

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): **June 18, 2015**

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.

Item 8.01. Other Events.

On June 18, 2015, TG Therapeutics, Inc. issued a press release announcing updated clinical results from its Phase 2 study of TG-1101 (ublituximab) in combination with ibrutinib. The updated results from the Phase 2 study were delivered in an oral presentation by Dr. John Burke, Rocky Mountain Cancer Associates/US Oncology, Aurora, CO during the 13th International Congress on Malignant Lymphoma (ICML), being held from June 17 to June 20, 2015 in Lugano, Switzerland. A copy of the press release is being filed as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits.

99.1 Press Release, dated June 18, 2015.

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: June 18, 2015

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

INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated June 18, 2015.

Updated Results from Phase 2 Clinical Trial of TG-1101 (Ublituximab) in Combination with Ibrutinib Confirms Robust Clinical Activity with a Favorable Safety Profile in Patients With Previously Treated, High-Risk Chronic Lymphocytic Leukemia (CLL)

- 95% Overall Response Rate (ORR) in Patients with High-Risk CLL, the same patient population being studied in the Company's on-going Phase 3 GENUINE study being conducted under Special Protocol Assessment (SPA)
- 20% of High-Risk CLL patients achieved a confirmed or unconfirmed Complete Response (CR) and/or Minimal Residual Disease (MRD) negativity by the end of the study period (month 6)
- Median nodal reduction of 85% by month 6 amongst High-Risk CLL patients
- Combination of TG-1101 + Ibrutinib continues to be well tolerated with limited Grade 3/4 events observed

NEW YORK, NY, June 18, 2015 -- TG Therapeutics, Inc. (Nasdaq:TGTX), today announced updated clinical results from its Phase 2 study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with ibrutinib, the oral BTK inhibitor. The updated results from the Phase 2 study were delivered in an oral presentation by Dr. John Burke, Rocky Mountain Cancer Associates/US Oncology, Aurora, CO during the 13th International Congress on Malignant Lymphoma (ICML), being held from June 17 - June 20, 2015 in Lugano, Switzerland.

OVERVIEW OF THE UPDATED RESULTS PRESENTED ON TG-1101 + IBRUTINIB

Today's presentation included data from 44 patients with relapsed and/or refractory CLL treated with TG-1101 in combination with ibrutinib at the labeled dose of 420 mg. Forty patients were evaluable for efficacy, of which 50% (20 patients) were considered "High-Risk", defined as the presence of a 17p del, 11q del and/or p53 mutation, the same criteria which is being used for the current Phase 3 GENUINE study.

Dr. Jeff Sharman, Medical Director of Hematology Research for the US Oncology Network, and Study Chair for both the Phase 2 and the Phase 3 GENUINE Study stated: "The updated Phase 2 data continues to demonstrate that adding ublituximab to ibrutinib can induce not only significant response rates for high-risk CLL patients, but has the potential to impact depth of response, with higher CR and MRD negative rates observed compared to historical data with ibrutinib monotherapy. The Phase 3 study is now up and running, and we look forward to a strong collaboration with all investigators, as this is a very attractive protocol for patients with high-risk CLL."

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "We continue to be pleased with the performance of the combination of TG-1101 plus ibrutinib and continue to believe the combination represents a best-in-class treatment for patients with relapsed/refractory CLL, especially in patients with high-risk disease, which is generally known to be chemotherapy resistant. We expect, if approved, TG-1101 will be the first chemo-free combination approved with ibrutinib for patients with relapsed/refractory CLL. The data presented today gives us additional confidence that the outcome of our Phase 3 GENUINE Study will be successful and we will be able to offer patients a novel chemo-free treatment option. We greatly appreciate the dedication to the program from our Study Chair Dr. Jeff Sharman and all the participating sites and physicians across the country that are participating in this important clinical trial."

Safety and Tolerability of TG-1101 + ibrutinib

TG-1101 in combination with ibrutinib was well tolerated in the 44 CLL patients evaluable for safety, with day 1 infusion related reactions (IRR) being the most frequently reported adverse event (regardless of causality), the majority of which were Grade 1 or 2 in severity. Only 3 Grade 3 or 4 adverse events were observed in > 5% of patients: neutropenia (11%), anemia (11%), and IRR (7%). Adverse events were manageable with only 7% of CLL patients (3/44) discontinuing from the study due to an adverse event: 1 diarrhea (attributed to ibrutinib) and 2 non-related adverse events. Overall, aside from day 1 IRR, the addition of TG-1101 to ibrutinib did not appear to alter the safety and tolerability profile of ibrutinib monotherapy.

Clinical Activity of TG-1101 + ibrutinib

Of the 44 CLL patients treated, 40 were evaluable for response. The 4 patients who were not evaluable included 2 who discontinued due to an adverse event and 2 who withdrew consent, in each case, prior to a first efficacy assessment. Of the 20 CLL patients with previously treated high-risk disease, the patient population we are currently studying in our Phase 3 GENUINE study, 95% (19/20) achieved an objective response with 20% achieving MRD negativity and/or a CR or an unconfirmed CR (pending bone marrow confirmation) as per the iwCLL (Hallek 2008). Additionally, disease response improved for the high-risk CLL patients from a median 64% nodal reduction by month 3 to a median 85% nodal reduction by month 6.

Amongst all 40 CLL patients evaluable for efficacy, 88% (35/40) achieved an objective response per the iwCLL (Hallek 2008) criteria and 4 patients, or an additional 10%, achieved nodal reductions ranging from 20%-55%, without disease progression.

TG-1101 also 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 and 70% of patients achieving normal ALC ranges (< 4,000/uL) by month 6.

ADDITIONAL ICML MEETING PRESENTATIONS

In addition to the TG-1101 + ibrutinib data, the following data, which was presented previously at ASCO and EHA, was presented at the 13th International Congress on Malignant Lymphoma (ICML) meeting:

- Single agent TGR-1202 in patients with relapsed or refractory CLL, NHL or other B-cell Malignancies: Oral Presentation (Owen A. O'Connor, MD, PhD)
- Combination of TG-1101 + TGR-1202 (the Company's "1303" combination) in patients with relapsed/refractory NHL and high-risk CLL: Poster Presentation (Matt Lunning, DO)
- Chemo-free triplet combination of TG-1101 + TGR-1202 + ibrutinib in patients with B-cell malignancies: Oral Presentation (Loretta Nastoupil, MD)

A copy of all data presentations from the ICML Lugano meeting can be found at <http://tgtxinc.com/pipeline/publications.cfm>.

ABOUT THE GENUINE PHASE 3 TRIAL (TG-1101 + IBRUTINIB)

The Phase 3 trial, the “GENUINE” trial, evaluating TG-1101 (ublituximab) in combination with ibrutinib compared to ibrutinib alone for the treatment of patients with previously treated high-risk CLL is now open in over 120 centers across the US and is actively enrolling patients. The trial is being conducted under Special Protocol Assessment (SPA) which provides agreement that the Phase 3 trial design adequately addresses objectives that would support the regulatory submission for drug approval.

The GENUINE 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.

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 pre-clinical programs to develop IRAK4 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, 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 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 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 TG-1101 and TGR-1202 will not continue, including the underlying assumptions providing us confidence in the successful outcome of the Phase 3 GENUINE study; 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 studies or earlier positive trends in safety, particularly with respect to the incidence of colitis and liver toxicity will not be maintained; 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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