Tango Therapeutics Announces FDA Clearance of Investigational New Drug Application for TNG348, a Novel USP1 Inhibitor for the Treatment of BRCA1/2-mutant and Other HRD+ Cancers

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BOSTON, Sept. 06, 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 TNG348, a novel inhibitor of USP1 (ubiquitin-specific protease 1), for the treatment of BRCA1/2 mutant and other HRD+ (homologous recombination deficient) cancers.

"FDA clearance to start the TNG348 phase 1/2 clinical study is an important step in the development of a novel treatment with the potential to treat a substantial number of ovarian, prostate and breast cancers. We plan to initiate the TNG348 clinical trial in the first half of 2024," said Barbara Weber, M.D., President and Chief Executive Officer of Tango Therapeutics. "Preclinical data demonstrate that USP1 inhibition blocks DNA repair with a mechanism distinct from PARP inhibitors and that TNG348 is active in xenografts with both primary and acquired resistance to PARP inhibitors. Preclinical data further show that USP1 is synergistic with PARP inhibitors in xenograft models naïve to PARPi therapy. These data suggest that TNG348 may benefit patients who have progressed on a PARP inhibitor or be used in combination for patients currently being treated with single agent PARPi therapy."

The phase 1/2 clinical trial will evaluate the safety, pharmacokinetics, pharmacodynamics and efficacy of TNG348 as a single agent and in combination with olaparib, a PARP inhibitor, in patients with BRCA1/2-mutant and other HRD+ cancers. HRD+ cancers, including BRCA1/2 mutations, represent up to 50% of ovarian cancers, 25% of breast cancers, 10% of prostate cancers and 5% of pancreatic cancers.

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: FDA clearance of the TNG348 clinical study is an important step in the development of a novel treatment for certain cancers; TNG348 has the potential to treat a substantial number of ovarian, prostate and breast cancers; the Company plans to initiate the TNG348 clinical trial in the first half of 2024; TNG348 may benefit patients who have progressed on a PARP inhibitor or be used in combination for patients currently being treated with single agent PARPi therapy; the phase 1/2 clinical trial will evaluate the safety, pharmacokinetics, pharmacodynamics and efficacy of TNG348 as a single agent and in combination with olaparib in patients with BRCA1/2-mutant and other HRD+ cancers; 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 trial) 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, may not be able to continue dose escalation on anticipated timelines, 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 the Company is are unable to raise capital when needed or on attractive terms, Tango would be forced to delay, scale back or discontinue some 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; 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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