



June 6, 2016

## **TG Therapeutics, Inc. Announces Long-Term Follow-up of TGR-1202 Demonstrates a Differentiated Safety Profile and High Response Rates in CLL and NHL in Data Presented at the 52nd Annual Meeting of the American Society of Clinical Oncology**

*High response rates observed across CLL, DLBCL & indolent NHL*

*Integrated analysis of 165 patients exposed to TGR-1202 monotherapy or the combination of TGR-1202 plus TG-1101 continues to demonstrate a favorable safety profile*

*Durations of exposure upwards of 3+ years with less than 8% of patients having discontinued due to adverse events*

CHICAGO, June 06, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced long term follow-up data of TGR-1202, the Company's once daily PI3K delta inhibitor, both alone and in combination with TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody. An integrated analysis of the follow-up data from both studies is being presented today, Monday June 6, 2016 at the 52nd Annual Meeting of the American Society of Clinical Oncology (ASCO), being held in Chicago, Illinois. The poster is being presented from 8:00am - 11:30am CT, and will be reviewed during a discussion session from 1:15pm - 2:45pm CT in Room E354b of McCormick Place.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "We continue to be impressed with the safety and activity profile of TGR-1202, especially in combination with TG-1101, together making our proprietary "1303" combination. This data, which includes 3 year follow up, reinforces our belief that TGR-1202 is a differentiated PI3K delta inhibitor from others in the class. The integrated analysis, which includes 165 patients treated with TGR-1202 alone or in combination with TG-1101, demonstrates that the toxicities observed with other PI3K delta inhibitors such as liver toxicity, colitis, pneumonitis and infection are rare with TGR-1202 with discontinuations due to TGR-1202 related AEs occurring in less than 8% of patients. We see this as particularly compelling given the recent setbacks for idelalisib with the closure of a series of randomized studies due to safety concerns. The data presented today provides strong evidence to support the hypothesis that the adverse events seen with idelalisib are not necessarily a class effect." Mr. Weiss continued, "Not only does TGR-1202 appear to have a best-in-class safety and efficacy profile with the convenience of once per day dosing, but also demonstrates that a tolerable PI3K delta inhibitor can induce long-term responses in patients with CLL rivaling BTK inhibitors. However, unlike BTK inhibitors, whose activity has been primarily limited to CLL and MCL, TGR-1202 has also demonstrated significant activity in the larger indications of Follicular Lymphoma and DLBCL. Our UNITY program is designed to highlight the breadth of utility of TG-1303 across a wide range of B-cell malignancies, starting with CLL, and now moving into DLBCL and iNHL to follow soon, and we believe its high level of activity, tolerability and ease of administration will make TG-1303 an important new treatment option for these patients."

The poster, entitled "Long-term follow-up of the PI3K delta inhibitor TGR-1202 demonstrates a differentiated safety profile and high response rates in CLL and NHL: Integrated-analysis of TGR-1202 monotherapy and combined with ublituximab" (Abstract Number: 7512), includes data from 165 patients with relapsed or refractory hematologic malignancies, 90 of which were treated with TGR-1202 and 75 of which were treated with TGR-1202 in combination with TG-1101. Patients were heavily pretreated, with the majority of patients having seen 3 or more prior lines of therapy and 52% (85/165) of patients being refractory to their immediate prior therapy.

### **Highlights from the poster include:**

#### **Safety and Tolerability:**

- | Discontinuations due to TGR-1202 adverse events have been limited (~8%)
- | Grade 3/4 adverse events commonly associated with PI3K delta inhibitors have been rare, with pneumonia (~5%) and pneumonitis ( < 1.5%), ALT/AST elevations (~3%) and colitis ( < 1.5%), the latter occurring with no apparent association to time on therapy
  - | The two cases of colitis ( < 1.5%) occurred at doses exceeding the Phase 3 dose and did not appear to be time dependent (1000 mg and 1200 mg, at 4 mos. and 24 mos., respectively, after initiating therapy)
- | 165 patients have been treated with TGR-1202 between the two studies with 80 patients on drug for 6+ months, 43 patients for 12+ months, and the longest patients on daily TGR-1202 for 3+ years
- | Safety and efficacy profile of TG-1303 supports multi-drug combinations including ongoing triple therapy combination

studies with novel agents such as ibrutinib, pembrolizumab and bendamustine

#### **Activity:**

- | At the Phase 3 dose of 800mg, the following responses were observed:
  - | 88% (14/16) ORR in patients with CLL including 2 CR's (one of which was a 17p del) plus a PR in an ibrutinib refractory patient
  - | 57% (4/7) ORR in patients with DLBCL with compelling activity observed in GCB subtype
  - | 53% (9/17) ORR in patients with follicular and marginal zone lymphoma (iNHL)
- | ORR in iNHL for patients treated at higher doses (1200mg of the initial formulation or ≥600 mg of the micronized formulation), was not only greater with the TG-1303 combination (55%) as opposed to monotherapy with TGR-1202 (41%), but the depth of response was significantly greater with the combination (CR rate of 5% for monotherapy vs. 30% for the TG-1303 combination)
- | Three (3) Complete Responses were observed in patients with DLBCL treated at higher doses of TGR-1202 in combination with TG-1101, 2 of which were of GCB subtype, supporting our UNITY-DLBCL Phase 2b design
- | 25% ORR in ibrutinib refractory patients, highlighting the challenge of treating patients that break through ibrutinib therapy and the potential risks of initiating ibrutinib therapy early

#### **POSTER PRESENTATION DETAILS**

A copy of the poster presentation is available on the Company's website at [www.tgtherapeutics.com](http://www.tgtherapeutics.com), located on the Publications Page, within the Pipeline section.

#### **TG THERAPEUTICS INVESTOR & ANALYST EVENT DETAILS**

TG Therapeutics will also host a reception this evening, Monday, June 6, 2016 beginning at 7:00pm CT, with featured presentations beginning promptly at 7:10pm CT. The event will take place at the Peninsula Chicago Hotel in the Avenues Ballroom. This event will be webcast live and will be available on the Events page, located within the Investors & Media section of the Company's website at [www.tgtherapeutics.com](http://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 June 2016 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 and autoimmune diseases. 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, with TG-1101 recently entering clinical development for autoimmune disorders. The Company also has pre-clinical programs to develop IRAK4 inhibitors, BET inhibitors, and 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, the BET 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, the BET 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, the BET 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 combination of TG-1101 and TGR-1202, referred to as TG-1303, will not prove to be a safe and efficacious backbone for triple and quad combination therapies; 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](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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