 1 trial (NCT06403436) to evaluate the safety, tolerability, pharmacokinetics, and efficacy in patients with advanced solid tumors. The company recently received two U.S. FDA Fast Track designations for the treatment of patients with advanced or metastatic EGFR-mutant or KRAS-G12C-mutant NSCLC with disease progression on at least one prior line of therapy.

About TOLREMO

TOLREMO therapeutics is redefining cancer treatment by targeting non-oncogene addiction – a fundamental driver of cancer and drug resistance that functions in parallel to oncogenic pathways. We uncovered the epigenetic regulator CBP/p300's role as a key mediator in this process, in addition to being a validated target in liquid tumors. Our small molecule inhibitor of CBP/p300's bromodomain, TT125-802, is differentiated from other agents in the class by lack of significant hematologic toxicities, specifically thrombocytopenia, which allows for higher dosing required for anti-tumor activity. It is the first CBP/p300 bromodomain inhibitor to report single-agent activity in solid tumors. By selectively blocking CBP/p300's multi-modal functions, TT125-802 has transformative potential across solid tumors and hematologic malignancies, both as monotherapy and in combination with standard-of-care therapies. Enabled by TT125-802's broad applicability, TOLREMO strives to deliver an impactful and durable clinical benefit to cancer patients in need.

CONTACTS

TOLREMO therapeutics AG
Stefanie Flückiger-Mangual, PhD, CEO and Co-founder
stefanie.flueckiger@tolremo.com

Trophic Communications
Stephanie May, PhD, & Marie Weickert, PhD
+ 49 171 185 5682
tolremo@trophic.eu