TG Therapeutics Provides Business Update and Reports Fourth Quarter and Year-End 2021 Financial Results

March 1, 2022

Conference call to be held today, Tuesday, March 1, 2022, at 8:30 AM ET

NEW YORK, March 01, 2022 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the fourth quarter and year ended December 31, 2021, and recent company developments, along with a business outlook for 2022.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, "While we've faced numerous challenges over the last several months, we continued to progress our programs forward toward commercialization. With both MS and CLL BLA/sNDA submissions pending at the FDA, we continue to see 2022 as potentially the most transformative year in the Company's history." Mr. Weiss continued, "We are looking forward to the upcoming ODAC meeting where we can showcase the clinical profile of UKONIQ® monotherapy in its approved indications and in combination with ublituximab in CLL. We are also very excited about the evolving profile of ublituximab and its potential role in the treatment of RMS. We continue to receive positive feedback from the MS community about the safety, efficacy and one hour infusion offered by ublituximab."

2021 Highlights & Recent Developments

Ublituximab in Multiple Sclerosis

- U.S. Food and Drug Administration (FDA) accepted the Biologics License Application (BLA) for ublituximab, as a treatment for patients with relapsing forms of multiple sclerosis (RMS) and set a Prescription Drug User Fee Act (PDUFA) goal date of September 28, 2022.
- Presented positive results, including new analyses, from the ULTIMATE I and II Phase 3 trials at the 2021 Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and at the 2022 Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) annual forum. 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, multiple sclerosis functional composite (MSFC) score, neutralizing antibodies and antidrug antibodies, and pharmacodynamics of B-cell depletion.

Ublituximab plus UKONIQ® (umbralisib) (U2) in Chronic Lymphocytic Leukemia

- FDA accepted 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. FDA notified the Company that it plans to host a meeting of the Oncologic Drugs Advisory Committee (ODAC), in connection with its review of the pending BLA/sNDA for U2, in the March/April 2022 timeframe. Due to the pending ODAC meeting, the Company does not expect a decision on the BLA/sNDA by the current PDUFA goal date of March 25, 2022.
- Related to the concerns giving rise to the ODAC, FDA imposed a partial clinical hold on studies of U2 and its components in CLL and NHL.

UKONIQ 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 $6.5 million in total net UKONIQ revenue from launch through the end of Q4 2021, approximately ten 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.

TG-1701 in B-cell Malignancies

- Presented updated data on TG-1701, our investigational bruton tyrosine kinase (BTK) inhibitor, as a monotherapy and in combination with U2 in patients with B-cell malignancies at the 2021 American Society of Hematology (ASH) annual meeting.

Strengthened Cash Position

- Ended the year with more than $350 million in cash, cash equivalents and investment securities.

Key Objectives for 2022

- Obtain a favorable outcome at the upcoming ODAC meeting.
- Obtain FDA approval of U2 in CLL and SLL.
- Obtain FDA approval of ublituximab in RMS.
- 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 Fourth Quarter and Full Year 2021

- **Product Revenue, net:** Product revenue, net was approximately $2.3 million and $6.5 million for the three and twelve months ended December 31, 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 $62.6 million and $222.6 million for the three and twelve months ended December 31, 2021, compared to $43.0 million and $165.9 million for the three and twelve months ended December 31, 2020. The increase was due primarily to an increase in manufacturing expenses, as well as an increase in non-cash compensation R&D expense during the twelve months ended December 31, 2021 over the comparable period in 2020.

- **SG&A Expenses:** Total selling, general and administrative (SG&A) expense was $32.4 million and $128.1 million for the three and twelve months ended December 31, 2021, and $43.9 million and $107.9 million for the three and twelve months ended December 31, 2020. The increase during the twelve months ended December 31, 2021 was primarily attributable 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/SLL and ublituximab in RMS. The decrease during the three months ended December 31, 2021 was primarily related to non-cash compensation expense related to milestone-based vesting of restricted stock grants during the comparable period in 2020.

