Tango Therapeutics Announces First Patient Dosed in TNG260 Phase 1/2 Trial in Patients With STK11-Mutant Cancers

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BOSTON, July 24, 2023 (GLOBE NEWSWIRE) -- Tango Therapeutics, Inc. (NASDAQ: TNGX), a clinical-stage biotechnology company committed to discovering and delivering the next generation of precision cancer medicines, today announced that the first patient has been dosed in the phase 1/2 trial evaluating TNG260 in combination with pembrolizumab in patients with STK11-mutant cancers. TNG260 is a first-in-class inhibitor of the CoREST complex (Co-repressor of Repressor Element-1 Silencing Transcription).

“The TNG260 phase 1/2 clinical trial is the first trial to use genetic patient selection in combination with checkpoint inhibitor therapy to reverse the cancer-specific immune evasion caused by STK11 loss of function mutations. Resistance to immunotherapy is a major challenge faced by patients with STK11-mutant cancers, which TNG260 is specifically designed to overcome,” said Adam Crystal, M.D., Ph.D., President of Research and Development of Tango Therapeutics. “Our pipeline of precision oncology treatments based on synthetic lethality has advanced significantly this year, as we now have initiated three clinical trials.”

The phase 1/2 trial will evaluate the safety, pharmacokinetics (PK), pharmacodynamics and efficacy of TNG260, with a one cycle single agent run-in phase to evaluate the safety and PK of TNG260, in combination with pembrolizumab, in patients with locally advanced or metastatic solid tumors with an STK11 loss-of-function mutation. STK11 loss-of-function mutations occur in approximately 15% of non-small cell lung cancer, 15% of cervical, 10% of carcinoma of unknown primary, 5% of breast and 3% of pancreatic cancers. Based on preclinical xenograft studies and retrospective clinical analyses, the majority of STK11-mutant cancers are thought to have primary resistance to checkpoint inhibition.

The CoREST complex plays a central role in regulating immunomodulatory signaling in STK11-mutant cancers. In preclinical studies, TNG260 reverses the immune evasion effect of STK11 loss-of-function mutations, restoring sensitivity to an anti-PD-1 antibody, inducing complete remissions in the majority of animals and creating immune memory that prevents re-implantation and regrowth of the tumor.

In April 2023, the U.S. Food and Drug Administration granted Fast Track designation for TNG260 in combination with an anti-PD-1 antibody for the treatment of patients with previously treated advanced non-small cell lung cancer with STK11-mutations.

About Tango Therapeutics
Tango Therapeutics is a clinical-stage biotechnology company dedicated to discovering novel drug targets and delivering the next generation of precision medicine for the treatment of cancer. Using an approach that starts and ends with patients, Tango leverages the genetic principle of synthetic lethality to discover and develop therapies that take aim at critical targets in cancer. This includes expanding the universe of precision oncology targets into novel areas such as tumor suppressor gene loss and their contribution to the ability of cancer cells to evade immune cell killing. For more information, please visit www.tangotx.com.

Forward-Looking Statements

Certain statements in this press release may be considered forward-looking statements. Forward-looking statements generally relate to future events, Tango’s future operating performance and goals, the anticipated benefits of therapies and combination therapies (that include a Tango pipeline product), expectations, beliefs and development objectives for Tango’s product pipeline and clinical trials. In some cases, you can identify forward-looking statements by terminology such as “may”, “should”, “expect”, “intend”, “will”, “goal”, “estimate”, “anticipate”, “believe”, “predict”, “designed,” “potential” or “continue”, or the negatives of these terms or variations of them or similar terminology. For example, implicit or explicit statements concerning the following include or constitute forward-looking statements: TNG260 in combination with checkpoint inhibitor therapy may reverse the cancer-specific immune evasion caused by STK11 loss of function mutations; TNG260 is designed to overcome resistance to immunotherapy, a major challenge faced by patients with STK11-mutant cancers; ; the expected benefits of the Company's development candidates, including TNG260 in combination with a checkpoint inhibitor; and the expected timing of: (i) development candidate declaration for certain targets, (ii) initiating IND-enabling studies; (iii) filing INDs; (iv) clinical trial initiation and (v) disclosing initial, interim and final clinical trial results. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Tango and its management, are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: Tango has limited experience conducting clinical trials (and will rely on a third party to operate its clinical trials) and may not be able to commence the clinical trial (including opening clinical trial sites, dosing the first patient, and enrolling and dosing an adequate number of clinical trial participants) when expected and may not generate results (including final or initial safety, efficacy data and proof-of-mechanism and proof-of-concept) in the anticipated timeframe (or at all); the benefits of Tango pipeline products, development candidates and potential combination therapies that are seen in pre-clinical experiments may not be present in clinical trials or in use commercially or may not be safe and/or effective in humans; Tango has a limited operating history and has not generated any revenue to date from product sales, and may never become profitable; other companies may be able to identify and develop product candidates more quickly than the Company and commercially introduce the product prior to the Company; the Company’s proprietary discovery platform is novel and may not identify any synthetic lethal targets for future development; the Company may not be able to identify development candidates on the schedule it anticipates due to technical, financial or other reasons; the Company may not be able to file INDs for development candidates on time, or at all, due to technical or financial reasons or otherwise; the Company may utilize cash resources more quickly than anticipated; Tango will need to raise capital in the future and if we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue some of our development programs or future commercialization efforts (which may delay filing of INDs,

dosing patients, reporting clinical trial results and filing new drug applications); we may be unable to advance our preclinical development programs into and through the clinic for safety or efficacy reasons or commercialize our product candidates or we may experience significant delays in doing so as a result of factors beyond Tango's control; the Company may not be able to realize the benefits of Fast Track designation (and such designation may not advance any anticipated approval timelines); Tango's approach to the discovery and development of product candidates is novel and unproven, which makes it difficult to predict the time, cost of development, and likelihood of successfully developing any products; Tango may not identify or discover additional product candidates or may expend limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success; our products candidates may cause adverse or other undesirable side effects (or may not show requisite efficacy) that could, among other things, delay or prevent regulatory approval; our dependence on third parties for conducting clinical trials and producing drug product; our ability to obtain and maintain patent and other intellectual property protection for our technology and product candidates or the scope of intellectual property protection obtained is not sufficiently broad; and delays and other impacts on product development and clinical trials from the COVID-19 pandemic. Additional information concerning risks, uncertainties and assumptions can be found in Tango's filings with the SEC, including the risk factors referenced in Tango's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as supplemented and/or modified by its most recent Quarterly Report on Form 10-Q. You should not place undue reliance on forward-looking statements in this presentation, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Tango specifically disclaims any duty to update these forward-looking statements.

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