
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **December 6, 2014**

TG Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-32639
(Commission File Number)

36-3898269
(IRS Employer Identification No.)

3 Columbus Circle, 15th Floor
New York, New York 10019
(Address of Principal Executive Offices)

(212) 554-4484
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
 - Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.
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Item 8.01. Other Events.

On December 6, December 8, and December 9, 2014, TG Therapeutics, Inc. issued press releases announcing certain data regarding its clinical studies of TGR-1202, TG-1101 in combination with ibrutinib, and TG-1101 in combination with TGR-1202, respectively. Copies of the press releases are being filed as Exhibits 99.1, 99.2 and 99.3 and incorporated in this Item by reference.

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits.

99.1 Press Release, dated December 6, 2014.

99.2 Press Release, dated December 8, 2014.

99.3 Press Release, dated December 9, 2014.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TG Therapeutics, Inc.
(Registrant)

Date: December 9, 2014

By: /s/ Sean A. Power
Sean A. Power
Chief Financial Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated December 6, 2014.
99.2	Press Release, dated December 8, 2014.
99.3	Press Release, dated December 9, 2014.

Interim Data from Phase 1 Dose Escalation Clinical Trial of TGR-1202, the Once-Daily PI3K Delta Inhibitor, Demonstrates Significant Clinical Activity and Lack of Hepatic Toxicity in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia and Non-Hodgkin's Lymphoma

- 93% (13/14) of evaluable CLL patients treated at dose levels $\geq 800\text{mg}$ of original formulation or any dose of the micronized formulation achieved a $>50\%$ reduction in nodal size (a nodal PR) and 50% (7/14) achieved a partial response per iwCLL (Hallek 2008) criteria
- 100% (6/6) of CLL and iNHL patients achieving TGR-1202 drug concentrations above 4,000ng/ml responded at the first or second efficacy assessment with at least a nodal PR for CLL or PR for iNHL; Expansion cohorts now open at 800mg QD for CLL and 1200mg QD for iNHL, the dose level that appears to provide patients (3/3) with drug concentrations $>4,000\text{ng/ml}$
- No drug related hepatic toxicity or colitis observed with 55 patients treated to date and median time on study of approximately 6 months and some patients on study for over 1.5 years
- TGR-1202 has been well-tolerated with no dose-related trends in adverse events observed and no MTD reached to date, dose escalation continues now at 1800mg QD

SAN FRANCISCO, CA, December 6, 2014-- TG Therapeutics, Inc. (Nasdaq:TGTX), today announced updated clinical results from its ongoing Phase I single agent dose escalation study of TGR-1202, the Company's oral, once-daily, PI3K delta inhibitor. Data from this Phase I study is being presented today at a poster session during the 56th American Society of Hematology (ASH) Annual Meeting and Exposition in San Francisco, CA.

Dr. Howard A. Burris, the Principal Investigator for the study and Chief Medical Officer and Executive Director of the Drug Development Program at the Sarah Cannon Research Institute in Nashville, TN stated, "We continue to be excited by the activity and safety seen with TGR-1202, particularly in patients with CLL. The absence to date of liver toxicity and colitis, which have been observed with other PI3K-delta inhibitors, is very encouraging. The overall safety profile demonstrated by TGR-1202 makes it well suited for combination therapy regimens. We are excited to expand enrollment in this Phase I study."

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "Today's data presentation on TGR-1202 in both an expanded number of patients and with longer treatment durations provides further confirmation of what we and investigators believe are best-in-class attributes in comparison to other PI3K-delta inhibitors both approved and in development. From an activity perspective, the nodal PRs and true PRs are shaping up to be comparable to the best single agent drugs for CLL and as we dose escalate we continue to see a dose and time response relationship further supporting our original hypothesis that we may be able to drive greater activity than other PI3k delta's due to our unique pharmacokinetic and safety profile. Given our focus in creating best-in-class novel combinations that offer a high level of activity with low toxicity, we are particularly encouraged by the continued absence of liver toxicity and lack of colitis seen to date with TGR-1202, especially considering that the median time on study for patients has been approximately 6 months and some patients have been on study for over a year and a half. Accordingly, we believe the single agent profile of TGR-1202 positions it well as an ideal agent for combination therapy, especially in combination with our proprietary, glycoengineered anti-CD20 monoclonal antibody, TG-1101 for which preliminary data will be presented on Tuesday morning."

