

June 3, 2013

## **TG Therapeutics, Inc. Announces Presentation of Interim Results From Its Phase I/II Clinical Trial of Single-Agent Ublituximab (TG-1101) in Patients With Rituximab Relapsed/Refractory Non-Hodgkin's Lymphoma**

*TG-1101 Well Tolerated and Induced 50% Overall Response Rate (5/10)*

*40% of Rituximab-Refractory Patients (2/5) Achieve a Complete Response*

*100% of Marginal Zone Lymphoma Patients (3/3) Achieve a Complete or Partial Response*

NEW YORK, June 3, 2013 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (TGTX) today announced preliminary results from a Phase 1 clinical study of single-agent ublituximab (TG-1101) in patients with rituximab relapsed and/or refractory Non-Hodgkin's Lymphoma (NHL), presented at the American Society of Clinical Oncology Meeting on June 2, 2013. The poster presentation, entitled "A Phase I dose-escalation trial of ublituximab (TG-1101), a novel anti-CD20 monoclonal antibody (mAb), for rituximab relapsed/refractory B-cell lymphoma patients," was presented by Principal Investigator, Dr. Owen A. O'Connor of Columbia University (Abstract #8575). The poster is available on the Company's website ([www.tgtherapeutics.com](http://www.tgtherapeutics.com)) under the quick links section entitled "Publications."

### **PRELIMINARY DATA FROM THE DOSE ESCALATION PORTION OF PHASE I/II STUDY**

The poster presentation highlighted preliminary safety and efficacy data from 4 cohorts of 3 patients each at dose levels of 450mg, 600mg, 900mg and 1200mg. All 12 patients (7 Follicular (FL), 3 Marginal Zone (MZL) and 2 Mantle Cell Lymphoma (MCL)) were evaluable for safety while 10/12 patients were evaluable for efficacy (2 patients were too early for efficacy evaluation (TETE)). Among these 12 patients, the median number of prior therapies was 4 (range 2-6), with 100% and 75% of patients receiving at least 1 and 2 prior rituximab-based regimens, respectively. Fifty percent (50%) of enrolled patients were considered refractory to a rituximab-based regimen, defined as progressing on or within 6 months following their last rituximab-based regimen.

Ublituximab (TG-1101) was well tolerated with the majority of adverse events being Grade 1 and 2, with minimal Infusion Related Reactions (IRR) observed. Only one Grade 3 event was reported. All 12 patients completed all planned infusions. Infusion time decreased significantly from the first (mean of 4 hours) to the fourth and maintenance infusions (mean of ~ 1.5 hours).

The summary of response data is described below:

<u>Lymphoma Type</u>	<u>N</u>	<u>CR</u>	<u>PR</u>	<u>SD</u>	<u>PD</u>	<u>TETE</u>	<u>CR %</u>	<u>ORR %</u>
Follicular (FL)	7	1	1	3	1	1	17%	33%
Marginal Zone (MZL)	3	2	1				67%	100%
Mantle Cell (MCL)	2				1	1		
<b>Total</b>	<b>12</b>	<b>3</b>	<b>2</b>	<b>3</b>	<b>2</b>	<b>2</b>	<b>30%</b>	<b>50%</b>

*Abbreviations: Complete Response (CR); Partial Response (PR); Stable Disease (SD); Progressive Disease (PD); Overall Response Rate (ORR); Too Early to Evaluate (TETE); Rituximab (RTX)*

Median Progression-Free Survival (PFS) has not been reached. Responses were observed in both rituximab relapsed and refractory patients, including patients who have seen several lines of rituximab therapy. Of the 5 patients enrolled that were refractory to rituximab, 2 patients (40%) achieved a CR. Decreases in overall tumor volume were seen in 9/10 of the evaluable patients. Notably, 100% (3/3) of patients with Marginal Zone Lymphoma responded to ublituximab (TG-1101) therapy, two of which achieved a CR. Among the 5 responding patients, all achieved a response that was better than (n=4) or equal to (n=1) their prior rituximab-based treatment:

<u>Dose</u>	<u>Diagnosis</u>	<u>Prior RTX Therapies</u>	<u>RTX Status</u>	<u>RTX Response</u>	<u>Ublituximab Response</u>	<u>Months on Study</u>
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450	MZL	3	Refractory	PD	CR	10+
600	MZL	2	Relapsed	PR	CR	7+
900	MZL	1	Relapsed	SD	PR	5+
900	FL	1	Relapsed	PR	PR	6+
900	FL	3	Refractory	PD	CR	4+

*+ Patients still on study with continuing response*

Commenting on the Phase I data, Dr. Owen A. O'Connor, Director of Lymphoid Malignancies, Professor of Medicine and Experimental Therapeutics at Columbia Medical Center, New York Presbyterian Medical Center in NY, and Study Chair for the Phase I trial stated: "We are very impressed with the activity we've seen to date with ublituximab, especially with complete responses in patients who achieved a less than optimal response to rituximab, including patients with Marginal Zone Lymphoma, a subtype known to be a low CD20 expressing tumor. Ublituximab has been very well tolerated at all dose levels allowing patients to benefit from higher ublituximab doses and maintenance dosing without compromising safety."

Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer added, "While these results are early, we are very encouraged by the high observed response rates as well as the quality of such responses in terms of durability and in comparison to each patient's prior rituximab - based treatment, many of which included multi-drug regimens. These data are also consistent with the high response rates seen in our CLL Phase 1 study, previously reported. We look forward to aggressively recruiting patients to the expansion cohorts of this single agent TG-1101 study in order to better define the safety and efficacy demonstrated in this dose-escalation group, and to presenting data from these expansion cohorts at the American Society of Hematology meeting at the end of this year."

**ABOUT TG THERAPEUTICS, INC.**

TG Therapeutics is an innovative, clinical-stage biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. Currently, the company is developing two therapies targeting hematological malignancies. TG-1101 (ublituximab) is a novel, glycoengineered, third generation 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. TG Therapeutics is headquartered in New York City.

**Cautionary Statement**

Some of the statements included in this press release, particularly those anticipating future clinical trials and business prospects for TG-1101 and TGR-1202 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 and TGR-1202; the risk that early clinical results that supported our decision to move forward into expansion cohorts will not be reproduced once additional patients are treated with TG-1101; 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; 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](http://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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CONTACT: Jenna Bosco

Director- Investor Relations

TG Therapeutics, Inc.

Telephone: 212.554.4484

Email: [ir@tgtxinc.com](mailto:ir@tgtxinc.com)



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