



TG Therapeutics Provides Business Update and Reports Fourth Quarter and Year-End 2019 Financial Results

March 3, 2020

Conference call to be held today, Tuesday, March 3, 2020 at 8:00 AM ET

NEW YORK, March 03, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTx) today announced its financial results for the fourth quarter and year ended December 31, 2019 and recent company developments, along with a business outlook for 2020.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "2019 was a transformational year for TG as we were able to report positive outcomes for umbralisib in both previously treated marginal zone lymphoma and follicular lymphoma from the UNITY-NHL trial. We also confirmed a submission pathway with the FDA and early this year commenced a single rolling submission based on these data, which we hope to complete in the first half of this year." Mr. Weiss continued, "Looking forward, we expect 2020 to be yet another impactful year as we await the topline results from our Phase 3 programs in CLL and MS and potentially our first FDA approval around year-end."

2019 Highlights & Recent Developments

- **Marginal Zone Lymphoma & Follicular Lymphoma:**

- Received breakthrough therapy designation (BTD) for patients with marginal zone lymphoma (MZL) who have received at least one prior therapy including an anti-CD20 regimen, and orphan drug designation for umbralisib for the treatment of patients with MZL.
- Announced positive outcome from the MZL cohort of the UNITY-NHL Phase 2b trial, which met the primary endpoint of Overall Response Rate (ORR), as determined by Independent Review Committee (IRC).
- Presented interim safety and efficacy data from the MZL cohort of UNITY-NHL during oral presentations at the American Association of Cancer Research (AACR) annual meeting, the 55th American Society of Clinical Oncology (ASCO) annual meeting and the 2019 International Conference on Malignant Lymphoma (ICML).
- Announced positive outcome from the follicular lymphoma (FL) cohort of the UNITY-NHL Phase 2b trial, with ORR results meeting the Company's prespecified 40 – 50% target, as determined by IRC. The Company plans to present the data at a future medical conference.
- Received guidance from the FDA allowing submission of a single New Drug Application (NDA) for MZL and FL indications. In January 2020, a rolling NDA submission for umbralisib to treat adult patients with previously treated MZL and FL was initiated, with completion of submission targeted for first half of 2020.

- **Chronic Lymphocytic Leukemia:**

- Awaiting topline progression free survival (PFS) results from the Company's Phase 3 UNITY-CLL trial evaluating "U2" (the combination of umbralisib and ublituximab) in patients with frontline and previously treated chronic lymphocytic leukemia (CLL).
- Final long-term results from the Phase 3 GENUINE study demonstrated that ublituximab in combination with ibrutinib improved PFS, as determined by IRC.
- Presented triple therapy data at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition from the Phase 1/2 study of ublituximab in combination with umbralisib and venetoclax, in patients with relapsed/refractory CLL, during an oral session.

- **Multiple Sclerosis:**

- Updated Phase 2 extension trial data for ublituximab in relapsing forms of multiple sclerosis (RMS), as well as the ULTIMATE I & II Phase 3 RMS program study design and demographic data, were presented at the 35th Annual Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).
- Awaiting topline data from the Company's Phase 3 ULTIMATE I & II trials evaluating ublituximab in patients with RMS.

- **Early Pipeline:**

- TG-1801: Commenced a Phase 1 first-in-human, dose-escalation study of TG-1801, the Company's anti-CD47/CD19 bispecific antibody, in patients with relapsed or refractory B-cell lymphoma and presented the first preclinical data of TG-1801 at the 24th European Hematology Association (EHA) annual congress.
- TG-1701: Presented the first clinical data from TG-1701, the Company's once daily, oral, BTK inhibitor, as a single agent and as a triple therapy in combination with U2 at ASH 2019.

Key Objectives for 2020

- Report topline PFS results from the Phase 3 UNITY-CLL trial evaluating U2 in patients with frontline and previously treated CLL, and if successful, target a potential New Drug Application (NDA)/Biologics Licensing Application (BLA) submission by year-end.
- Complete rolling NDA submission for umbralisib in patients with previously treated MZL and FL, in the first half of 2020.
- Report topline results from the Phase 3 ULTIMATE I & II trials in RMS, in the second half of 2020.
- 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 2019

- **R&D Expenses:** Other research and development (R&D) expense (not including non-cash compensation and non-cash in-licensing expense) was \$29.5 million and \$148.3 million for the three and twelve months ended December 31, 2019, respectively, compared to \$51.1 million and \$149.8 million for the three and twelve months ended December 31, 2018, respectively. The decrease in R&D expense is primarily attributable to the winding down of our late-stage clinical development programs during the year ended December 31, 2019.
- **G&A Expenses:** Other general and administrative (G&A) expense (not including non-cash compensation) was \$2.9 million and \$9.5 million for the three and twelve months ended December 31, 2019, respectively, as compared to \$1.7 million and \$7.9 million for the three and twelve months ended December 31, 2018, respectively.
- **Net Loss:** Net loss was \$39.6 million and \$172.9 million for the three and twelve months ended December 31, 2019, respectively, compared to a net loss of \$53.9 million and \$173.5 million for the three and twelve months ended December 31, 2018, respectively. Excluding non-cash items, the net loss for the three and twelve months ended December 31, 2019 was approximately \$34.0 million and \$161.4 million, respectively, compared to a net loss of \$52.4 million and \$156.6 million for the three and twelve months ended December 31, 2018, respectively.
- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were \$140.4 million as of December 31, 2019. The Company believes its cash, cash equivalents and investment securities on hand as of December 31, 2019, will be sufficient to fund the Company's planned operations well into 2021.