OVERVIEW OF THE DATA PRESENTED ON TGR-1202

Today's poster presentation includes data from 55 patients with relapsed or refractory hematologic malignancies treated with TGR-1202 at doses ranging from 50 mg to 1800 mg QD of the initial formulation and 200 mg to 1200 mg of the recently introduced micronized formulation of TGR-1202, which exhibits enhanced absorption over the initial formulation.

Safety and Tolerability

TGR-1202 has been well-tolerated with no dose-related trends in adverse events observed and no MTD reached to date. Grade 3/4 events continue to be limited, with neutropenia (13%) and thrombocytopenia (7%) the only Grade 3/4 events occurring in >5% of patients. Notably, of the 55 patients evaluable for safety, no drug related hepatic (liver) toxicity or events of colitis have been observed, with the median time on study of approximately 6 months and some patients on daily TGR-1202 for over 1.5 years. To date, out of 55 patients treated with TGR-1202, only 2 (<4%) patients were withdrawn due to an adverse event (one deemed unrelated, and one possibly related to TGR-1202).

Clinical Activity

Significant clinical activity was observed in patients with CLL treated at doses ≥ 800 mg of the initial formulation of TGR-1202 or with any dose of the improved micronized formulation, with all (14/14) patients exhibiting significant nodal reductions. Thirteen of fourteen evaluable patients (93%) exhibited a nodal response (>50% reduction in nodal size) and 50% of patients (7/14) achieved a partial response per the iwCLL (Hallek 2008) criteria.

Among all disease types, 43 patients had been treated at doses ≥ 800 mg of the initial formulation of TGR-1202 or with any dose of the micronized formulation and were evaluable for efficacy (including patients who started at lower doses and were escalated), with 31/43 (72%) achieving a reduction in tumor burden with TGR-1202. In both CLL and indolent NHL (iNHL), an exposure/time/response relationship was noted where patients with higher TGR-1202 plasma concentrations on day 30 of treatment were observed to exhibit greater responses to TGR-1202 at early efficacy assessments. For instance, at drug concentrations >4000ng/ml, 100% (6/6) of subjects who exhibited such concentrations on day 30 of treatment (4 CLL and 2 iNHL) achieved rapid responses (either nPR or PR at first or second assessment). The concentration threshold for response appears to be moderately higher with iNHL than with CLL. Of the 3 iNHL responders, 2 patients exhibited concentrations >4,000ng/ml, while the third responder had lower TGR-1202 exposure and exhibited a longer time to response. An additional 9 patients of varying NHL histologies with lower initial TGR-1202 exposure remain on study with tumor burden reductions ranging from 19%-46%, pending further efficacy assessments. Additional responses were noted in patients with Hodgkin's lymphoma and Mantle Cell Lymphoma.

Next Dosing Cohorts

All patients (3/3) treated at 1200mg of the micronized formulation in the fed state achieved blood concentrations in excess of 4000ng/ml, the first dose level which appears to consistently provide blood concentrations above those target levels. To confirm these findings, the 1200mg micronized dose has been chosen for use in an expansion cohort in patients with NHL. Given activity observed in CLL at lower concentrations, a CLL expansion cohort is currently enrolling at 800mg micronized. Additionally, all patients currently on study have now been transitioned to the micronized formulation of TGR-1202.

PRESENTATION DETAILS

The posters being presented today for TGR-1202 include the following:

Title: TGR-1202, a Novel Once Daily PI3K δ Inhibitor, Demonstrates Clinical Activity with a Favorable Safety Profile, Lacking Hepatotoxicity, in Patients with Chronic Lymphocytic Leukemia and B-Cell Lymphoma.

