TG Therapeutics Recaps Schedule of Upcoming Data Presentations at the XIX International Workshop on Chronic Lymphocytic Leukemia (iwCLL)

September 13, 2021

Investor & Analyst Virtual Event to Discuss Phase 1 U2 + Venetoclax Data to be held Monday, September 20, 2021 at 8:30 AM ET

NEW YORK, Sept. 13, 2021 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today recapped the schedule of upcoming data presentations at the XIX International Workshop on Chronic Lymphocytic Leukemia (iwCLL), being held virtually September 17 – 20, 2021. Full text abstracts are now available through the iwCLL virtual platform, and details of the upcoming data presentations are below.

The Company will also host a virtual investor and analyst event on Monday, September 20, 2021 at 8:30 AM ET, to review the updated Phase 1 data evaluating the investigational combination of UKONIQ® (umbralisib) and ublituximab (U2) plus venetoclax presented at iwCLL, as well as provide an overview of the ULTRA-V Phase 2/3 trial.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, “We are pleased to see the iwCLL full text abstracts are now available, highlighting updated data from four combination trials including our proprietary U2 doublet regimen. Of particular note, is the updated U2 plus venetoclax Phase 1 data showing among 46 relapsed or refractory CLL patients, an overall response rate of 100% including 35% complete response rate. Additionally, at cycle 12, the data show 88% of evaluable patients achieved undetectable minimal residual disease (uMRD) in the peripheral blood, and 72% uMRD in the bone marrow. These data are encouraging, and we look forward to additional updates at the iwCLL conference as well as reviewing these data and an overview of the ULTRA-V program evaluating the U2 plus venetoclax combination during the virtual event we have planned for Monday, September 20, 2021.”

IwCLL 2021 PRESENTATION INFORMATION

Oral Presentation Title: Umbralisib Plus Ublituximab (U2) Is Superior to Obinutuzumab Plus Chlorambucil (O+Chl) in Patients with Treatment-Naïve (TN) and Relapsed/Refractory (R/R) Chronic Lymphocytic Leukemia (CLL): Results from the Phase 3 UNITY-CLL Study

- Abstract Number: 1083667
- Presentation Date/Time: Saturday, September 18, 2021 at 1:30 PM EDT/ 19:30 CEST
- Session: Session 6: Front-Line Therapy of CLL
- Lead Author: Wojciech Jurczak, MD, PhD, Maria Sklodowska-Curie National Research Institute of Oncology, Krakow, Poland

Oral Presentation Title: A Phase 1/2 Study of Umbralisib, Ublituximab, and Venetoclax in Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia (CLL)

- Abstract Number: 1083987
- Presentation Date/Time: Sunday, September 19, 2021 at 10:50 AM EDT/ 16:50 CEST
- Session: Session 8: New Agents in CLL Clinical Trials
- Lead Author: Paul M. Barr, MD, Wilmot Cancer Institute, University of Rochester Medical Center, Rochester, NY

Oral Poster Presentation Title: TG-1701, a Selective Bruton Tyrosine Kinase (BTK) Inhibitor, as Monotherapy and in Combination with Ublituximab and Umbralisib (U2) in Patients with Chronic Lymphocytic Leukemia

- Abstract Number: 1083634
- Presentation Date/Time: Sunday, September 19, 2021 at 2:00 PM EDT/ 20:00 CEST
- Session: Poster Session
- Lead Author: Chan Y. Cheah MBBS, DMSc, Linear Clinical Research, and Department of Haematology, Sir Charles Gairdner Hospital, Nedlands Western Australia, and Medical School, University of Western Australia, Crawley, Western Australia

Poster Presentation Title: Phase I/II Study of Umbralisib (TGR-1202), Ublituximab (TG-1101), and Pembrolizumab in Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia and Richter’s Transformation: 5-Year Follow-up

- Abstract Number: 1083523
- Presentation Date/Time: Available on demand
- Session: Virtual Poster Gallery
- Lead Author: Lindsey E. Roeker, MD, CLL Program, Leukemia Service, Division of Hematologic Oncology, Memorial Sloan-Kettering Cancer Center, New York, NY

The above full text abstracts are now available via the iwCLL virtual platform at https://iwcll2021.org/.

At the time of each presentation, the data presented will be available on the Publications page, located within the Pipeline section, of the Company's website at www.tgtherapeutics.com/publications.cfm.

INVESTOR & ANALYST VIRTUAL EVENT INFORMATION
The Company will host a virtual event on Monday, September 20, 2021 at 8:30 AM ET, to discuss the updated Phase 1 data evaluating UKONIQ® (umbralisib) and ublituximab (U2) in combination with venetoclax in patients with CLL as well as provide an overview of the Phase 2/3 ULTRA-V program.

