TG Therapeutics Announces Global License Agreement with Precision BioSciences for the Development and Commercialization of Precision's Allogeneic CD19 CAR T Cell Therapy Program for the Treatment of Autoimmune Diseases

January 9, 2024

US IND filing targeted for mid-2024

NEW YORK, Jan. 09, 2024 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), "the Company," today announced that it has entered into an agreement with Precision BioSciences, Inc. (NASDAQ GS: DTIL) to acquire a worldwide license to Precision's Azercabtagene Zapreleucel (azer-cel), an allogeneic CD19 CAR T cell therapy program for autoimmune diseases and all other non-oncology indications. Azer-cel is an allogeneic (off the shelf) CAR T program and the Company has near-term plans to evaluate the program in multiple autoimmune indications, with an investigational new drug (IND) filing targeted for mid-2024.

Michael S. Weiss, Chairman and Chief Executive Officer of TG Therapeutics stated, "We are excited to expand our autoimmune portfolio and leverage our robust drug development and commercialization expertise in partnering with Precision on this CAR T program. We look forward to exploring azer-cel's potential to be a meaningful therapy for patients with various autoimmune disorders with a target IND filing mid-2024."

"We are excited to partner with TG Therapeutics to extend the therapeutic opportunity for our allogeneic CAR T product azer-cel to address unmet medical needs in autoimmune conditions and other diseases beyond oncology. TG Therapeutics has a strong track record of development, regulatory and commercial success in the multiple sclerosis space, and we believe they will bring their expertise to the development of azer-cel for autoimmune diseases," said Michael Amoroso, President and Chief Executive Officer of Precision BioSciences.

Under the terms of the agreement, TG Therapeutics will receive exclusive worldwide rights to develop and commercialize azer-cel in non-oncology indications, and in exchange, Precision will receive upfront and potential near-term economics valued at $17.5 million. The upfront payment of $7.5 million will consist of cash and the purchase of Precision common stock by TG Therapeutics at a 100% premium to the 30-day VWAP prior to purchase. Precision will also receive $2.5 million in deferred consideration due within 12 months as an equity investment in Precision's common stock at a 100% premium to the then 30-day VWAP prior to purchase. Upon the achievement of certain near-term clinical milestones, Precision will receive an additional $7.5 million payment, consisting of cash and the purchase of Precision common stock by TG at a 100% premium to the then current 30-day VWAP. Precision is also eligible to receive up to $288 million in additional payments based on the achievement of certain clinical, regulatory, and commercial milestones, in addition to high-single-digit to low double-digit royalties on net sales.

ABOUT TG THERAPEUTICS

TG Therapeutics is a fully integrated, commercial stage, biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell diseases. In addition to a research pipeline including several investigational medicines, TG has received U.S. Food and Drug Administration (FDA) approval for BRIUMVI® (ublituximab-xiiy), for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, as well as approval by the European Commission (EC) and the Medicines and Healthcare Products Regulatory Agency (MHRA) for BRIUMVI to treat adult patients with RMS who have active disease defined by clinical or imaging features in Europe and the United Kingdom, respectively. For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and on LinkedIn.

Cautionary Statement

This press release contains 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.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release. In addition to the risk factors identified from time to time in our reports filed with the U.S. Securities and Exchange Commission (SEC), factors that could cause our actual results to differ materially include the below.

Such forward looking statements include, but are not limited to, statements regarding the azer-cel allogeneic CD19 CAR T cell therapy program for all non-oncology indications. Factors that could cause our actual results to differ materially include the following: our ability to successfully and cost-effectively complete preclinical and clinical trials related to the CD19 CAR T cell therapy program; the risk that early clinical trial results that may have influenced our decision to undertake the development of the azer-cel allogeneic CD19 CAR T cell therapy program will not be reproduced in future studies; the risk that the company will not move forward with the development or commercialization of the azer-cel allogeneic CD19 CAR T cell therapy program for any non-oncology indications; the risk the IND is not filed or accepted by regulatory authorities in the timeline provided or at all; the risk that the azer-cel allogeneic CD19 CAR T cell therapy does not exhibit a clinical profile that is suitable for autoimmune disease; the risk that the equity investments in Precision may not appreciate in value, hold value, or have any value in the future. Further discussion about risks and uncertainties can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in our other filings with the U.S. Securities and Exchange Commission.

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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