- Abstract Number: 1984
- Session: 642. CLL: Therapy, excluding Transplantation: Poster I
- Date and Time: Saturday, December 6, 2014: 5:30 PM- 7:30 PM PT
- Location: West Building, Level 1
- Presenter: Howard A. Burris III, MD, Sarah Cannon Research Institute, Nashville, TN

Title: Complementary Targeting of PI3K and the Proteasome Causes Potent Inhibition of mTORC1 and NF-KappaB in Models of B- and T-Cell Lymphoma

- Abstract Number: 1770
- Session: 625. Lymphoma: Pre-Clinical – Chemotherapy and Biologic Agents: Poster I
- Date and Time: Saturday, December 6, 2014: 5:30 PM-7:30 PM PT
- Location: West Building, Level 1
- Presenter: Changchun Deng, MD, PhD, Columbia University Medical Center, New York, NY

A copy of the poster presentations are available on the Publications Page, located within the Pipeline section of the Company's website at www.tgtherapeutics.com.

EVENT WEBCAST DETAILS

The company will host an investor/analyst event Monday December 8, 2014 from 7:45pm PT – 9:00pm PT. This event will be audio webcast on the Events Page, located within the Investors & Media section of the Company's website at www.tgtherapeutics.com, as well as archived for future review. This event will also be broadcast via conference call. In order to access the conference line, please call 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), and reference Conference Title: TG Therapeutics 2014 Investor & Analyst Event.

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, also for B-cell malignancies and autoimmune diseases. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included in this press release, particularly those, anticipating results that might be achieved at higher doses of, and longer exposures to, TGR-1202, anticipating future clinical trials, the timing of commencing or completing such 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 pre-clinical and clinical results that supported our decision to move forward with TG-1101 and TGR-1202 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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CONTACT:

Jenna Bosco
Director- Investor Relations
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com

Data from Phase 2 Clinical Trial of TG-1101 (Ublituximab) and Ibrutinib Shows Compelling Clinical Activity in Patients with Previously Treated, High-Risk Chronic Lymphocytic Leukemia (CLL)

- 95% (19/20) Overall Response Rate (ORR) in Patients with High-Risk CLL, the patient population to be studied in recently announced Phase 3 Clinical Trial being conducted under Special Protocol Assessment (SPA)
- 87% (34/39) ORR per iwCLL criteria in all evaluable CLL patients plus an additional 10% of patients with a nodal PR or nodal reductions ranging from 20%-45% without disease progression
- 88% (7/8) ORR in all evaluable Mantle Cell Lymphoma (MCL) patients with a 38% (3/8) Complete Response rate
- Combination of TG-1101 + Ibrutinib well tolerated with limited Grade 3/4 events reported to date

SAN FRANCISCO, CA, December 8, 2014 TG Therapeutics, Inc. (Nasdaq: TGTX), today announced clinical results from its Phase 2 study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with ibrutinib (IMBRUVICA®), the oral BTK inhibitor from Pharmacyclics (Nasdaq: PCYC) and Janssen Biotech, Inc. Data from the Phase 2 study is being presented during the 56th Annual American Society of Hematology (ASH) meeting being held in San Francisco, CA.

The poster presentation includes data from 54 patients with relapsed and/or refractory CLL, SLL or MCL treated with TG-1101 at doses of 600 mg or 900 mg, in combination with ibrutinib at an oral daily dose of 420 mg for patients with CLL/SLL, and 560 mg for patients with MCL. High-risk CLL was defined as the presence of 17p del, 11q del and/or p53 mutation.

Dr. Jeff Sharman, Medical Director of Hematology Research for the US Oncology Network, and Study Chair for the Phase 2 trial stated: "We continue to be impressed with the clinical activity and safety profile of ublituximab in combination with ibrutinib, especially in the high-risk CLL patient group which we will be evaluating in the upcoming Phase 3 trial. This data not only shows ublituximab can be safely combined with ibrutinib, but also can induce rapid and deeper responses compared to prior trials of ibrutinib alone. I am very excited, along with the team of investigators at US Oncology, to lead the upcoming Phase 3 trial and believe it will be an attractive protocol with great interest from patients for this study."

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "We are thrilled by the data presented today by Dr. Sharman and colleagues which further supports our previously announced Phase 3 strategy for TG-1101. The high-risk CLL patient group, which achieved a 95% ORR, is the same patient population we will be studying in our randomized Phase 3 trial which utilizes ORR as a primary endpoint to support accelerated approval. We were also quite encouraged by the high overall response and complete response rates in Mantle Cell Lymphoma (MCL), particularly compared to the published data on single agent ibrutinib. These results, coupled with a favorable safety profile, which does not appear to differ significantly from that of single agent ibrutinib, continues to support our belief that TG-1101 plus ibrutinib is an attractive treatment option for patients with relapsed refractory CLL and MCL. We thank Dr. Sharman and all the investigators from this Phase 2 trial, and look forward to the imminent launch of our Phase 3 trial of TG-1101 with ibrutinib."