- **Net Loss:** Net loss was $93.3 million and $348.1 million for the three and twelve months ended December 31, 2021, compared to $88.2 million and $279.4 million for the three and twelve months ended December 31, 2020. Excluding non-cash compensation, the net loss for the three and twelve months ended December 31, 2021 was approximately $79.0 million and $286.8 million, compared to a net loss of $54.7 million and $199.1 million for the three and twelve months ended December 31, 2020.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $350.3 million as of December 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, March 1, 2022, at 8:30 AM ET, to discuss the Company’s fourth quarter and year-end 2021 financial results and provide a business outlook for 2022.

In order 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 replay at www.tgtherapeutics.com, 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 three 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® (umbralisib);

plans and timelines for FDA review of the marketing applications for ublituximab in combination with umbralisib (U2) in chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) and ublituximab in relapsing forms of multiple sclerosis (RMS) and, if approved, commercializing U2 and ublituximab; 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 the Company's future cash position.

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: the risk that the outcome of the planned ODAC meeting regarding UKONIQ in its currently approved indications and U2 in CLL is not favorable, or, even if favorable, the FDA does not approve U2 or does so in a narrowly defined population or imposes certain restrictions or warnings that negatively impact the commercial potential of U2 in CLL, the currently approved indications for UKONIQ, or any future indications for UKONIQ or ublituximab; the risk that we are not able to maintain marketing authorization for UKONIQ in the U.S., including the risk we may fail to satisfy post-approval regulatory requirements, such as the submission of sufficient data from a confirmatory clinical study; the risk that the FDA does not approve ublituximab in RMS; our ability to build upon our commercial infrastructure to successfully commercialize U2 in CLL and SLL and ublituximab in RMS, if approved, and continue to market UKONIQ in its currently approved indications; our ability to meet 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, U2, and ublituximab; ;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 (including efficacy and safety) are analyzed; the risk that preclinical and clinical results for the Company's drug candidates may not support further development of such drug candidates; the Company's reliance on third parties for manufacturing, distribution and supply, and a range of other support functions for our clinical and commercial products, including UKONIQ and ublituximab; the timing of completion of our ongoing clinical trials and initiation of future clinical trials, including the risk that FDA may not remove the partial clinical holds on studies evaluating t U2 and its components in CLL and non-Hodgkin lymphoma; 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 December 31,		Year ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Product revenue, net	$2,283	$--	$6,537	$--
License revenue	38	38	152	152
Total revenue	2,321	38	6,689	152
Costs and expenses:				
Cost of product revenue	210	--	790	--
Research and development:				
Noncash compensation	4,986	5,811	24,047	13,962
Other research and development	57,660	37,149	198,532	151,934
Total research and development	62,646	42,960	222,579	165,896
Selling, General and administrative:				
Noncash compensation	9,370	27,709	37,227	66,327
Other selling, general and administrative	23,042	16,150	90,863	41,523
Total selling, general and administrative	32,412	43,859	128,090	107,850
Total costs and expenses	95,268	86,819	351,459	273,746

Operating loss	(92,947)	(86,781)	(344,770)	(273,594)
Other expense (income):				
Interest expense	1,079	1,291	5,638	6,329
Other expense (income)	(688)	145	(2,307)	(542)
Total other expense, net	391	1,436	3,331	5,787
Net loss	$(93,338)	$(88,217)	$(348,101)	$(279,381)
Basic and diluted net loss per common share	$(0.70)	$(0.71)	$(2.63)	$(2.42)
Weighted average shares used in computing basic and diluted net loss per common share	132,557,597	124,096,131	132,222,753	115,333,693

Condensed Balance Sheet Information (in thousands):

	December 31, 2021 (Unaudited)	December 31, 2020*
Cash, cash equivalents and investment securities	$350,296	$605,426
Total assets	379,629	625,642
Accumulated deficit	(1,328,698)	(980,597)
Total equity	237,153	519,350

* Condensed from audited financial statements