TG Therapeutics Provides Business Update and Reports First Quarter 2021 Financial Results

May 10, 2021

Conference call to be held today, Monday, May 10, 2021 at 8:30 AM ET

NEW YORK, May 10, 2021 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the first quarter ending March 31, 2021 and recent company developments, along with a business outlook for 2021.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "2021 has been an incredibly impactful year, kicking off with our first approval coming ahead of schedule for UKONIQ to treat both relapsed or refractory Marginal Zone Lymphoma and Follicular Lymphoma. That was followed by the completion of a BLA submission for ublituximab in combination with UKONIQ (U2) to treat patients with CLL, and the full presentation of positive results from the ULTIMATE I & II Phase 3 trials in relapsing forms of MS. As a fully integrated commercial organization we are pleased with our progress thus far with the UKONIQ launch and we look forward to continuing to build our commercial infrastructure to support the potential approval and commercialization of U2 in CLL and ublituximab in RMS."

2021 Highlights & Recent Developments

UKONIQ™ (umbralisib) in Relapsed or Refractory Marginal Zone Lymphoma & Follicular Lymphoma

- Received accelerated approval from the U.S. Food and Drug Administration (FDA) on February 5, 2021 for UKONIQ to treat adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen and adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.
- Launch efforts underway across the U.S. UKONIQ has payor coverage for 85-90% of Medicare and commercial lives and is included in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for MZL and FL, consistent with the FDA-approved indications.
- Published results from the UKONIQ monotherapy cohorts of the UNITY-NHL Phase 2b trial in patients with relapsed or refractory indolent non-Hodgkin Lymphoma (NHL) in the Journal of Clinical Oncology.

Ublituximab plus UKONIQ (U2) in Chronic Lymphocytic Leukemia

- Completed a rolling submission of a Biologics License Application (BLA) to the FDA requesting approval of U2, as a treatment for patients with chronic lymphocytic leukemia (CLL), including both previously untreated and relapsed/refractory patients, based on the positive results from the UNITY-CLL Phase 3 trial.
- Completed enrollment in the ULTRA-V Phase 2 trial, and launched the ULTRA-V Phase 3 randomized trial evaluating the triple combination of U2 plus venetoclax in patients with treatment naïve and relapsed or refractory CLL.

Ublituximab in Multiple Sclerosis

- Presented positive results from the ULTIMATE I & II Phase 3 trials at the American Academy of Neurology 2021 Annual Meeting. Both trials met their primary endpoint with ublituximab treatment demonstrating a statistically significant reduction in annualized relapse rate (ARR) over a 96-week period compared to teriflunomide in patients with relapsing forms of multiple sclerosis (RMS).

TG-1701 in B-cell Malignancies

- Updated data from TG-1701, our BTK inhibitor, as a monotherapy and in combination with U2 in patients with B-cell malignancies has been accepted for presentation at the American Society of Clinical Oncology (ASCO) annual meeting being held in June 2021.

Remaining Key Objectives for 2021

- Focus on the commercialization of UKONIQ in relapsed/refractory MZL and FL and expand commercialization capabilities in preparation for a potential launch of U2 for CLL and ublituximab in MS
- Submit a BLA for ublituximab for the treatment of patients with RMS in Q3 2021, based on positive results from the ULTIMATE I & II Phase 3 trials
- Receive notification from the FDA that the BLA for U2 in CLL has been accepted for filing and work closely with the Agency on its review of the application
- Enroll into the newly launched ULTRA-V Phase 3 trial evaluating the triple combination of U2 plus venetoclax

- Continue to advance our early pipeline candidates including TG-1501 (cosibelimab), TG-1701 and TG-1801

Financial Results for the Three Months Ended March 31, 2021

- **Product Revenue, net:** Product revenue, net was approximately $0.8 million for the three months ended March 31, 2021, compared to zero during the comparable period in 2020. Net product revenues represent U.S. sales from our sole commercial product, UKONIQ, which received accelerated approval from the FDA on February 5, 2021, with launch later in the month.

- **R&D Expenses:** Total research and development (R&D) expense was $63.1 million for the three months ended March 31, 2021, compared to $36.0 million for the three months ended March 31, 2020. The increase was due primarily to licensing milestone fees of approximately $14.0 million incurred during the first quarter of 2021 and an increase of approximately $5.5 million in non-cash compensation R&D expenses over the comparable quarter in 2020.

- **SG&A Expenses:** Total selling, general and administrative (SG&A) expense was $26.8 million for the three months ended March 31, 2021 and $14.3 million for the three months ended March 31, 2020. The increase was due primarily to increased personnel and other selling, general and administrative costs associated with preparations for, and now execution of, the commercial launch of UKONIQ. We expect our selling, general and administrative expenses to increase for the remainder of 2021 in preparation for the potential launch of ublituximab as part of the U2 combination for CLL and as a monotherapy in MS.

- **Net Loss:** Net loss was $90.6 million for the three months ended March 31, 2021 compared to $51.1 million for the three months ended March 31, 2020. Excluding non-cash compensation, the net loss for the three months ended March 31, 2021 was approximately $74.0 million, compared to a net loss of $40.0 million for the three months ended March 31, 2020.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $523.8 million as of March 31, 2021, which the Company believes will be sufficient to fund the Company's planned operations into 2023.

