



Tango Therapeutics Announces FDA Clearance of Investigational New Drug Application for TNG260, a First-in-Class CoREST Inhibitor for the Treatment of STK11-Mutant Cancers

April 3, 2023

BOSTON, April 03, 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 U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for TNG260, a first-in-class inhibitor of the CoREST complex (Co-repressor of Repressor Element-1 Silencing Transcription), for the treatment of STK11-mutant cancers.

"FDA clearance of our IND application to initiate the TNG260 phase 1/2 trial is an important milestone in the development of this novel treatment for STK11-mutant cancers. STK11 mutations drive resistance to standard of care immunotherapy and are a major challenge in treating many cancers, including non-small cell lung cancer," said Barbara Weber, M.D., President and Chief Executive Officer of Tango Therapeutics. "We expect that TNG260 will be among the first oncology molecules to leverage the benefits of genetically-based patient selection (STK11-mutation) with checkpoint inhibitor therapy. We look forward to initiating the Phase 1/2 clinical trial of TNG260 in the second half of 2023."

STK11 loss-of-function mutations are present in approximately 15% of non-small cell lung cancer (NSCLC), 15% of cervical, 10% of carcinoma of unknown primary, 5% of breast and 3% of pancreatic cancers. The Phase 1/2 clinical trial will evaluate the safety, pharmacokinetics, pharmacodynamics and efficacy of TNG260 in combination with pembrolizumab in patients with locally advanced or metastatic cancer of any solid tumor with an STK11 loss-of-function mutation.

The CoREST complex has been shown to play a major role in regulating the expression of immunomodulatory proteins in STK11-mutant cancers. In syngeneic models with an STK11 mutation and an intact immune system, the combination of TNG260 with an anti-PD-1 antibody resulted in sustained complete tumor regressions and the induction of immune memory that prevented re-implantation of the same tumor xenograft.

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, statements concerning the following include or constitute forward-looking statements: the Company expects that TNG260 will be among the first oncology molecules to leverage the benefits of genetically-based patient selection (STK11-mutation) with checkpoint inhibitor therapy; Tango looks forward to initiating the Phase 1/2 clinical trial of TNG260 in second half of 2023; the Phase 1/2 TNG260 clinical trial to be conducted will evaluate safety, pharmacokinetics, pharmacodynamics and efficacy of TNG260 in combination with pembrolizumab in patients with locally advanced or metastatic cancer of any solid tumor with an STK11 loss-of-function mutation;; the expected benefits of the Company's development candidates and other product candidates; 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 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 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) in the anticipated timeframe (or at all); benefits of product candidates seen in preclinical analyses may not be evident when tested in clinical trials or when used in broader patient populations (if approved for commercial sale); 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; 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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