OVERVIEW OF THE DATA PRESENTED ON TG-1101 + IBRUTINIB

Safety and Tolerability

TG-1101 in combination with ibrutinib was well tolerated in the 54 patients evaluable for safety, with day 1 infusion related reactions (IRR) being the most frequently reported adverse event (regardless of causality). Only two Grade 3 or 4 adverse events were observed in > 5% of patients: IRR (6%) and neutropenia (6%). Adverse events were manageable with only 7% of patients discontinuing from the study due to an adverse event: 1 diarrhea; 1 rash (both of which were attributed to ibrutinib); and 2 non-related adverse events. Overall, aside from day 1 IRR, the addition of TG-1101 did not appear to alter the safety profile seen historically with single agent ibrutinib.

Clinical Activity

Of the 54 patients treated, 39 CLL and 8 MCL patients were evaluable for response (2 SLL patients were enrolled and also included in the safety analysis). The 5 CLL patients who were not evaluable included 3 who discontinued due to an adverse event and 2 who withdrew consent prior to their first efficacy assessment.

The breakdown of responses is as follows:

Overall Response Rate (Assessed ≤6 months) ⁽¹⁾								
Type	Pts (n)	CR (n)	PR* (n)	PR (n)	nPR (n)	SD (n)	PD (n)	ORR (%) (CR/PR)
CLL patients (all)	39	1	3	30	1	3	1	87%
<i>High-Risk Subset</i>	20	1	2	16	-	-	1	95%
MCL patients	8	3	-	4	-	1	-	88%

CR: Complete Response; PR*: CR pending bone marrow confirmation; PR: Partial Response by iwCLL (Hallek 2008) or Cheson Criteria; nPR: nodal PR; SD: Stable Disease > 12 weeks; PD: Progressive Disease

(1) As per the protocol, the study was a designed to assess ORR through end of month 5 of treatment. Following month 6, patients were off protocol, and at their physician's discretion, remained on ibrutinib, as per the ibrutinib label. As of the analysis, not all patients have been assessed through the end of month 5.

Of the 20 CLL patients with previously treated high-risk disease, 19 or 95% had a complete or partial response as per the iwCLL (Hallek 2008) criteria. This is the same patient population that will be studied in the Company's recently announced Phase 3 Clinical Trial which will be conducted pursuant to a Special Protocol Assessment with the FDA.

For the entire group of 39 CLL patients evaluable for efficacy, 92% (36/39) reported a nodal response (> 50% reduction in their disease burden). Overall, 87% achieved an objective response per the iwCLL (Hallek 2008) criteria plus an additional 10% of patients with a nodal PR or nodal reductions ranging from 20%-45%, without disease progression. In addition, in patients with CLL, TG-1101 appeared to abrogate ibrutinib related lymphocytosis with patients experiencing a median 75% reduction in their absolute lymphocyte count (ALC) by the end of month 3 following initiation of combination therapy.

In patients with Mantle Cell Lymphoma (MCL), an 88% overall response rate was seen with a 38% complete response rate.

TG-1101 + IBRUTINIB PHASE 3 STUDY PROGRAM – THE GENUINE TRIAL

As previously announced, TG Therapeutics, Inc. has reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design, endpoints and statistical analysis approach of a Phase 3 clinical trial for TG-1101 (ublituximab), its glycoengineered anti-CD20 monoclonal antibody, in combination with Imbruvica® (ibrutinib) for the treatment of Chronic Lymphocytic Leukemia (CLL) in patients with high risk cytogenetics. The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that would support the regulatory submission for drug approval.

The GENUINE phase 3 trial is a randomized controlled clinical trial, with patients receiving either TG-1101 plus ibrutinib or ibrutinib alone. The trial will enroll approximately 330 patients, with approximately the first two-thirds of the patients included in the ORR assessment. As per the SPA, the Company plans to use the ORR data from the trial as the basis for submission of a Biologics License Application (BLA) for accelerated approval for TG-1101. All patients will then be followed for progression free survival (PFS) assessment, which is designed to support full approval.

