TG Therapeutics Receives Orphan Drug Designation for Umbralisib from the U.S. Food and Drug Administration for the Treatment of Follicular Lymphoma

March 5, 2020

NEW YORK, March 05, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced that the U.S. Food and Drug Administration (FDA) granted orphan drug designation to umbralisib, the Company's investigational dual inhibitor of PI3K-delta and CK1-epsilon, for the treatment of patients with follicular lymphoma (FL).

Umbralisib is being evaluated across several types of lymphoma in the UNITY-NHL Phase 2b registration directed clinical trial. The FL cohort of the UNITY-NHL trial is designed to evaluate the safety and efficacy of umbralisib in patients with FL who have received at least two prior lines of therapy including an anti-CD20 monoclonal antibody and an alkylating agent. In October 2019, the Company announced that the FL cohort met the primary endpoint of overall response rate (ORR), and in January the Company initiated a rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for umbralisib as a treatment for patients with previously treated marginal zone lymphoma (MZL) and FL.

The FDA has previously granted orphan drug designation to umbralisib, for the treatment of patients with all three types of MZL: nodal, extranodal, and splenic MZL.

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics, stated, "The receipt of orphan drug designation for umbralisib to treat patients with FL is another important milestone in the development and anticipated commercialization of umbralisib in MZL and FL." Mr. Weiss continued, "We were pleased to announce last year that both the MZL and FL cohorts of the UNITY-NHL trial met their primary endpoints and have commenced our first rolling submission for these indications. We are excited by the progress so far and look forward to completion of this submission targeted in the first half of this year."

ABOUT ORPHAN DRUG DESIGNATION

Orphan drug designation is granted by the U.S. FDA to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. Orphan drug designation provides certain incentives which may include tax credits towards the cost of clinical trials and prescription drug user fee waivers. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity.

ABOUT FOLLICULAR LYMPHOMA

Follicular lymphoma (FL) is typically a slow-growing or indolent form of non-Hodgkin lymphoma (NHL) that arises from B-lymphocytes, making it a B-cell lymphoma. Follicular lymphoma is generally not curable and is a chronic disease. Patients can live for many years with this form of lymphoma. With an annual incidence in the United States of approximately 15,000 newly diagnosed patients[1], FL is the most common indolent lymphoma accounting for approximately 20 percent of all NHL cases[2].

ABOUT THE UNITY-NHL PHASE 2b STUDY—FOLLICULAR LYMPHOMA COHORT

The multicenter, open-label, UNITY-NHL Phase 2b study follicular lymphoma (FL) cohort was designed to evaluate the safety and efficacy of single agent umbralisib in patients with FL who have received at least two prior lines of therapy, including an anti-CD20 regimen and an alkylating agent. The primary endpoint is overall response rate (ORR) as determined by Independent Review Committee (IRC) assessment. Secondary endpoints include safety, duration of response, and progression-free survival (PFS).

In October of 2019, the Company announced that the primary endpoint of ORR as determined by IRC was met for all treated FL patients (n=118). The results met the Company's prespecified response target of 40-50% ORR. In January of 2020, the Company announced the initiation of a rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) requesting accelerated approval of umbralisib as a treatment for patients with previously treated marginal zone lymphoma (MZL) and follicular lymphoma (FL).

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the company is developing multiple therapies targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. TG Therapeutics is also developing umbralisib (TGR-1202), an oral, once-daily dual inhibitor of PI3K-delta and CK1-epsilon, which may lead to a differentiated safety profile. Both ublituximab and umbralisib, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with ublituximab also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought into Phase 1 clinical development, TG-1501, its anti-PD-L1 monoclonal antibody, TG-1701, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor and TG-1801, its anti-CD47/CD19 bispecific antibody. TG Therapeutics is headquartered in New York City.

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[1] American Cancer Society "Key Statistics for Non-Hodgkin Lymphoma"

[2] Lymphoma Research Foundation “Follicular Lymphoma”

Cautionary Statement
Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. In addition to the risk factors identified from time to time in our reports filed with the Securities and Exchange Commission, factors that could cause our actual results to differ materially are the following: the risk that the interim data (the “Interim Results”) from the UNITY-NHL MZL cohort will not be reproduced when the final analysis is conducted on all patients, including the risk that the final results will demonstrate a lower ORR and/or enhanced toxicities, which may not support a submission for accelerated approval; the risk that umbralisib will not receive accelerated approval based on data from the UNITY-NHL MZL or FL cohorts; the risk that duration of response or progression free survival data from the UNITY-NHL cohort when available for all patients will not be positive; the risk that safety issues will arise when the final safety data are cleaned and analyzed for all patients in the UNITY-NHL MZL or FL cohorts; the risk that the positive Interim Results from the UNITY-NHL MZL or FL cohorts will not be reproduced in other cohorts of the UNITY-NHL study or in other studies being conducted by the Company; the risk that our belief that umbralisib has a differentiated safety profile will not be shared by physicians or the FDA or will not be reproduced in the final analysis of the UNITY-NHL MZL or FL cohorts, in other cohorts of the UNITY-NHL study, in the UNITY-CLL study or in any other of our on-going studies; the risk that we are not able to successfully and cost effectively complete all the preclinical, clinical and CMC requirements necessary to support accelerated approval. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. This press release and prior releases are available at www.tgtherapeutics.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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