TG Therapeutics Provides Business Update and Reports Fourth Quarter and Year-End 2020 Financial Results

March 2, 2021

Conference call to be held today, Tuesday, March 2, 2021 at 8:30 AM ET

NEW YORK, March 02, 2021 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the fourth quarter and year ended December 31, 2020 and recent company developments, along with a business outlook for 2021.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "2020 was a year of data and regulatory execution for us as we delivered results from our UNITY-NHL study that led to the approval of UKONIQ in relapsed/refractory MZL and FL and from UNITY-CLL that will be used to support the current rolling BLA submission for ublituximab in combination with umbralisib for patients with CLL. We also announced the top line results from our ULTIMATE MS Phase 3 trials that will be used to support a BLA submission for ublituximab in MS. These successful outcomes were made possible by the hard work of everyone at TG over many years and has positioned us for an exciting 2021." Mr. Weiss continued, "With the UKONIQ launch underway, we are excited to keep the momentum going and expect this year to complete our BLA submission for U2 in CLL, present final results from the ULTIMATE trials and then submit a BLA for ublituximab in MS, and continue to advance our triple therapy combination trials and our early pipeline."

2020 Highlights & Recent Developments

- **FDA Accelerated Approval of UKONIQ™ (umbralisib) in Relapsed/Refractory MZL & FL**
  - Received accelerated approval from the U.S. Food and Drug Administration (FDA) for UKONIQ 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.
  - Presented umbralisib monotherapy results from the UNITY-NHL Phase 2b trial in patients with relapsed or refractory MZL, FL and small lymphocytic lymphoma (SLL) at the 62nd American Society of Hematology (ASH) annual meeting.
  - Received orphan drug designation (ODD) from the FDA for umbralisib for the treatment of FL.
- **Chronic Lymphocytic Leukemia**
  - Presented results from the UNITY-CLL Phase 3 trial at the 62nd ASH annual meeting showing the trial met its primary endpoint of ublituximab and umbralisib (U2) significantly improving progression-free survival (PFS) over obinutuzumab plus chlorambucil.
  - Initiated 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.
  - Granted Fast Track Designation by the FDA for the combination of U2 for the treatment of adult patients with CLL.
  - Presented data from the triple combination of U2 plus venetoclax in patients with relapsed or refractory (R/R) CLL and data from the combination of U2 plus TG-1701, the Company's BTK inhibitor, in patients with R/R CLL or B-cell lymphoma, at the 62nd ASH annual meeting.
  - Published final results from the Phase 3 GENUINE trial evaluating ublituximab in combination with ibrutinib, in patients with relapsed or refractory high-risk CLL, in The Lancet Haematology.
- **Multiple Sclerosis**
  - Announced that the Phase 3 ULTIMATE I & II 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).
  - Published results from the multicenter Phase 2 trial evaluating ublituximab in RMS, in the Multiple Sclerosis Journal.

- **Strengthened Cash Position**
  - Ended the year with more than $600 million in cash, cash equivalents and investment securities.

Key Objectives for 2021

- Continue the commercialization of UKONIQ in relapsed/refractory MZL and FL and expand commercialization capabilities in preparation for a potential launch of ublituximab
- Present results from the ULTIMATE I & II Phase 3 trials evaluating ublituximab in RMS and prepare a BLA submission
- Complete the rolling BLA submission of ublituximab, in combination with umbralisib, for the treatment of patients with CLL
- Complete enrollment in the ULTRA-V Phase 2b trial and begin a 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 Fourth Quarter and Full Year 2020

- **R&D Expenses:** Other research and development (R&D) expense (not including non-cash compensation) was $37.1 million and $151.9 million for the three and twelve months ended December 31, 2020, respectively, compared to $29.5 million and $148.3 million for the three and twelve months ended December 31, 2019, respectively. The increase in R&D expense during the year ended December 31, 2020 is primarily attributable to an increase in licensing milestones as well as clinical trial and personnel expense of approximately $34.4 million, partially offset by a decrease in manufacturing expense of approximately $30.6 million. We expect our other research and development costs to remain at consistent levels throughout 2021.