PRESENTATION DETAILS

A poster titled "Ublituximab (TG-1101), A Novel Glycoengineered Anti-CD20 Monoclonal Antibody, In Combination With Ibrutinib is Highly Active In Patients With Relapsed and/or Refractory CLL and MCL; Results of a Phase II Trial", is being presented today, Monday December 8, 2014, from 6:00pm – 8:00pm PT, during the American Society of Hematology (ASH) Annual Meeting being held at the Moscone Center in San Francisco, CA. The poster, Abstract Number: 4679, is being presented in the West Building, Level 1 of the Moscone Center. A copy of this poster presentation is available on the Publications Page, located within the Pipeline section of the Company's website at www.tgtherapeutics.com.

EVENT WEBCAST DETAILS

The company will host an investor/analyst event tonight, Monday December 8, 2014 from 7:45pm PT – 9:00pm PT. This event will be audio webcast on the Events Page, located within the Investors & Media section of the Company's website at www.tgtherapeutics.com, as well as archived for future review. This event will also be broadcast via conference call. In order to access the conference line, please call 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), and reference Conference Title: TG Therapeutics 2014 Investor & Analyst Event.

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CAUTIONARY STATEMENT

Some of the statements included in this press release, particularly those anticipating future clinical trials, the timing of commencing, completing or reporting such trials and the 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 pre-clinical and clinical results that supported our decision to move forward with TG-1101 and TGR-1202 will not be reproduced in additional patients or in future studies; 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 our ongoing or contemplated drug combinations may not prove tolerable or efficacious; 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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CONTACT: Jenna Bosco
Director- Investor Relations
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com

Preliminary Data From Ongoing Phase I/II Dose Escalation Study of TG-1101 (Ublituximab) in Combination with TGR-1202 in Heavily Pre-treated Relapsed/Refractory B-Cell Malignancies Demonstrates Encouraging Clinical Activity and Safety

- 100% of evaluable CLL/SLL patients (9/9) had nodal reductions, with 6 of 9 patients achieving a PR with the remaining 3 patients on study with nodal reductions ranging from 15% to 45% and a peripheral response (normalization or >50% decrease in ALC) pending additional assessments
- 83% (5/6) of patients with Non-Hodgkin's Lymphoma; 3/3 DLBCL and 2/3 Follicular Lymphoma (FL) responded to the combination at the highest dose tested, including 2 CR's in patients with DLBCL confirmed by independent review
- Collectively, 87 patients have been treated with TGR-1202, alone or in combination with TG-1101, without the observance of drug-related hepatic toxicity
- Dose escalation continues with TGR-1202 at 800mg micronized
- The combination of TG-1101, TGR-1202, and ibrutinib ("Triple Therapy") was safely administered to 5 patients with heavily pre-treated NHL, CLL, and Richter's transformation with no dose limiting toxicities observed, and no Grade 3 or 4 events observed to date
- 2 of the first 3 evaluable patients responded to the Triple Therapy, including an ibrutinib-refractory, rituximab-refractory patient with Follicular Lymphoma

SAN FRANCISCO, CA, December 9, 2014 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq: TGTX), an innovative, clinical-stage biopharmaceutical company today announced clinical results from its Phase 1/2 clinical study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with TGR-1202, the Company's novel once per day PI3K delta inhibitor. These data are being presented today in an oral presentation by Dr. Matthew Lunning from the University of Nebraska Medical Center at the 56th Annual American Society of Hematology (ASH) meeting being held in San Francisco, CA.

"We continue to be very impressed with the safety profile and activity observed to date in a heavily pre-treated population of patients with the combination of ublituximab and TGR-1202," said Dr. Matthew Lunning. "The activity seen to date has been impressive across all disease types, but of particular interest is the high level of activity seen in DLBCL, specifically the GCB subtype, a population of patients in dire need of effective therapies in the relapsed / refractory setting. We were also very excited to introduce a cohort into the study that explored the triple combination of ublituximab, TGR-1202, and ibrutinib, and have been very pleased with the early safety and activity profile of this combination."