To attend the live event, please visit the Events page, located within the Investors & Media section, of the Company's website at http://ir.tgtherapeutics.com/events. Following the live event, an archive file will be available for replay, for a period of 30 days after the call.

ABOUT U2 PLUS VENETOCLAX PHASE 1 TRIAL
The Phase 1/2 trial, (NCT03379051), is a multi-center, dose-escalation trial designed to assess the safety and efficacy of UKONIQ and ublituximab (U2) plus venetoclax in patients with relapsed or refractory CLL. The primary objective of the trial is to evaluate the safety of venetoclax after U2 induction. The secondary objectives are clinical efficacy as defined by overall response rate (ORR), including complete response (CR) rate, progression-free survival (PFS), and undetectable minimal residual disease (uMRD) rate after 12 cycles of therapy. The trial enrolled approximately 50 CLL patients and is being led by Dr. Paul Barr of the Wilmot Cancer Institute, University of Rochester Medical Center.

ABOUT ULTRA-V PHASE 2 TRIAL
The ULTRA-V Phase 2 trial, (NCT03801525), is an open-label, multicenter, trial designed to investigate the efficacy and safety of UKONIQ and ublituximab (U2) combined with venetoclax in subjects with CLL. The primary endpoint of the trial is overall response rate (ORR) and complete response (CR) rate. The trial enrolled approximately 165 patients with front-line and previously treated CLL at 26 sites throughout the United States.

ABOUT ULTRA-V PHASE 3 TRIAL
The ULTRA-V Phase 3 trial is an open-label, multicenter, randomized controlled clinical trial comparing the time-limited triple combination of UKONIQ and ublituximab (U2) plus venetoclax, to an active control arm of continuous U2. The Phase 3 trial includes two independent randomized cohorts of CLL subjects: a treatment-naïve cohort and a previously treated cohort, with each cohort being enrolled and evaluated independently of each other. The primary endpoint for the trial is progression-free survival (PFS). This trial is being led by Richard R. Furman, MD, Director of CLL Research Center at Weill Cornell Medicine and targeting over 60 U.S. trial sites.

ABOUT TG THERAPEUTICS, INC.
TG Therapeutics is a fully-integrated, commercial stage biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. In addition to an active research pipeline including five investigational medicines across these therapeutic areas, TG has received accelerated approval from the U.S. FDA for UKONIQ® (umbralisib), for the treatment of adult patients with relapsed/refractory marginal zone lymphoma who have received at least one prior anti-CD20-based regimen and relapsed/refractory follicular lymphoma who have received at least three prior lines of systemic therapies. Currently, the Company has three programs in Phase 3 development for the treatment of patients with relapsing forms of multiple sclerosis (RMS) and patients with chronic lymphocytic leukemia (CLL) and several investigational medicines in Phase 1 clinical development. For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and Linkedin.

UKONIQ® is a registered trademark of TG Therapeutics, Inc.

ABOUT UKONIQ® (umbralisib)
UKONIQ is the first and only oral inhibitor of phosphoinositide 3 kinase (PI3K) delta and casein kinase 1 (CK1) epsilon. PI3K-delta is known to play an important role in supporting cell proliferation and survival, cell differentiation, intercellular trafficking and immunity and is expressed in both normal and malignant B-cells. CK1-epsilon is a regulator of oncoprotein translation and has been implicated in the pathogenesis of cancer cells, including lymphoid malignancies.

UKONIQ is indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen and for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

These indications are approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION
Infections: Serious, including fatal, infections occurred in patients treated with UKONIQ. Grade 3 or higher infections occurred in 10% of 335 patients, with fatal infections occurring in <1% . The most frequent Grade ≥3 infections included pneumonia, sepsis, and urinary tract infection. Provide prophylaxis for Pneumocystis jirovecii pneumonia (PJP) and consider prophylactic antivirals during treatment with UKONIQ to prevent CMV infection, including CMV reactivation. Monitor for any new or worsening signs and symptoms of infection, including suspected PJP or CMV, during treatment with UKONIQ. For Grade 3 or 4 infection, withhold UKONIQ until infection has resolved. Resume UKONIQ at the same or a reduced dose. Withhold UKONIQ in patients with suspected PJP of any grade and permanently discontinue in patients with confirmed PJP. For clinical CMV infection or viremia, withhold UKONIQ until infection or viremia resolves. If UKONIQ is resumed, administer the same or reduced dose and monitor patients for CMV reactivation by PCR or antigen test at least monthly.

Neutropenia: Serious neutropenia occurred in patients treated with UKONIQ. Grade 3 neutropenia developed in 9% of 335 patients and Grade 4 neutropenia developed in 9%. Monitor neutrophil counts at least every 2 weeks for the first 2 months of UKONIQ and at least weekly in patients with neutrophil count <1 x 109/L (Grade 3-4) neutropenia during treatment with UKONIQ. Consider supportive care as appropriate. Withhold, reduce dose, or discontinue UKONIQ depending on the severity and persistence of neutropenia.