CONFERENCE CALL INFORMATION

The Company will host a conference call today, May 10, 2021, at 8:30 AM ET, to discuss the Company's first quarter ended March 31, 2021 financial results and provide a business outlook for the remainder of 2021.

To participate in the conference call, please call 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), Conference Title: TG Therapeutics. A live audio webcast will be available on the Events page, located within the Investors & Media section, of the Company's website at http://ir.tgtherapeutics.com/events. An audio recording of the conference call will also be available for a period of 30 days after the call.

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is a fully-integrated, commercial stage biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. In addition to an active research pipeline including five investigational medicines across these therapeutic areas, TG has received accelerated approval from the U.S. FDA for UKONIQ™ (umbralisib), for the treatment of adult patients with relapsed/refractory marginal zone lymphoma who have received at least one prior anti-CD20-based regimen and relapsed/refractory follicular lymphoma who have received at least three prior lines of systemic therapies. Currently, the Company has two programs in Phase 3 development for the treatment of patients with relapsing forms of multiple sclerosis (RMS) and patients with chronic lymphocytic leukemia (CLL) and several investigational medicines in Phase 1 clinical development. For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and Linkedin.

UKONIQ™ is a trademark of TG Therapeutics, Inc.

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. Such forward looking statements include but are not limited to statements regarding the Company's plans, goals, strategies, timelines, anticipated milestones, and expectations for our current or future approved drugs and drug candidates, including the continued U.S. approval and commercialization of UKONIQ™ (umbralisib); plans and timelines for marketing applications and review expectations for ublituximab in combination with UKONIQ in CLL or ublituximab monotherapy in RMS and, if approved, commercializing the combination regimen in CLL or ublituximab monotherapy in RMS; the initiation of clinical trials or the results of ongoing and planned clinical trials; the potential benefits of any of the Company's current or future approved drugs or drug candidates in treating patients; and financial guidance regarding the period in which we will have sufficient capital resources to fund our operations.

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 Securities and Exchange Commission, factors that could cause our actual results to differ materially include the following: our ability to establish, maintain and enhance our commercial infrastructure, and to successfully market and sell UKONIQ or future products, if approved; our ability to meet post-approval regulatory requirements for UKONIQ and future products, including submission of sufficient data from a confirmatory clinical study, and post-approval compliance obligations (on topics including but not limited to product quality, product distribution and supply chain, pharmacovigilance, and sales and marketing); the potential for variation from the Company's projections and estimates about the potential market for UKONIQ or the Company's product

candidates due to a number of factors, including for example, limitations that regulators may impose on the required labeling for the product; our ability to reach certain regulatory milestones at all or within the timelines projected; our ability to submit a BLA for ublituximab in RMS within the timeline projected; our ability to obtain, or to obtain within the timeline projected, marketing authorization for our product candidates, including ublituximab in combination with UKONIQ in CLL and ublituximab monotherapy in RMS; our ability to successfully complete analyses of our clinical study results and present data within the timeframes projected; the risk that the interim, top-line and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints are analyzed; the risk that preclinical and clinical results for the Company's drug candidates may not support further development of such drug candidates; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; the Company's reliance on third parties for manufacturing, distribution and supply, and a range of other support functions for its clinical and commercial products, including UKONIQ; the uncertainties inherent in research and development; the risk that the ongoing COVID-19 pandemic and associated government control measures have an adverse impact on our research and development plans or commercialization efforts; the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; our financial performance; and the sufficiency of our existing capital resources to fund our future operating expenses. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 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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TG Therapeutics, Inc.
Selected Condensed Consolidated Financial Data

Statements of Operations Information (in thousands, except share and per share amounts; unaudited):

	Three Months Ended	
	March 31, 2021	**March 31, 2020**
Revenue		
Product revenue, net	$ 755	**$** -
License revenue	38	38
Total revenue	793	38
Costs and expenses:		
Cost of product revenue	139	-
Research and development		
Non-cash compensation	7,511	1,979
Other research and development	55,583	34,043
Total research and development	63,094	36,022
Selling, general and administrative		
Non-cash compensation	9,107	9,089
Other selling, general and administrative	17,655	5,172
Total selling, general and administrative	26,762	14,261
Total operating expenses	89,995	50,283
Operating loss	(89,202)	(50,245)
Other (income) expense:		
Interest expense	1,898	1,201
Other income	(472)	(330)
Total other (income) expense	1,426	871
Consolidated net loss	$ (90,628)	$ (51,116)
Net loss per common share:		

Basic and diluted	$ (0.69)	$ (0.48)
Weighted average shares of common stock outstanding:		
Basic and diluted	131,898,626	105,461,892

Condensed Balance Sheet Information (in thousands):

	March 31, 2021 (Unaudited)	December 31, 2020*
Cash, cash equivalents and investment securities	$ 523,848	$ 605,426
Total assets	548,699	625,642
Accumulated deficit	(1,071,225)	(980,597)
Total equity	445,285	519,350

* Condensed from audited financial statements