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "We remain focused on developing the most efficacious, least toxic treatment options for patients with B-cell malignancies, and believe the data presented today by Dr. Lunning is a major step in that direction. We are very pleased with the early safety and activity profile of our proprietary combination, and look forward to additional follow-up and to seeing the effects of higher doses. Based on the safety and efficacy profile, we believe the combination has the potential to be the leading backbone for incremental combination therapy, as illustrated by the early triple combination data presented today." Mr. Weiss added, "We look forward to further dose escalations in this study while at the same time evaluating designs for our first registration trial for this proprietary combination, ideally to be announced in the first half of 2015."

OVERVIEW OF THE DATA:

The presentation includes data from 27 patients on the combination of TG-1101 and TGR-1202 with relapsed and/or refractory B-cell malignancies, with a median 3 prior lines of therapy, 65% of patients having seen 2 or more prior lines of rituximab, and 41% of patients refractory to prior therapy. The study has explored doses of 600mg and 900mg of TG-1101, and escalating doses of TGR-1202 beginning at 800mg (initial formulation) and escalating to 600mg of the micronized formulation. Five additional patients were treated in the triple combination cohort evaluating the combination of TG-1101, TGR-1202, and ibrutinib in which ibrutinib was dosed per its label in combination with TG-1101 at 900mg and TGR-1202 at 400mg and 600mg micronized. Based on recently reported safety and exposure-response relationship data for TGR-1202 as a single agent, the Company intends to continue dose escalation in this trial to 1200mg micronized with the potential for higher dose levels.

Safety and Tolerability – All Patients

The combination of TG-1101 and TGR-1202 was well tolerated in the 27 patients evaluable for safety, with day 1 infusion related reactions (IRR) being the most frequently reported adverse event. All IRR events were manageable without dose reductions, and all but one event was Grade 1 or 2 in severity. Other adverse events included neutropenia, nausea, and diarrhea, with neutropenia being the only Grade 3/4 adverse event reported in > 10% of patients (33%). Consistent with the data observed to date in the ongoing TGR-1202 single agent Phase 1 study, no drug-related events of hepatic toxicity (ALT/AST elevations) were observed among the 27 patients treated to date with the combination of TG-1101 and TGR-1202. Additionally, no events of hepatic toxicity were observed amongst the 5 patients treated with the triple combination of TG-1101, TGR-1202, and ibrutinib. Collectively, with the results from the Phase 1 single agent study of TGR-1202, 87 patients have been treated with TGR-1202, alone or in combination with TG-1101, without the observance of drug-related hepatic toxicity. Additionally, in those 87 patients, there have been no events of colitis observed to date, with patients on the combination of TG-1101 and TGR-1202 for up to 9 months, and patients on single agent TGR-1202 upwards of 19+ months.

The triple combination of TG-1101, TGR-1202, and ibrutinib was well tolerated in the 5 patients evaluable for safety. No DLTs were observed and no Grade 3/4 events have been reported, with IRR, nausea, fatigue, and diarrhea being the most commonly reported Grade 1/2 adverse events. No dose reductions or dose delays have occurred.

Clinical Activity of TG-1101 + TGR-1202 in Chronic Lymphocytic Leukemia (CLL)

Of the 11 CLL/SLL patients enrolled to date, 9 were evaluable for efficacy. One patient was found to be ineligible prior to first efficacy assessment and one CLL patient is on the triple therapy and too early to evaluate. Patients in this group were heavily pre-treated with 67% (6/9) harboring a 17p del and/or 11q del.

A summary of the CLL/SLL data reported is as follows:

- All 9 evaluable patients exhibited nodal reductions with 6 of 9 achieving a Partial Response by the iwCLL (Hallek 2008) or Cheson criteria
- The remaining 3 patients achieved nodal reductions ranging from ~15% to 45% accompanied by either a normalization of ALC or a greater than 50% reduction of ALC, sometimes referred to as a “peripheral response”
- All evaluable CLL patients remain on study (durations of 3+ to 9+ months) pending further efficacy assessments and intra-patient dose escalation, which is permitted per protocol

The lymphocytosis generally observed in CLL patients treated with TGR-1202, similar to other PI3K delta and BTK inhibitors, appears to be mitigated by the addition of TG-1101.

