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

November 4, 2021

Conference call to be held today, Thursday, November 4, 2021 at 8:30 AM ET

NEW YORK, Nov. 04, 2021 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the third quarter ended September 30, 2021 and recent company developments, along with a business outlook for the remainder of 2021.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, “The third quarter of 2021 was an exciting time for us, as we achieved another major milestone by submitting a Biologics License Application (BLA) with the U.S. FDA for ublituximab to treat patients with relapsing forms of multiple sclerosis (RMS). With an estimated 1 million Americans currently living with multiple sclerosis, we believe if approved, ublituximab will provide an attractive new treatment option for patients battling RMS, which is the most common disease course.”

Mr. Weiss continued, “For the remainder of 2021 and into 2022, we look forward to continuing to execute on the UKONIQ launch in patients with relapsed or refractory marginal zone and follicular lymphoma, and also continuing to prepare for the potential launches of ublituximab in combination with UKONIQ or U2 in CLL and ublituximab in RMS.”

2021 Highlights & Recent Developments

Ublituximab in Multiple Sclerosis

- Submitted a Biologics License Application (BLA) to the U.S. FDA for ublituximab to treat patients with relapsing forms of multiple sclerosis (RMS).
- Presented positive results, including new analyses, from the ULTIMATE I and II Phase 3 trials at the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). As previously reported, 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 RMS. Additional secondary, tertiary and post-hoc sensitivity analyses were also presented, including T1 and T2 lesions, no evidence of disease activity (NEDA), brain volume and multiple sclerosis functional composite (MSFC) score.

Ublituximab plus UKONIQ® (U2) in Chronic Lymphocytic Leukemia

- Received FDA acceptance of a 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 based on results from the UNITY-CLL Phase 3 trial, which included both treatment-naïve and relapsed or refractory (R/R) CLL 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 Phase 2 portion of the ULTRA-V trial and launched the Phase 3 portion of the ULTRA-V trial, a randomized trial evaluating the triple combination of U2 plus venetoclax in patients with treatment-naïve and R/R CLL.
- Presented updated results from the Phase 1 trials of U2 plus venetoclax evaluating patients with R/R CLL at the 2021 International Workshop on Chronic Lymphocytic Leukemia (iwCLL).

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 $4.3M in total net UKONIQ revenue from launch through the end of Q3 2021, approximately seven months.
- Achieved broad U.S. payor coverage for more than 95% of Medicare and commercial lives and inclusion in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for MZL and FL.
- Published results from an integrated safety analysis of UKONIQ in *Blood Advances.*

TG-1701 in B-cell Malignancies

- Presented updated data from TG-1701, our bruton tyrosine kinase (BTK) inhibitor, as a monotherapy and in combination with U2 in patients with B-cell malignancies at the 2021 iwCLL meeting.

Remaining Key Objectives for 2021 and Early 2022

- Continue 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.
- Seek to obtain U.S. FDA approval of U2 in CLL and SLL by the PDUFA goal date of March 25, 2022.
- Continue to enroll patients 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) our PDL1 inhibitor, TG-1701 our BTK inhibitor and TG-1801 our CD47/CD19 bispecific antibody.

Financial Results for the Three and Nine Months Ended September 30, 2021

- **Product Revenue, net:** Product revenue, net was approximately $2.0 million and $4.3 million for the three and nine months ended September 30, 2021. 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 $52.0 million and $159.9 million for the three and nine months ended September 30, 2021, compared to $50.5 million and $122.9 million for the three and nine months ended September 30, 2020. The increase was due primarily to costs associated with the submission of our BLA for ublituximab in RMS, manufacturing costs, as well as an increase in non-cash compensation R&D expense during the nine months ended September 30, 2021 over the comparable period in 2020.

- **SG&A Expenses:** Total selling, general and administrative (SG&A) expense was $34.9 million and $95.7 million for the three and nine months ended September 30, 2021, and $35.3 million and $64.0 million for the three and nine months ended September 30, 2020. The increase during the nine months ended September 30, 2021 was due to 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 $85.6 million and $254.8 million for the three and nine months ended September 30, 2021, compared to $87.2 million and $191.2 million for the three and nine months ended September 30, 2020. Excluding non-cash compensation, the net loss for the three and nine months ended September 30, 2021 was approximately $71.6 million and $207.8 million, compared to a net loss of $58.8 million and $144.4 million for the three and nine months ended September 30, 2020.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $381.4 million as of September 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, November 4, 2021, at 8:30 AM ET, to discuss the Company’s third quarter ended September 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 and ublituximab monotherapy in RMS and, if approved, commercializing the combination regimen in CLL and ublituximab monotherapy in RMS; the timing of 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.

All forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks and 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, as well as 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 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 September 30,		Nine months ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue				
Product revenue, net	$1,992	$--	$4,254	$--
License revenue	38	38	114	114
Total revenue	2,030	38	4,368	114
Costs and expenses:				
Cost of product revenue	292	--	580	--
Research and development:				
Noncash compensation	4,534	4,618	19,061	8,150
Other research and development	47,433	45,846	140,872	114,785
Total research and development	51,967	50,464	159,933	122,935
Selling, general and administrative:				
Noncash compensation	9,463	23,712	27,857	38,618
Other selling, general and administrative	25,436	11,584	67,821	25,373
Total selling, general and administrative	34,899	35,296	95,678	63,991
Total operating expenses	87,158	85,760	256,191	186,926
Operating loss	(85,128)	(85,722)	(251,823)	(186,812)

Other expense (income):				
Interest expense	1,038	1,610	4,559	5,038
Other income	(529)	(169)	(1,619)	(687)
Total other expense (income), net	509	1,441	2,940	4,351
Consolidated net loss	$(85,637)	$(87,163)	$(254,763)	$(191,163)
Net loss per common share:				
Basic and diluted	$(0.65)	$(0.73)	$(1.93)	$(1.70)
Weighted average shares of common stock outstanding:				
Basic and diluted	132,353,119	119,176,336	132,109,912	112,380,784

Condensed Balance Sheet Information (in thousands):

	September 30, 2021 (Unaudited)	**December 31, 2020***
Cash, cash equivalents and investment securities	381,400	605,426
Total assets	409,687	625,642
Accumulated deficit	(1,235,359)	(980,597)
Total equity	311,517	519,350

* Condensed from audited financial statements