Diarrhea or Non-Infectious Colitis: Serious diarrhea or non-infectious colitis occurred in patients treated with UKONIQ. Any grade diarrhea or colitis occurred in 53% of 335 patients and Grade 3 occurred in 9%. For patients with severe diarrhea (Grade 3, i.e., > 6 stools per day over baseline) or

abdominal pain, stool with mucus or blood, change in bowel habits, or peritoneal signs, withhold UKONIQ until resolved and provide supportive care with antidiarrheals or enteric acting steroids as appropriate. Upon resolution, resume UKONIQ at a reduced dose. For recurrent Grade 3 diarrhea or recurrent colitis of any grade, discontinue UKONIQ. Discontinue UKONIQ for life-threatening diarrhea or colitis.

Hepatotoxicity: Serious hepatotoxicity occurred in patients treated with UKONIQ. Grade 3 and 4 transaminase elevations (ALT and/or AST) occurred in 8% and <1%, respectively, in 335 patients. Monitor hepatic function at baseline and during treatment with UKONIQ. For ALT/AST greater than 5 to less than 20 times ULN, withhold UKONIQ until return to less than 3 times ULN, then resume at a reduced dose. For ALT/AST elevation greater than 20 times ULN, discontinue UKONIQ.

Severe Cutaneous Reactions: Severe cutaneous reactions, including a fatal case of exfoliative dermatitis, occurred in patients treated with UKONIQ. Grade 3 cutaneous reactions occurred in 2% of 335 patients and included exfoliative dermatitis, erythema, and rash (primarily maculo-papular). Monitor patients for new or worsening cutaneous reactions. Review all concomitant medications and discontinue any potentially contributing medications. Withhold UKONIQ for severe (Grade 3) cutaneous reactions until resolution. Monitor at least weekly until resolved. Upon resolution, resume UKONIQ at a reduced dose. Discontinue UKONIQ if severe cutaneous reaction does not improve, worsens, or recurs. Discontinue UKONIQ for life-threatening cutaneous reactions or SJS, TEN, or DRESS of any grade. Provide supportive care as appropriate.

Allergic Reactions Due to Inactive Ingredient FD&C Yellow No. 5: UKONIQ contains FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons, frequently in patients who also have aspirin hypersensitivity.

Embryo-fetal Toxicity: Based on findings in animals and its mechanism of action, UKONIQ can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females and males with female partners of reproductive potential to use effective contraception during treatment and for at least one month after the last dose.

Serious adverse reactions occurred in 18% of 221 patients who received UKONIQ. Serious adverse reactions that occurred in ≥2% of patients were diarrhea-colitis (4%), pneumonia (3%), sepsis (2%), and urinary tract infection (2%). Permanent discontinuation of UKONIQ due to an adverse reaction occurred in 14% of patients. Dose reductions of UKONIQ due to an adverse reaction occurred in 11% of patients. Dosage interruptions of UKONIQ due to an adverse reaction occurred in 43% of patients.

The most common adverse reactions (>15%), including laboratory abnormalities, in 221 patients who received UKONIQ were increased creatinine (79%), diarrhea-colitis (58%, 2%), fatigue (41%), nausea (38%), neutropenia (33%), ALT increase (33%), AST increase (32%), musculoskeletal pain (27%), anemia (27%), thrombocytopenia (26%), upper respiratory tract infection (21%), vomiting (21%), abdominal pain (19%), decreased appetite (19%), and rash (18%).

Lactation: Because of the potential for serious adverse reactions from umbralisib in the breastfed child, advise women not to breastfeed during treatment with UKONIQ and for at least one month after the last dose.

Please visit www.tgtherapeutics.com/prescribing-information/uspi-ukon for full Prescribing Information and Medication Guide.

Cautionary Statement
This press release contains 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. Such forward-looking statements include but are not limited to statements regarding our clinical programs, including our clinical trials evaluating the investigational combination of UKONIQ® (umbralisib) and ublituximab (U2) plus venetoclax.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release. In addition to the risk factors identified from time to time in our reports filed with the U.S. Securities and Exchange Commission (SEC), factors that could cause our actual results to differ materially include the following: the risk that the data from the U2 plus venetoclax trials or any other trials that we announce or publish may change, or the perceived profile of our products or combination regimens may be impacted, as more data or additional endpoints (including efficacy and safety) are analyzed; the risk that the clinical development of our products and regimens will take longer and/or cost more than planned; the uncertainties inherent in research and development; the risk that the clinical results from our registrational trials will not support regulatory approval of our investigational products or regimens; the risk that if approved, our products will not be commercially successful; and the risk that the ongoing COVID-19 pandemic and associated government control measures have an adverse impact on our research and development plans or commercialization efforts. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in our other filings with the SEC.

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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