

# TG Therapeutics Enters Into a Global Collaboration With Checkpoint Therapeutics to Develop and Commercialize Novel Immuno-Oncology Targeted Antibodies

# Under the Terms of the Agreement, TG Therapeutics Will Have the Exclusive Right to Develop Anti-PD-L1 and Anti-GITR Antibodies in Hematological Malignancies

NEW YORK, March 4, 2015 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX), announced today an agreement with Checkpoint Therapeutics, Inc., a newly formed subsidiary of Coronado Biosciences, Inc. (Nasdaq:CNDO) to develop and commercialize Checkpoint's fully human anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. Checkpoint will develop and commercialize these antibodies in solid tumors. The antibodies were generated in the laboratory of Dr. Wayne Marasco, MD, PhD, a Professor in the Department of Cancer Immunology and AIDs at Dana-Farber Cancer Institute (Dana-Farber). Both programs are currently in pre-clinical development and are anticipated to enter the clinic in 2016. Under the terms of the agreement, TG Therapeutics will make an up-front payment as well as make development and sales-based milestone payments and will pay a tiered single digit royalty on net sales.

Mr. Michael S. Weiss, Executive Chairman, Interim CEO and President stated, "We are very excited to add Dr. Marasco's anti-PD-L1 and anti-GITR programs to our growing portfolio of agents targeting hematological malignancies. Dr. Marasco is a recognized world expert in human antibody engineering and one of the pioneers of immunotherapy and we look forward to his continued involvement and guidance as Chair of the Scientific Advisory Board of our new partner, Checkpoint Therapeutics, Inc." Mr. Weiss continued, "Checkpoint inhibitors and other immuno-oncology targeted agents have already demonstrated the ability to transform the way we treat cancer by unlocking the immune system, offering the promise of deep and durable remissions. While the recent introduction of novel targeted agents has already revolutionized the way we treat hematological malignancies, we at TG believe that incorporation of immuno-therapy will prove to be a second paradigm-shift in the treatment of these diseases, and it is our goal to be at the forefront leading this charge. As we've said previously, we will continue to build our portfolio to optimize our combination approach to provide the best possible outcomes to patients with B-cell malignancies without the need to use harsh chemotherapy, ideally pushing toward a cure. It is believed that these two antibodies can work synergistically together and we believe that adding them to the already marked activity we are seeing with our proprietary combination of TG-1101 and TGR-1202 across CLL and NHL could greatly enhance the therapeutic benefit to patients with hematological malignancies. Our goal is to advance both of these antibodies into the clinic in the second half of next year."

## ABOUT ANTI-PD-L1 & ANTI-GITR

Anti-PD-L1 antibodies target programmed cell death ligand 1 (PD-L1). Signals from PD-L1 on tumor cells and in tumor microenvironment help those tumors avoid immune attack and elimination by preventing activation of tumor specific effector T-cells. Anti-PD-L1 antibodies are designed to block that signal permitting effector T-cells to attack the cancer. Anti-GITR antibodies target glucocorticoid-induced tumor necrosis factor receptor related protein (GITR), which is regularly expressed on the surface of regulatory T-cells (Tregs) and is expressed on the surface of effector T-cells after their activation. Modulation of GITR with agonistic antibodies has been shown to amplify the antitumor immune responses in animal models via multiple mechanisms. Anti-GITR antibodies are designed to activate the GITR receptor thereby increasing the proliferation and function of effector T cells. At the same time, ligation of GITR on surface of Tregs could abrogate suppressive function of these cells on tumor specific effector T-cells thus further augmenting T-cell immune response. While targeting PD-1/PD-L1 axes alone has already demonstrated impressive anticancer efficacy and durable responses in humans, its efficacy appears to be limited to certain patients. It is believed the effects of anti-PD-L1 intervention can be enhanced by utilizing a co-stimulatory antibody, like one targeting GITR, that can turn on tumor specific effector T-cells. Combining immunotherapies like anti-PD-L1 that counters the tumor's immune-evading defense system with an anti-GITR that activates effector T-cells, represents a rational approach to use the body's own immune system to help fight cancer. Pre-clinical research on the combination of the two approaches has yielded very encouraging results to support synergistic potential of this combination.

## 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. 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, 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 are in clinical development for

patients with hematologic malignancies. The Company also has a pre-clinical program to develop IRAK4 inhibitors, also for B-cell malignancies and autoimmune diseases. TG Therapeutics is headquartered in New York City.

#### ABOUT CHECKPOINT THERAPEUTICS, INC.

Checkpoint Therapeutics is an innovative, immuno-oncology company spun out of the labs of Dr. Wayne Marasco of Dana-Farber Cancer Institute, a teaching hospital affiliated with Harvard Medical School, as a newly formed subsidiary of Coronado Biosciences, Inc. (Nasdaq:CNDO). Checkpoint is developing novel checkpoint inhibitors and other immuno-oncology drug candidates that may be active on their own but are designed to also work synergistically together and with other immunooncology agents and targeted drugs. Checkpoint plans to build a portfolio of complimentary drug candidates to treat a wide variety of solid tumors and, through its partnership with TG Therapeutics, hematological cancers. Currently, the company is developing three antibodies targeting anti-PD-L1, anti-GITR and anti-CAIX. Checkpoint Therapeutics is headquartered in New York City.

#### **Cautionary Statement**

Some of the statements included in this press release, particularly those anticipating future clinical trials, timing of clinical trials for anti-PD-L1 and anti-GITR antibodies and business prospects and potential uses for anti-PD-L1 and anti-GITR antibodies 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. Among the factors that could cause our actual results to differ materially are the following: our ability to identify anti-PD-L1 and anti-GITR antibodies; the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data analyses from prior pre-clinical and clinical trials; and other risk factors identified from time to time in our reports filed with the 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 only.

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