Conference Call Information

The Company will host a conference call today, March 3, 2020, at 8:00 AM ET, to discuss the Company's fourth quarter and year-end 2019 financial results and provide a business outlook for 2020.

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 Year-End 2019 Earnings Call. 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 biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the company is developing multiple therapies targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. TG Therapeutics is also developing umbralisib (TGR-1202), an oral, once-daily dual inhibitor of PI3K-delta and CK1-epsilon, which may lead to a differentiated safety profile. Both ublituximab and umbralisib, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with ublituximab also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought into Phase 1 clinical development, TG-1501, its anti-PD-L1 monoclonal antibody, TG-1701, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor and TG-1801, its anti-CD47/CD19 bispecific antibody. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included in this press release may be 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. 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 are the following: the risk that the interim data (the "Interim Results") from the UNITY-NHL MZL cohort will not be reproduced when the final analysis is conducted on all patients, including the risk that the final results will demonstrate a lower ORR and/or enhanced toxicities, which may not support a filing for accelerated approval; the risk that the final analysis of the UNITY-NHL MZL or FL cohorts will be insufficient to support a filing for accelerated approval; the risk that umbralisib will not receive accelerated approval based on data from the UNITY-NHL MZL or FL cohorts even if the final results are deemed positive by the Company and support a filing for accelerated approval; the risk that duration of response or progression free survival data from the UNITY-NHL cohort when available for all patients will not be positive; the risk that safety issues will arise when the final safety data are cleaned and analyzed for all patients in the UNITY-NHL MZL or FL cohorts; the risk that the positive Interim Results from the UNITY-NHL MZL or FL cohorts will not be reproduced in other cohorts of the UNITY-NHL study or in other studies being conducted by the Company; the risk that our belief that umbralisib has a differentiated safety profile will not be shared by physicians or the FDA or will not be reproduced in the final analysis of the UNITY-NHL MZL or FL cohorts, in other cohorts of the UNITY-NHL study, in the UNITY-CLL study or in any other of our on-going studies; the risk that PFS data from UNITY-CLL will not be positive or, if positive, will not be accepted for filing by the FDA, or

ultimately receive approval for the combination of U2 in CLL; the risk that the anticipated timeline for completing the submission of the umbralisib NDA in MZL and FL based on the UNITY NHL data or for regulatory review of such submission and the timeline for data releases, submission, and regulatory approval for UNITY-CLL and ULTIMATE-MS trials, or the projected advancements of our early pipeline will be delayed due to a variety of factors, including, without limitation, available resources, program reprioritization, slower than expected event rates for UNITY-CLL and/or requests from FDA or foreign regulators; the risk that we are not able to successfully and cost effectively complete all the preclinical, clinical and CMC requirements necessary to support accelerated approval; the risk that we are unable to manage cash in line with our expectations and meet our development milestones and/or continue our operations without raising capital; the risk that we are unable to raise capital on acceptable terms; the risk that early clinical trial results that may have influenced our decision to proceed with additional clinical trials may not be replicated; and other risk factors identified from time to time in our reports filed with the 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 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,	
	2019	2018	2019	2018
License revenue	\$38	\$38	\$152	\$152
Costs and expenses:				
Research and development:				
Noncash stock expense associated with in-licensing agreements	--	--	100	4,000
Noncash compensation	1,488	1,207	5,811	5,598
Other research and development	29,454	51,069	148,269	149,793
Total research and development	30,942	52,276	154,180	159,391
General and administrative:				
Noncash compensation	4,133	251	5,523	7,288
Other general and administrative	2,923	1,661	9,504	7,873
Total general and administrative	7,056	1,912	15,027	15,161
Total costs and expenses	37,998	54,188	169,207	174,552
Operating loss	(37,960)	(54,150)	(169,055)	(174,400)
Other expense (income):				
Interest expense	1,899	221	5,287	877
Other income	(288)	(510)	(1,471)	(1,795)
Total other expense (income), net	1,611	(289)	3,816	(918)
Net loss	\$(39,571)	\$(53,861)	\$(172,871)	\$(173,482)
Basic and diluted net loss per common share	\$(0.44)	\$(0.68)	\$(1.96)	\$(2.30)

Weighted average shares used in computing basic and diluted net loss per common share

95,659,624	78,634,710	88,368,844	75,466,813
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Consolidated Balance Sheet Information (in thousands):

	December 31, 2019 (Unaudited)	December 31, 2018
Cash, cash equivalents and investment securities	\$140,435	\$68,901
Total assets	163,014	83,616
Accumulated deficit	(701,216)	(528,345)
Total equity	38,615	24,036



Source: TG Therapeutics, Inc.