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

August 2, 2021

Conference call to be held today, Monday, August 2, 2021 at 8:30 AM ET

NEW YORK, Aug. 02, 2021 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the second quarter ending June 30, 2021 and recent company developments, along with a business outlook for the remainder 2021.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, "We are pleased with the progress made throughout the second quarter, including our ongoing launch of UKONIQ in relapsed or refractory MZL and FL, FDA's acceptance of our BLA/sNDA for the combination of ublituximab and UKONIQ (U2) to treat CLL and SLL, and the continued advancement of our clinical programs. We have built a strong commercialization infrastructure to launch UKONIQ and have received positive feedback from healthcare providers on their experiences with the product and with the TG team. We believe this solid commercialization foundation will support, if approved, the launch of U2 in CLL and ublituximab in relapsing forms of multiple sclerosis."

Mr. Weiss continued, "We look forward to an exciting second half of 2021, during which we plan to submit a BLA for ublituximab to treat patients with relapsing forms of multiple sclerosis, continue executing on the launch of UKONIQ in MZL and FL, and continue preparations for potential commercialization of U2 in CLL and ublituximab in RMS."

2021 Highlights & Recent Developments

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

- Launched UKONIQ in the U.S. for the treatment of 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.
- Generated $2.3M in total net UKONIQ revenue from launch through the end of Q2 2021, approximately 4 months.
- Achieved broad U.S. payor coverage for more than 90% of Medicare and commercial lives and inclusion in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for MZL and FL.

Ublituximab plus UKONIQ (U2) in Chronic Lymphocytic Leukemia

- Received FDA acceptance of a Biologics License Application (BLA) for ublituximab and a supplemental New Drug Application (sNDA) for UKONIQ, both submissions requesting approval of U2 as a treatment for patients with chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL). These applications were primarily based on results from the UNITY-CLL Phase 3 trial, which included both treatment-naïve and relapsed or refractory (R/R) patients. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of March 25, 2022 for both applications.
- 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 R/R CLL.

Ublituximab in Multiple Sclerosis

- Presented positive results from the ULTIMATE I and II Phase 3 trials at the 2021 American Academy of Neurology (AAN) annual meeting and the 7th Congress of the European Academy of Neurology (EAN). 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

- Presented updated data from TG-1701, our BTK inhibitor, as a monotherapy and in combination with U2 in patients with B-cell malignancies at the 2021 American Society of Clinical Oncology (ASCO) annual meeting, the 2021 European Hematology Association (EHA) virtual congress and the 16th International Congress on Malignant Lymphoma (ICML).

Remaining Key Objectives for 2021 and Early 2022

- Focus on the commercialization of UKONIQ in R/R MZL and FL and expand commercialization capabilities in preparation for a potential launch of U2 in CLL and ublituximab in RMS
- Submit a BLA for ublituximab for the treatment of patients with RMS in Q3 2021, based on positive results from the ULTIMATE I and II Phase 3 trials

- Obtain approval for U2 in CLL and SLL by the PDUFA goal date of March 25, 2022
- 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 and Six Months Ended June 30, 2021

- **Product Revenue, net:** Product revenue, net was approximately $1.5 million and $2.3 million for the three and six months ended June 30, 2021, compared to zero during the comparable periods 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.

- **R&D Expenses:** Total research and development (R&D) expense was $44.9 million and $108.0 million for the three and six months ended June 30, 2021, compared to $36.5 million and $72.5 million for the three and six months ended June 30, 2020. The increase was due primarily to licensing milestone fees of approximately $4.0 million and $18.0 million incurred during the three and six months ended June 30, 2021, and an increase in non-cash compensation R&D expense over the comparable periods in 2020.

- **SG&A Expenses:** Total selling, general and administrative (SG&A) expense was $34.0 million and $60.8 million for the three and six months ended June 30, 2021, and $14.4 million and $28.7 million for the three and six months ended June 30, 2020. The increase was due primarily to increased personnel and other selling, general and administrative costs associated with execution of the launch of UKONIQ and planning for the potential launches of U2 in CLL and ublituximab in RMS. We expect our selling, general and administrative expenses to increase for the remainder of 2021 as we continue to prepare for those potential 2022 launches.

- **Net Loss:** Net loss was $78.5 million and $169.1 million for the three and six months ended June 30, 2021, compared to $52.9 million and $104.0 million for the three and six months ended June 30, 2020. Excluding non-cash compensation, the net loss for the three and six months ended June 30, 2021 was approximately $62.2 million and $136.2 million, compared to a net loss of $45.5 million and $85.6 million for the three and six months ended June 30, 2020.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $456.2 million as of June 30, 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, August 2, 2021, at 8:30 AM ET, to discuss the Company’s second quarter ended June 30, 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 registered 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; 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. 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 from those expressed or implied by any forward-looking statements contained in this press release 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, including 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 or for the indications sought, marketing authorization for our product candidates, including ublituximab in combination with UKONIQ in CLL/SLL, inclusive of treatment-naïve and R/R patients, 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 regulatory authorities disagree with the conclusions we have reached or data we have publicly disclosed and we are unable to obtain approval for, or successfully commercialize, our product candidates; 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 June 30,		Six months ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue				
Product revenue, net	$ 1,507	$ --	$ 2,262	$ --
License revenue	38	38	76	76
Total revenue	1,545	38	2,338	76
Costs and expenses:				
Cost of product revenue	148	--	288	--
Research and development:				
Noncash compensation	7,016	1,553	14,527	3,532
Other research and development	37,855	34,896	93,438	68,939
Total research and development	44,871	36,449	107,965	72,471
Selling, general and administrative:				
Noncash compensation	9,288	5,817	18,395	14,906
Other selling, general and administrative	24,729	8,617	42,384	13,789
Total selling, general and administrative	34,017	14,434	60,779	28,695
Total operating expenses	79,036	50,883	169,032	101,166
Operating loss	(77,492)	(50,845)	(166,694)	(101,090)

Other expense (income):				
Interest expense	1,623	2,228	3,521	3,429
Other income	(618)	(189)	(1,090)	(519)
Total other expense (income), net	1,005	2,039	2,431	2,910
Consolidated net loss	$ (78,497)	$ (52,884)	$ (169,125)	$ (104,000)
Net loss per common share:				
Basic and diluted	$ (0.59)	$ (0.47)	$ (1.28)	$ (0.95)
Weighted average shares of common stock outstanding:				
Basic and diluted	132,072,996	112,353,414	131,986,293	108,926,690

Condensed Balance Sheet Information (in thousands):

	June 30, 2021	December 31, 2020*
	(Unaudited)	
Cash, cash equivalents and investment securities	456,216	605,426
Total assets	481,400	625,642
Accumulated deficit	(1,149,722)	(980,597)
Total equity	383,130	519,350

* Condensed from audited financial statements