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TG Therapeutics Announces Initiation of National Cancer Institute/SWOG-Sponsored Randomized Phase II Trial in Follicular Lymphoma

TGR-1202 (umbralisib) selected as the PI3K Delta inhibitor to be used in this multiple arm comparison study

NEW YORK, Nov. 27, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics (NASDAQ:TGTX) announced today that along with SWOG, the global cancer clinical trials group funded by the National Cancer Institute (NCI), it has initiated a three arm Phase II trial evaluating the combination of TGR-1202 (umbralisib), the Company's PI3K delta inhibitor, plus obinutuzumab, compared to the combination of obinutuzumab plus lenalidomide, and obinituzumab plus CHOP, in patients with early relapsing or refractory Follicular Lymphoma (FL) (Grade I, II, IIIa). Target enrollment will be 50 patients per arm.

The primary outcome of this study is to assess the Complete Response (CR) rate following six cycles of treatment. Key secondary outcomes include ORR, DOR and PFS. The safety profile of each of these regimens will also be evaluated. The study will be independently run by SWOG, which has received NC funding since 1956. TG has agreed to provide TGR-1202 free of charge for use in the study. The goal of the study is to identify safe and effective novel combinations that can be used to manage these challenging early relapsing Follicular Lymphoma (FL) patients. The study is now open at over 100 hospitals, cancer centers, and other clinical sites across the US. More information about the study can be found at www.clinicaltrials.gov, Identifier NCT03269669.

Dr. Paul Barr, director of the Clinical Trials Office for Wilmot Cancer Institute at the University of Rochester Medical Center and leader of this Phase II trial, stated: "This is an extremely important study for patients with early, relapsed follicular lymphoma because they need new treatment options. Follicular lymphoma patients who relapse within two years of front-line immuno-chemotherapy are generally recognized to have the poorest outcomes. We chose these arms based on the best available clinical research suggesting these were the most promising targets for therapeutic intervention in the treatment of FL. The PI3K delta class have shown impressive single agent activity in the treatment of FL, however, the safety profile of the currently available first generation PI3K delta's are not ideal. We are pleased that TG has agreed to supply TGR-1202 for this study, as this agent appears to offer a unique safety profile compared to prior PI3K-delta inhibitors while still maintaining encouraging clinical activity in patients with NHL. We are very excited that enrollment has now begun and expect a very rapid enrollment period."

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased that SWOG has selected TGR-1202 for inclusion in this important trial. We believe this trial will showcase treatment strategies that may significantly improve outcomes for early relapsing patients and in particular, demonstrate the utility of TGR-1202 in FL. To us, the inclusion of TGR-1202 validates our belief of best-in-class qualities of TGR-1202 and the importance of PI3K delta class in 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 two therapies targeting hematological malignancies and autoimmune diseases. TG-1101 (ublituximab) 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 TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202, or the combination of which is referred to as "U2," are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future. TG Therapeutics is headquartered in New York City.

ABOUT SWOG

SWOG is part of the National Cancer Institute's National Clinical Trials Network, the nation's oldest and largest cancer research network, and is a major part of the cancer research infrastructure in the U.S. and the world. SWOG has over 12,000 members in 46 states and six foreign countries who design and conduct cancer clinical trials to improve the lives of

people with cancer. Founded in 1956, SWOG's 1,300 trials have led to the approval of 14 cancer drugs, changed more than 100 standards of cancer care, and saved more than 2 million years of human life. Learn more at swog.org.

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 NCI does not complete a clinical trial evaluating a combination of TGR-1202 plus a CD20 in follicular lymphoma; the risk that PI3K delta inhibitors, particularly TGR-1202, are not efficacious as a treatment option for follicular lymphoma; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303 or "U2", and being studied in the UNITY clinical trials, will not prove to be a safe and efficacious combination treatment option for any indication; the risk that the company does not persue a registration strategy with the UNITY-NHL data; the risk that early clinical trial results, that may have influenced our decision to proceed with additional clinical trials, will not be reproduced in the final data presented; the risk that the final data will not support regulatory approval or filing. 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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