TG Therapeutics and Novimmune SA Announce Global Agreement for Development and Commercialization of a Novel Anti-CD47/ Anti-CD19 Bispecific Antibody

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NEW YORK, June 20, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) and Novimmune SA, today announced that the companies have entered into an exclusive global agreement to collaborate on the development and commercialization of Novimmune's novel first-in-class anti-CD47/anti-CD19 bispecific antibody known as TG-1801 (previously NI-1701). The companies will jointly develop the product on a worldwide basis, focusing on indications in the area of hematologic B-cell malignancies.

TG Therapeutics will make up-front and milestones payments based on early clinical development, and will be responsible for the costs of clinical development of the products through the end of Phase II, after which TG Therapeutics and Novimmune will be jointly responsible for all development and commercialization costs of the product. TG Therapeutics and Novimmune will each maintain an exclusive option, exercisable at specific times during development, for TG Therapeutics to license the rights to TG-1801, in which case Novimmune will be eligible to receive additional payments contingent on certain clinical, regulatory and commercial milestones, totaling approximately $185MM as well as tiered royalties on net sales.

TG-1801, a fully-human IgG1, designed to target and deplete B-cells via multiple mechanisms, is based on Novimmune's kappa-lambda -body format which allows preservation of all favorable properties of a conventional monoclonal antibody while adding bispecific functionalities. One mechanism unique to this bispecific antibody involves blocking of CD47 referred to as the "do not eat me" signal for the body's phagocytic cells specifically directed to CD19 positive cells. The net effect is highly targeted, potent anti-B-cell tumor phagocytic activity, while avoiding the general toxicity concerns associated with earlier agents targeting the CD47 pathway. Moreover, the co-targeting of CD19 is not only expected to enhance safety but by retaining its IgG1 Fc functionality, this agent is designed to provide a secondary mechanism of anti-tumor activity through the induction of antibody dependent cellular cytotoxicity (ADCC).

TG-1801 is expected to be the first anti-CD47 bispecific antibody worldwide that will go into clinical trials, which are expected to commence later this year or early in 2019.

"We are delighted to see our first bispecific antibody move forward into the clinic with an experienced partner in the field of hematological malignancies, and to provide proof of principle for our completely novel approach," said Chairman and Chief Executive Eduard Holdener. "We are excited about the potential benefit that this new approach could bring to B-cell lymphoma patients."

"We are excited to enter into this collaboration with Novimmune, a leader in antibody engineering, and whose innovations in the field of CD47 bispecific antibodies have generated a potentially more effective and safer approach for targeting of CD47, which was recently validated in the clinical studies as a very promising pathway for tumor targeting, especially in combination with anti-CD20 monoclonal antibodies," stated Michael S. Weiss, Executive Chairman and CEO of TG Therapeutics. Mr. Weiss continued, "TG Therapeutics is focused on building the most comprehensive and effective portfolio for the treatment of hematologic malignancies and autoimmune diseases. TG-1801 has demonstrated encouraging pre-clinical anti-tumor activity both as a single agent and in combination with anti-CD20 monoclonal antibodies. With the addition of TG-1801 to our pipeline, we now have three targeted immunotherapies in-house that can potentially be used together to create a novel non-chemo treatment option that uses the body's immune system to fight B-cell cancers, including NHL and CLL."

About NOVIMMUNE

Novimmune SA is a privately held, Swiss biopharmaceutical company focused on the discovery and development of antibody-based drugs for the targeted treatment of inflammatory diseases, immune-related disorders, and cancer. The company is headquartered in Geneva and runs a Clinical and Commercial Development Center in Basel. The company currently employs 155 people. More information is available on the company website at www.novimmune.com.

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 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 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 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 early clinical trial results, that may have influenced our decision to proceed with additional clinical trials, will not be reproduced in future

studies; the risk that TG-1801 will not be the first anti-CD47 bispecific antibody worldwide that will go into clinical development; the risk that the company will not move forward with the development of TG-1801, formerly known as NI-1701. 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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