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TG Therapeutics, Inc. Recaps Data from Triple Combination Therapy Trials at the 22nd European Hematology Association Annual Congress

NEW YORK, June 26, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), recapped clinical data from two triple combination therapy trials using TGR-1202 (umbralisib), the Company's oral, next generation PI3K delta inhibitor and TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, as the backbone of the combinations. The data presentations include a recap of the data from the combination of TGR-1202, TG-1101, and ibrutinib, as well as from the triple combination of TGR-1202, TG-1101, and bendamustine. Data from these trials were presented this past weekend at the 22nd European Hematology Association (EHA) Annual Congress in Madrid, Spain. These data sets were presented earlier this month at the American Society of Clinical Oncology (ASCO) annual meeting and/or at the 14th International Conference on Malignant Lymphoma (ICML).

Highlights from the presentations include the following:

Oral Presentation: Chemo-free triplet combination of TGR-1202, ublituximab, and ibrutinib is well tolerated and highly active in patients with advanced CLL and NHL

This oral presentation includes data from patients with Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) and Non-Hodgkin's Lymphoma (NHL) treated with the triple combination of TGR-1202, TG-1101, and ibrutinib. All patients were relapsed or refractory to prior therapy, except 3 CLL patients who were treatment naïve. Three cohorts each for CLL/SLL and NHL were evaluated with TGR-1202 dose escalation starting with doses of 400 mg (cohort 1), followed by 600 mg (cohort 2) and 800 mg (cohort 3), in combination with TG-1101 at 900 mg and ibrutinib daily at 420 mg (CLL) and 560 mg (NHL).

Safety & Tolerability
Thirty-eight (38) patients were evaluable for safety (20 CLL/SLL patients, and 18 NHL patients). The triple combination appeared to be well tolerated in all patients, with neutropenia (32% all grades, 18% Grade 3/4) and pneumonia (18% all grades, 11% Grade 3/4), being the only Grade 3/4 AEs in > 10% of patients. Of the 38 patients treated to date, only two AEs (sepsis and pneumonia) led to treatment discontinuation. Median time on study was 11.1 months (range 0.4 - 30+ months) with 81% of patients on study > 6 months.

Clinical Activity
Clinical activity was observed at all dose levels with 36 of 38 patients evaluable for efficacy (19 CLL/SLL patients, and 17 NHL patients), with 2 patients having discontinued prior to first efficacy assessment (1 pneumonia, and 1 investigator discretion).

CLL/SLL Efficacy highlights include:

- 100% (19 of 19) Overall Response Rate (ORR), including a 32% Complete Response (CR) rate observed in patients with CLL/SLL (4 of 6 CR's pending bone marrow confirmation)
- 50% of the CLL patients had a 17p and/or 11q deletion
- 3 CLL patients had prior BTK and/or PI3Kδ inhibitor therapy, including one patient refractory to both idelalisib and ibrutinib who attained a complete response (ongoing for 1.5+ years)

NHL Efficacy highlights include:

- Response Rates observed in patients with NHL:
  - 100% (2 of 2) ORR, including one CR in patients with Marginal Zone Lymphoma (MZL)
  - 100% (4 of 4) ORR, including 50% CR rate in patients with Mantle Cell Lymphoma (MCL)
  - 80% (4 of 5) ORR, including 20% CR rate in patients with Follicular Lymphoma (FL)
  - 17% (1 of 6) ORR in patients with Diffuse Large B-cell Lymphoma (DLBCL)
- FL patients were heavily pretreated including 2 with prior Autologous Stem Cell Transplant (ASCT), 1 refractory to

prior ibrutinib, and 1 with 5 prior lines of rituximab based therapy

- DLBCL patients had a median of 4 prior therapies, and 4 of 6 were of non-GCB subtype

Poster Presentation: Combination of TGR-1202, Ublituximab, and Bendamustine is safe and highly active in patients with advanced DLBCL and Follicular Lymphoma

This poster presentation includes data from patients with relapsed or refractory Diffuse Large B-Cell Lymphoma (DLBCL) or Follicular Lymphoma (FL) treated with the triple combination of TGR-1202 (umbralisib), TG-1101 (ublituximab), and bendamustine. Thirty-three patients were evaluable for safety of which 24 were evaluable for efficacy (9 patients were note evaluable; 7 were too early to evaluate and 2 patients were off study prior to an efficacy assessment: 1 non-related adverse event (AE) and 1 investigator decision). The triple combination appears well tolerated with no discontinuations for a treatment related AE. No events of pneumonitis and no Grade 3/4 transaminitis were reported. Twenty-one patients (64%) were refractory to prior treatment. Mean time on study was approximately 6 months.

Efficacy highlights from this poster include:

- 100% (4 of 4) ORR, including a 50% CR rate, observed in patients with relapsed DLBCL
- 50% (6 of 12) ORR, including a 42% CR rate, observed in patients with refractory DLBCL with durable CR and PR responses observed (PR on-going for > 16+ months)
- 88% (7 of 8) ORR, including a 50% CR rate, observed in patients with relapsed or refractory FL

PRESENTATION DETAILS:

The above referenced presentations are available on the Publications page, located within the Pipeline section, of the Company's website at www.tgtherapeutics.com/publications.cfm.

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 (umbralisib), 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 also in 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 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: our ability to successfully and cost effectively complete clinical trials; the risk that early clinical trial results, including the safety and efficacy results seen with the combination of TG-1101 plus TGR-1202 plus bendamustine or with TG-1101 plus TGR-1202 plus ibrutinib, that may have supported the acceptance of our data for presentation or influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303 or as "U2", and being studied in the triple combinations of TG-1101 plus TGR-1202 plus bendamustine and TG-1101 plus TGR-1202 plus ibrutinib, and in the UNITY clinical trials and other combination trials, will not prove to be safe and efficacious for any indication or as a backbone for current or future triple and/or quad therapies. 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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