TG Therapeutics Receives Breakthrough Therapy Designation from the U.S. Food and Drug Administration for Umbralisib for the Treatment of Marginal Zone Lymphoma

January 22, 2019

Breakthrough Therapy Designation granted based on interim data from the Marginal Zone Lymphoma cohort of the UNITY-NHL trial

NEW YORK, Jan. 22, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), a biopharmaceutical company dedicated to developing medicines for patients with B-cell mediated diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for umbralisib (TGR-1202) for the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 regimen. There are currently no fully approved agents for MZL.

The Breakthrough Therapy Designation was based on interim data from the MZL cohort evaluating umbralisib monotherapy in the ongoing UNITY-NHL Phase 2b registration-directed clinical trial.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, “We look forward to working closely with the FDA to bring umbralisib, our novel PI3K-delta inhibitor to patients as quickly as possible. MZL patients who fail initial chemo-immunotherapy are left with limited treatment options. We believe umbralisib can play an important role in fulfilling this unmet medical need. The MZL single agent umbralisib cohort of the UNITY-NHL study is fully enrolled and we look forward to reporting top-line results from this cohort by mid-year and presenting the data at a major medical meeting in 2019.”

About Breakthrough Therapy Designation

The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a drug candidate that is planned to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies.

About Marginal Zone Lymphoma

Marginal zone lymphoma (MZL) comprises a group of indolent (slow growing) B-cell non-Hodgkin lymphomas (NHLs) that begin forming in the marginal zone of lymphoid tissue. With an annual incidence of approximately 7,500 newly diagnosed patients, MZL is the third most common B-cell NHL accounting for approximately eight percent of all NHL cases.[i] MZL consists of three different subtypes: extranodal MZL of the mucosal-associated lymphoid tissue (MALT), nodal marginal zone lymphoma (NMZL), and splenic marginal zone lymphoma (SMZL).

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. 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 inhibitor of PI3K-delta. Umbralisib uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K-delta inhibitors. 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 its anti-PD-L1 monoclonal antibody, TG-1501, as well as its covalently-bound Bruton Tyrosine Kinase (BTK) inhibitor, TG-1701, 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.

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: our ability to successfully and cost effectively complete preclinical and clinical trials; the risk that the interim clinical trial results from the UNITY-NHL MZL cohort that supported this Breakthrough Therapy Designation (BTD) will not be reproduced in the final data, or if positive, will not be sufficient to support a filing for approval, the risk that the interim data from the UNITY-NHL MZL cohort will not be reproduced in future studies or in other cohorts of the UNITY-NHL study; the risk that umbralisib will not receive accelerated approval based on data from the UNITY-NHL MZL cohort, the risk that the differentiated tolerability profile for umbralisib observed thus far in clinical trial will not be reproduced in the UNITY-NHL study, the UNITY-CLL study or any other on-going studies; the risk that the combination of ublituximab (TG-1101) and umbralisib (TGR-1202), referred to as U2 and being studied in the UNITY-CLL clinical trial, will not prove to be a safe and efficacious combination, or approved for any indication. 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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[i] Denlinger NM, Epperla N, William BM. Management of relapsed/refractory marginal zone lymphoma: focus on ibrutinib. Cancer Manag Res. 2018 Mar 27;10:615-624. doi: 10.2147/CMAR.S133291. eCollection 2018


Logo-TG-revised colors.jpg

Source: TG Therapeutics, Inc.