Tango Therapeutics Announces FDA Clearance of Investigational New Drug Application for TNG462; Provides Additional Business Updates

January 25, 2023

TNG908 granted Orphan Drug Designation in U.S. for the treatment of malignant glioma

BOSTON, Jan. 25, 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 an Investigational New Drug (IND) application for TNG462, a next-generation MTA-cooperative PRMT5 inhibitor for the treatment of patients with MTAP-deleted cancers. The Company also announced that TNG908 was granted Orphan Drug Designation (ODD) for the treatment of malignant glioma and provided additional business highlights.

“The IND clearance for TNG462 is a critical step toward addressing the significant unmet need of patients with MTAP-deleted solid tumors,” said Barbara Weber, M.D., President and Chief Executive Officer of Tango Therapeutics. “By advancing both TNG908 and TNG462 into the clinic, we not only increase our strategic optionality to develop and potentially commercialize a PRMT5 inhibitor, but also maximize the opportunity to help patients with MTAP-deleted cancers given the breadth of potential indications. We look forward to results from these trials to optimize our development plans for these programs.”

Recent Business Highlights

Pipeline Update

TNG462 IND cleared; first-in-human clinical trial initiation expected in mid-2023.

- The U.S. FDA has cleared the IND application for TNG462, a next-generation methylthioadenosine-cooperative (MTA) inhibitor of protein arginine methyl transferase 5 (PRMT5) for the treatment of cancers with methylthioadenosine phosphorylase (MTAP) deletion.
- The Company expects to initiate a Phase 1/2 clinical trial in mid-2023. The trial, which will require all patients to have an MTAP deletion, will evaluate cancers including non-small cell lung cancer, mesothelioma and cholangiocarcinoma. Unlike TNG908, glioblastoma will be excluded from the clinical trial as TNG462 does not cross the blood-brain barrier in preclinical non-human primate models.
- TNG462 has the same mechanism of action as TNG908 with enhanced potency and selectivity in MTAP-deleted xenograft models. In preclinical studies, TNG462 is 45X selective for MTAP-deletions (3-fold greater than TNG908) and 20 times more potent than TNG908, which may provide a wider therapeutic index and stronger target inhibition than TNG908.

TNG908 granted ODD for the treatment of malignant glioma.

- The FDA has granted Orphan Drug Designation (ODD) to TNG908 for the treatment of malignant glioma. ODD is granted to investigational therapies addressing rare medical diseases or conditions that affect fewer than 200,000 people in the United States. This designation provides for a seven-year marketing exclusivity period upon regulatory approval, as well as certain incentives, including federal grants and tax credits.
- TNG908, an MTA-cooperative PRMT5 inhibitor designed to selectively kill cancer cells with MTAP deletions, is currently being evaluated in a Phase 1/2 clinical trial.

Upcoming Milestones

- A dose escalation update is expected from the Phase 1/2 clinical trial of TNG908 in patients with MTAP-deleted solid tumors during the first half of 2023.
- The initiation of the Phase 1/2 clinical trial for TNG462, a next-generation MTA-cooperative PRMT5 inhibitor, is expected in mid-2023.
- The IND filing for TNG260, a first-in-class CoREST inhibitor, is on track for the first half of 2023.
- The IND filing for TNG348, a novel USP1 inhibitor that is being developed for treatment of BRCA1 and BRCA2-mutant cancers, is on track for mid-2023.

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", "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: first-in-human TNG462 Phase 1/2 clinical trial initiation expected in mid-2023; the IND clearance for TNG462 is a critical step toward addressing the significant unmet need of patients with MTAP-deleted solid tumors; by advancing both TNG908 and TNG462 into the clinic, the Company not only increases its strategic optionality to develop and potentially commercialize a PRMT5 inhibitor, but also maximize the opportunity to help patients with MTAP-deleted cancers given the breadth of potential indications; the Company is looking forward to results from the TNG908 and TNG462 trials to optimize our development plans for these programs; TNG462 may provide a wider therapeutic index and stronger target inhibition than TNG908; a dose escalation update is expected from the Phase 1/2 clinical trial of TNG908 in patients with MTAP-deleted solid tumors during the first half of 2023 (and the information to be provided in such update); TNG462 may provide even stronger target inhibition than TNG908 and thus enhanced clinical efficacy; the potential of the Company's PRMT5 therapies to address the high unmet need in MTAP-deleted cancers; the indications expected to be included in Company clinical trials; 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 in filing INDs and conducting clinical trials (and will rely on a third party to operate its clinical trials) and may not be able to initiate clinical trials (including opening clinical trial sites and enrolling and dosing an adequate number of clinical trial participants (including the first patient dosed in the trial)) when expected and may not generate results (including final or initial safety and efficacy data) 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, products in clinical trials, and potential combination therapies that are seen in pre-clinical experiments (as a single agent or in combination) 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 or orphan drug designation (and such designations 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, 2021, 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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