Similar to the trend observed in the single agent study of TGR-1202, responses to the combination of TG-1101 and TGR-1202 have been shown to improve overtime and dose escalation continues now at 800mg micronized and up to 1200mg micronized, with the possibility of dosing higher.

Clinical Activity of TG-1101 + TGR-1202 in Hodgkin's Lymphoma (NHL) / Richter's Syndrome

Of the 17 NHL or Richter's patients enrolled to date, all were evaluable for efficacy (7 DLBCL, 9 FL and 1 Richter's). Patients in this group were heavily pre-treated, with 53% refractory to their prior treatment regimen. In the DLBCL group, patients had a median of 3 prior lines therapy and 5 of the 7 patients had the GCB subtype, with one patient classified as "triple-hit" (overexpression of BCL2, BCL6, and MYC rearrangements). In the Follicular Lymphoma group, patients had a median of 5 prior lines of therapy, with 56% being deemed rituximab refractory.

Among patients with Non-Hodgkin's Lymphoma treated at the highest doses tested, 83% (5/6) of the patients (3/3 of DLBCL and 2/3 of FL) responded to the combination. Of particular note was the potential signal in DLBCL, where an ORR of 43% (3/7) was observed with 2 patients (29%) achieving a Complete Response (CR), both of which were confirmed by independent radiologic review. Two of the three DLBCL responders were GCB subtype, which has historically been less responsive to BCR targeted agents. The 3 DLBCL patients who achieved a response remain on study, progression-free for greater than 7 months.

Additionally, despite the advanced disease and multiple lines of rituximab-based therapy, all of the FL patients treated to date with the combination were stable at first assessment and exhibited a reduction in tumor mass. Consistent with the exposure-response data recently reported in the single agent dose escalation trial of TGR-1202, 2 of 3 patients with FL treated at the highest dose of TGR-1202, 600mg micronized, responded at the first assessment (day 60). The remaining patient had a nodal reduction and remains on study pending further efficacy assessments. Dose escalation of the combination continues with TGR-1202 now at 800mg micronized and up to 1200mg micronized, with the possibility of dosing higher.

Clinical Activity – Triple Therapy: TG-1101 + TGR-1202 + Ibrutinib

Of the 5 patients enrolled to date on the triple combination of TG-1101, TGR-1202, and ibrutinib, 3 were evaluable for efficacy (1 FL, 1 MCL, and 1 patient with Richter's Transformation) and 2 were too early to evaluate. Of the 3 evaluable patients, 2 responded (MCL and FL). The MCL patient was diagnosed as Stage IV, and had previously progressed within one year of an autologous stem cell transplant, and achieved a PET negative CR at the first response assessment (day 60). The FL patient had also been diagnosed as Stage IV, was refractory to both rituximab and ibrutinib, and achieved a PR at the first response assessment (day 60) with a 74% nodal reduction. Enrollment into the triple combination cohort continues, with TGR-1202 currently dosed at 600 mg, with additional dose escalations planned.

Presentation Details

The presentation, titled “Ublituximab, a Novel Glycoengineered Anti-CD20 mAb, in Combination with TGR-1202, a Next Generation Once Daily PI3K Delta Inhibitor, Demonstrates Activity in Heavily Pre-Treated and High Risk Chronic Lymphocytic Leukemia and B-Cell Lymphoma” was presented today, Tuesday, December 9, during the session titled “Lymphoma: Therapy with Biologic Agents, excluding Pre-Clinical Models: Indolent B-cell NHL and T-cell NHL”, from 8:00 to 9:30am Pacific Time. The presentation is available on the Events page, located within the Investors & Media section of the Company's website at www.tgtherapeutics.com.

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, also for B-cell malignancies and autoimmune diseases. TG Therapeutics is headquartered in New York City.

CAUTIONARY STATEMENT

Some of the statements included in this press release, particularly those, anticipating results that might be achieved at higher doses of, and longer exposures to, TGR-1202, anticipating future clinical trials, the timing of commencing or completing such 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 pre-clinical and clinical results that supported our decision to move forward with TG-1101 and TGR-1202 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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CONTACT: Jenna Bosco
Director- Investor Relations
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com
