

# TG Therapeutics, Inc. Announces Fourth Quarter and Year-End 2014 Financial Results and Business Update

## Investor Conference Call to be Held Thursday, March 12, 2015 at 8:30am ET

NEW YORK, March 11, 2015 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX) today announced its financial results for the fourth quarter and year ended December 31, 2014 and provided recent company developments along with a business outlook for 2015.

"2014 was an exciting and productive year for TG Therapeutics as we continued to aggressively move forward with the development of our lead drug candidates, TG-1101 and TGR-1202. We ended the year on a high note presenting a significant amount of data at the American Society of Hematology meeting. In addition to very encouraging data on the combination of TG-1101 and TGR-1202, we also presented data demonstrating high response rates for the combination of TG-1101 and ibrutinib, data that we believe supports our now on-going Phase 3 trial of that combination being conducted under a Special Protocol Assessment," stated Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer. "With TG-1101 and TGR-1202, we believe we have two drug candidates each with safety and efficacy profiles that are differentiated and uniquely suited for combination therapy, both with other novel agents, but most importantly, together in our proprietary '1303' combination regimen. For 2015, we plan to focus on recruitment into our GENUINE Phase 3 study, as well as our planned first Phase 3 clinical trial of the combination of TG-1101 and TGR-1202, with a longer term vision toward additional combination trials with the goal of continuing to push toward better patient outcomes."

## **Recent Developments & Highlights**

- Commenced the GENUINE Phase 3 Clinical Trial of TG-1101 in combination with ibrutinib
- Presented updated data from the Phase 2 trial of TG-1101 in combination with ibrutinib at the 56th American Society of Hematology (ASH) Annual Meeting in December, highlights from the presentation included:
  - 95% (19/20) Overall Response Rate (ORR) in Patients with High-Risk CLL, the patient population to be studied in GENUINE Phase 3 Clinical trial
  - Combination of TG-1101 + ibrutinib was well tolerated with limited Grade 3/4 events
- Presented updated data from the Phase 1 dose escalation trial of TGR-1202 at ASH in December, highlights from the presentation included:
  - 93% of evaluable CLL patients (13/14) treated at therapeutic dose levels achieved a nodal PR, with 50% (7/14) achieving an objective response per iwCLL (Hallek 2008) criteria
  - No drug related hepatic toxicity or colitis observed to date with a median time on study of approximately 6 months and some patients on study for over 1.5 years
- Presented preliminary data from Phase 1/2 dose escalation study of TG-1101 in combination with TGR-1202 at ASH in December, highlights from the presentation included:
  - 100% of evaluable CLL/SLL patients (9/9) had nodal reductions, with 6 of 9 patients achieving an objective response per iwCLL (Hallek 2008) criteria and the remaining patients on study awaiting further assessment
  - 43% ORR in Diffuse Large B-cell Lymphoma (DLBCL) (3/7), with 2 patients achieving an independently confirmed Complete Response (CR)
  - The combination of TG-1101, TGR-1202, and ibrutinib ("Triple Therapy") was safely administered to 5 patients, and no Grade 3 or 4 events were observed
  - 2 of the first 3 evaluable patients responded to the Triple Therapy, including an ibrutinib-refractory and rituximabrefractory patient with Follicular Lymphoma
- Entered into a global collaboration to develop and commercialize anti-PD-L1 and anti-GITR antibody research programs in the field of hematologic malignancies

## Key Objectives for 2015

- Aggressively recruit into the GENUINE Phase 3 Clinical Trial of TG-1101 in combination with ibrutinib
- Commence additional combination Phase 3 clinical trials, particularly for the Company's proprietary "1303" combination
  of TG-1101 plus TGR-1202 in patients with Chronic Lymphocytic Leukemia (CLL) and non-Hodgkin's Lymphoma (NHL)
- Launch new triple therapy combination trials in addition to the currently enrolling Phase 1/2 trial of TG-1101 plus TGR-1202 plus ibrutinib
- Commence clinical development for the Company's IRAK4 inhibitor program, expected in the second half of 2015
- Commence clinical development program for the treatment of autoimmune diseases
- Present updated data on Phase 1 and 2 clinical trials at major hematology/oncology conferences during 2015

## Financial Results for the Fourth Quarter and Full Year 2014

At December 31, 2014, the Company had cash, cash equivalents, investment securities, and interest receivable of \$78.9 million, as compared to \$45.4 million at December 31, 2013.

Pro-forma cash, cash equivalents, investment securities, and interest receivable as of December 31, 2014 are approximately \$98.2 million, including \$19.3 million of net proceeds from the utilization of the Company's at-the-market ("ATM") sales facility during the first quarter of 2015.

Our consolidated net loss for the year ended December 31, 2014, excluding non-cash items and a one-time upfront cash milestone payment, was approximately \$25.3 million. The consolidated net loss for the year ended December 31, 2014, inclusive of the items above, was \$55.8 million, or \$1.64 per diluted share, compared to a consolidated net loss of \$20.5 million for the year ended December 31, 2013, representing an increase in consolidated net loss of \$35.3 million. The increase in consolidated net loss of \$35.3 million. The increase in consolidated net loss during the year ended December 31, 2014 was primarily the result of \$8.1 million of expense (\$4.1 million of which was non-cash stock expense) recorded in conjunction with the Company's conversion from a JV agreement to a licensing agreement for TGR-1202, \$1.2 million in non-cash stock expense recorded in conjunction with the licensing arrangement for the IRAK4 inhibitors program, and a \$15.9 million increase in non-cash compensation expense related to equity incentive grants. Exclusive of the items mentioned above, other research and development expenses for TG-1101 and TGR-1202 increased \$7.1 million and \$3.8 million, respectively, over the comparable period in 2013.

