Press Release

TOLREMO therapeutics Receives Two FDA Fast Track Designations for TT125-802 in Pretreated, Advanced or Metastatic NSCLC With Either an EGFR or a KRAS-G12C Mutation

- TT125-802 is a small molecule CBP/p300 bromodomain inhibitor that shows clinical activity as single agent in solid tumors, including advanced EGFR-mutated and KRAS-G12C-mutated non-small cell lung cancer (NSCLC)

- 1 in 5 cancer-related deaths in the US are due to lung cancer, with NSCLC representing 87% of all lung cancer cases; 30% of all NSCLC have an EGFR or KRAS-G12C mutation

Basel, August 28, 2025 – TOLREMO therapeutics AG (TOLREMO), today announced that their lead candidate, TT125-802, received two Fast Track designations from the U.S. Food and Drug Administration (FDA) for the treatment of non-small cell lung cancer (NSCLC). One Fast Track designation was granted for the treatment of patients with locally advanced or metastatic NSCLC with an epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutation, with disease progression on at least one line of prior therapy including an EGFR inhibitor. The second Fast Track designation was granted for the treatment of patients with locally advanced or metastatic kirstin rat sarcoma viral oncogene homolog (KRAS)-G12C mutated NSCLC, with disease progression on at least one line of prior therapy including a KRAS G12C inhibitor.

TT125-802 is an orally available small-molecule inhibitor of CBP/p300, a fundamental driver of cancer cell survival and treatment resistance that functions in parallel to primary oncogenic pathways. Encouraging initial efficacy and safety data from the first-in-human Phase 1 clinical trial, presented at ASCO 2025, demonstrated impressive clinical monotherapy activity in solid tumors without causing thrombocytopenia.

"NSCLC is a major cause of cancer-related death. While oncogene-targeting drugs such as EGFR and KRAS inhibitors improve overall survival, a significant number of patients eventually experience disease progression, representing a high unmet medical need," said **Stefanie Flückiger-Mangual, PhD, Chief Executive Officer at TOLREMO.** "TT125-802 has the potential to address this challenge by blocking transcriptional pathways that drive tumor growth and treatment evasion in parallel to the driving oncogene. This is supported by our clinical data to date, demonstrating deep and durable responses to TT125-802 as a single agent in patients with drug-resistant KRAS-G12C- or EGFR-mutant NSCLC. The Fast Track designations in these indications provide us with an accelerated path on our mission to deliver our differentiated treatment approach to patients who urgently need it."

"TT125-802's highly selective mechanism of action and favorable safety profile without thrombocytopenia differentiate it from other agents in the class," added **Alan Sandler, MD, Scientific Advisory Board member at TOLREMO.** "The two Fast Track designations highlight TT125-802's broad potential to provide a new approach for tackling drug resistance and tumor survival in solid tumors, including EGFR- and KRAS-G12C mutant NSCLC. We are looking forward to working closely with the FDA to advance the clinical evaluation of TT125-802 as an innovative backbone therapy."

FDA Fast Track status is designed to facilitate the development and expedite the review of new therapies that are intended to treat serious conditions with unmet medical need. Programs granted Fast Track designation have access to more frequent interactions with the FDA during clinical development and may be eligible for accelerated approval and/or priority review if certain criteria are met.

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 Fast Track designations will support the company's clinical development strategy to advance TT125-802 in combination with an oncogene-targeting drug in KRAS- and EGFR-mutated NSCLC.

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 certain hematologic toxicities, specifically thrombocytopenia, which allows for higher dosing required for anti-tumor activity. It is the first CBP/p300 bromodomain inhibitor to show clinical evidence for single-agent activity in solid tumors. By selectively blocking CBP/p300's multi-modal functions, TT125-802 has transformative potential across solid tumors, both alone and in combination with oncogene-targeting therapies, and in hematologic malignancies. Enabled by TT125-802's broad applicability, TOLREMO strives to deliver an impactful and durable clinical benefit to cancer patients in need.

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