- **G&A Expenses:** Other general and administrative (G&A) expense (not including non-cash compensation) was $16.2 million and $41.5 million for the three and twelve months ended December 31, 2020, respectively, as compared to $2.9 million and $9.5 million for the three and twelve months ended December 31, 2019, respectively. The increase during the three and twelve months ended December 31, 2020 was due primarily to commercialization costs, including personnel, incurred in preparation for the U.S. launch of UKONIQ. We expect our other general and administrative expenses to increase modestly during 2021 in preparation for our launch of ublituximab.

- **Net Loss:** Net loss was $88.2 million and $279.4 million for the three and twelve months ended December 31, 2020, respectively, compared to a net loss of $39.6 million and $172.9 million for the three and twelve months ended December 31, 2019, respectively. The net loss for the twelve months ended December 31, 2020 included approximately $21.0 million of one-time milestone expenses related to our license agreements. Excluding non-cash compensation, the net loss for the three and twelve months ended December 31, 2020 was approximately $54.7 million and $199.1 million, respectively, compared to a net loss of $34.0 million and $161.5 million for the three and twelve months ended December 31, 2019, respectively.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $605.4 million as of December 31, 2020, 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 2, 2021, at 8:30 AM ET, to discuss the Company’s fourth quarter and year-end 2020 financial results and provide a business outlook for 2021.

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 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 umbralisib and, if approved, commercializing the combination regimen; the initiation of clinical trials or the results of ongoing and planned clinical trials; and the potential benefits of any of the Company's current or future approved drugs or drug candidates in treating patients.

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 and maintain a commercial infrastructure, and to successfully launch, market and sell UKONIQ or future products, if approved; 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 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 complete regulatory submissions within the timelines projected, including completion of the rolling BLA submission for ublituximab in combination with umbralisib in CLL; our ability to obtain, or to obtain within the timeline projected, marketing authorization for our product candidates, and to maintain marketing authorization for UKONIQ, including the risk we may fail to satisfy post-approval regulatory requirements, such as the submission of sufficient data from a confirmatory clinical study; our ability to successfully complete analyses of our clinical study results and present data within the timeframes projected, including the risk that we do not present data from the ULTIMATE I & II trials as currently planned; 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; 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 December 31,		Year ended December 31,	
	2020	**2019**	**2020**	**2019**
License revenue	$ 38	$ 38	$ 152	$ 152
Costs and expenses:				
Research and development:				
Noncash stock expense associated with in-licensing agreements	--	--	--	100
Noncash compensation	5,811	1,488	13,962	5,811
Other research and development	37,149	29,454	151,934	148,269
Total research and development	42,960	30,942	165,896	154,180
General and administrative:				
Noncash compensation	27,709	4,133	66,327	5,523
Other general and administrative	16,150	2,923	41,523	9,504

Total general and administrative	43,859	7,056	107,850	15,027
Total costs and expenses	86,819	37,998	273,746	169,207
Operating loss	(86,781)	(37,960)	(273,594)	(169,055)
Other expense (income):				
Interest expense	1,291	1,899	6,329	5,287
Other expense (income)	145	(288)	(542)	(1,471)
Total other expense, net	1,436	1,611	5,787	3,816
Net loss	$ (88,217)	$ (39,571)	$ (279,381)	$ (172,871)
Basic and diluted net loss per common share	$ (0.71)	$ (0.44)	$ (2.42)	$ (1.96)
Weighted average shares used in computing basic and diluted net loss per common share	124,096,131	95,659,624	115,333,693	88,368,844

Condensed Balance Sheet Information (in thousands):

	December 31, 2020 (Unaudited)	December 31, 2019*
Cash, cash equivalents and investment securities	$ 605,426	$ 140,435
Total assets	625,642	163,014
Accumulated deficit	(980,597)	(701,216)
Total equity	519,350	38,615

* Condensed from audited financial statements