Our consolidated net loss for the fourth quarter ended December 31, 2014, excluding non-cash items, was approximately \$13.8 million, which included approximately \$8.9 million of manufacturing and CMC readiness expenses in preparation for Phase 3 clinical trials and commercialization. The consolidated net loss for the fourth quarter ended December 31, 2014, inclusive of non-cash items, was \$18.8 million, or \$0.48 per diluted share, compared to a consolidated net loss of \$5.7 million during the comparable quarter in 2013, representing an increase in consolidated net loss of \$13.1 million. The increase in consolidated net loss during the fourth quarter ended December 31, 2014 was primarily the result of other research and development expenses for TG-1101 and TGR-1202 increasing \$9.0 million and \$0.2 million, respectively, over the comparable period in 2013. The increase in other research and development expenses related to TG-1101 was primarily the result of increased manufacturing and clinical trial expenses in preparation for the launch of Phase 3 registration programs. Also contributing to the increase in consolidated net loss during the quarter ended December 31, 2014 was a \$4.1 million increase in non-cash compensation expense related to equity incentive grants.

The Company will host an investor conference call Thursday, March 12, 2015, at 8:30am ET, to discuss the Company's 2014 financial results and provide a business outlook for 2015.

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 2014 Earnings Call. A live webcast of this presentation will be available on the Events page, located within the Investors & Media section, of the Company's website at <u>www.tgtherapeutics.com</u>. An audio recording of the conference call will also be available for replay at <u>www.tgtherapeutics.com</u>, 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 two therapies targeting hematological malignancies. TG-1101 (ublituximab) 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 TGR-1202, an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202 are in clinical development for patients with hematologic malignancies. The Company also has a pre-clinical program to develop IRAK4 inhibitors, as well as an antibody research program to develop anti-PD-L1 and anti-GITR antibodies. TG Therapeutics is headquartered in New York City.

#### **Cautionary Statement**

Some of the statements included in this press release, particularly those with respect to anticipating future clinical trials, the timing of commencing or completing such trials and business prospects for TG-1101, TGR-1202, the IRAK4 inhibitor program, and the anti-PD-L1 and anti-GITR antibodies 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. Among the factors that could cause our actual results to differ materially are the following: our ability to successfully and cost-effectively complete pre-clinical and clinical trials for TG-1101, TGR-1202, the IRAK4 inhibitor program and the anti-PD-L1 and anti-GITR antibodies; the risk that early pre-clinical and clinical results that supported our decision to move forward with TG-1101, TGR-1202, the IRAK4 inhibitor program and the anti-PD-L1 and anti-GITR antibodies will not be reproduced in additional patients or in future studies; the risk that trends observed which underlie certain assumptions of future performance of TGR-1202 will not continue, the risk that TGR-1202 will not produce satisfactory safety and efficacy results to warrant further development following the completion of the current Phase 1 study; the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data produced from prior pre-clinical and clinical trials; the risk that trials will take longer to enroll than expected; our ability to achieve the milestones we project over the next year; our ability to manage our cash in line with our projections, 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 (Unaudited):

	Three Months Ended December 31,		Year Ended December 31,	
	2014	2013	2014	2013
License revenue	\$ 38,095	\$ 38,095	\$ 152,381	\$ 152,381
Costs and expenses:				
Research and development:				
Noncash stock expense associated with in-licensing agreements			5,350,094	
Noncash compensation	2,329,270	149,206	8,731,566	1,041,519
Other research and development	12,807,504	3,606,385	26,004,687	12,621,161
Total research and development	15,136,774	3,755,591	40,086,347	13,662,680
General and administrative:				
Noncash compensation	2,709,166	797,942	12,373,726	4,161,629
Other general and administrative	913,279	662,728	3,413,400	2,496,461
Total general and administrative	3,622,445	1,460,670	15,787,126	6,658,090
Impairment of in-process research and development		2,797,600		2,797,600
Total costs and expenses	18,759,219	8,013,861	55,873,473	23,118,370
Operating loss	(18,721,124)	(7,975,766)	(55,721,092)	<u>(22,965,989)</u>
Other (income) expense:				
Interest income	(16,741)	(15,768)	(55,049)	(30,822)
Other income		(108,894)	(95,427)	(108,894)
Interest expense	234,787	240,872	930,701	952,888

Change in fair value of notes payable	(142,741)	(2,428,124)	(720,040)	(3,300,951)
Total other (income) expense	75,305	(2,311,914)	60,185	(2,487,779)
Net loss	(18,796,429)	(5,663,852)	(55,781,277)	(20,478,210)
Basic and diluted net loss per common share	\$ (0.48)	\$ (0.19)	\$ (1.64)	\$ (0.81)
Weighted average shares used in computing basic and diluted net loss	20.042.044	20 440 042	24.000.000	05 440 004
per common share	38,913,211	29,440,013	34,068,926	25,413,964

#### **Balance Sheet Information:**

	December 31, 2014 December 31, 2013*		
	(Unaudited)		
Cash, cash equivalents, investment securities and interest receivable	\$ 78,861,334	\$ 45,431,532	
Total assets	86,746,890	48,112,390	
Accumulated deficit	(95,185,280)	(39,404,003)	
Total equity	80,101,884	40,054,492	

#### \* Condensed from audited financial statements.

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