

TG THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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Address	2 GANSEVOORT STREET, 9TH FLOOR NEW YORK, NY, 10014
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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): **October 26, 2017**

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.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(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.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On October 26, 2017, TG Therapeutics, Inc. (the “Company”) issued a press release announcing results from the Phase 2 multicenter trial of TG-1101 (ublituximab) in relapsing forms of Multiple Sclerosis (RMS) presented during the 7th JointECTRIMS – ACTRIMS meeting in Paris, France. On October 27, 2017, the Company announced additional results from the Phase 2 multicenter trial of TG-1101 in RMS presented during the 7th JointECTRIMS – ACTRIMS meeting. Copies of the press releases are being filed as Exhibits 99.1 and 99.2 and incorporated in this Item by reference.

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits.

[99.1](#) Press Release, dated October 26, 2017.

[99.2](#) Press Release, dated October 27, 2017.

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: October 27, 2017

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

TG Therapeutics, Inc. Announces Updated Results from the Ongoing Phase 2 Study of TG-1101 (ublituximab) in Patients with Multiple Sclerosis at the 7th JointECTRIMS – ACTRIMS Meeting

100% reduction of T1 Gd-enhancing lesions at week 24 (n=20)

99% median B-cell depletion was observed at week 4 and maintained at week 24 (n=24)

TG-1101 was well tolerated across all patients including those receiving 1 hour infusions of the Phase 3 450mg dose

New York, NY, (**October 26, 2017**) TG Therapeutics, Inc. (NASDAQ: TGTX), today announced results from the Phase 2 multicenter trial of TG-1101 (ublituximab), the Company’s novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS). The data is being presented today in two posters during Poster Session 1, from 15:30 – 17:00 CEST, at the 7th JointECTRIMS – ACTRIMS meeting in Paris, France.

Michael S. Weiss, the Company’s Executive Chairman and Chief Executive Officer stated, “We are extremely pleased with the data presented today demonstrating not only sustained B-cell depletion by week 24 but even more importantly, complete elimination of T1 Gd-enhancing lesions, as well as a well-tolerated safety profile at our Phase 3 dose. We believe these data, although early, compare very favorably to the results seen with other anti-CD20s in the class, with TG-1101 exhibiting what could be a best-in-class profile. These data support our currently enrolling Phase 3 program in MS, which is being launched globally.” Mr. Weiss continued, “We look forward to presenting additional B-cell data tomorrow during the second poster session as well as presenting updated data, including additional patients, from this trial at conferences over the next year.”

“The clinical and MRI data presented today is highly encouraging and further confirms the compelling efficacy seen in Multiple Sclerosis patients treated with ublituximab. While still early, it appears ublituximab can be a highly competitive anti-CD20 with a shorter infusion time, which is a great benefit to our patients. We look forward to additional data from this Phase 2 trial and to participating in the Phase 3 ULTIMATE trials and advancing this important treatment option,” stated Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Associate Professor at the University of Texas Dell Medical School in Austin, TX and the Principal Investigator for this Phase 2 study.

This Phase 2 trial is a 52-week randomized, placebo controlled, multi-center study evaluating the safety and efficacy of TG-1101 (ublituximab) at accelerated infusion times. Today’s posters include data from 24 patients with RMS that were treated with TG-1101 across three dosing cohorts.

Poster Presentation Title: Patient characteristics, safety, and preliminary results of a placebo controlled, phase 2a multicenter study of ublituximab (UTX), a novel glycoengineered anti-CD20 monoclonal antibody (mAb), in patients with relapsing forms of multiple sclerosis

Poster Highlights:

- 99% median B-cell depletion was observed at week 4 and maintained at week 24 (6 months) (n=24)
- 96% of subjects (23/24) were relapse free at week 24
 - One confirmed relapse was reported in a patient initially randomized to the placebo arm. The relapse occurred 12 days after the patients first infusion of 150mg of TG-1101. The patient remains on study and has received the second and third infusions of TG-1101 and to date has remained relapse free.
- Mean EDSS improvement from baseline of 0.35 with 79% of subjects showing improved or stable EDSS
- TG-1101 was well tolerated across all patients including those receiving rapid infusions, as low as a one hour for the 450mg Phase 3 dose, and produced similar levels of B-cell depletion with no identified change in IRR or overall safety profile.

Poster Presentation Title: Preliminary results of phase 2 multicenter study of ublituximab (UTX), a novel glycoengineered anti-CD20 monoclonal antibody (mAb), in patients with relapsing forms of multiple sclerosis (RMS) demonstrates rapid Gd-enhancing lesions decrease

- TG-1101 completely eliminated all (100%) of T1 Gd-enhancing lesions at week 24 (n=20) (p=0.005)
- 7% Reduction in the T2 lesion volume at Week 24 from baseline (p=0.02), suggestive of a decrease in burden of disease
- 6.5% Reduction in T1 hypointense lesion volume at Week 24 from baseline (p=0.03)

These data presentations support the recently announced international Phase 3 program evaluating TG-1101 (ublituximab) for the treatment of relapsing form of Multiple Sclerosis (RMS). The Phase 3 trials, entitled ULTIMATE I and ULTIMATE II, are being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) and will be led by Lawrence Steinman, MD, of Stanford University.

POSTERS

A copy of the above posters can be found on the Publications page, located within the Pipeline section, of the Company's website at www.tgtxinc.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, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for multiple sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Statements included in this press release, particularly those with respect to anticipating the benefit of the early data seen in the Phase 2 MS trial and anticipating the timing of our MS Phase 3 program 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 the MS Phase 2 and Phase 3 trials; the risk that early clinical results that supported our decision to move forward will not be reproduced in additional patients in expansion cohorts or in the MS Phase 3 program; the risk that data included in the posters presented will be reproduced in subsequent data presentations; the risk that the clinical results from the MS Phase 3 program, will not be positive and/or will not support regulatory approval of TG-1101 for MS; the risk that TG-1101 will not have a differentiated profile from the other drugs in the class and that early signs of best-in-class attributes will not be supported by future results; 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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TG Therapeutics, Inc. Announces Additional Updated Results from the Ongoing Phase 2 Study of TG-1101 (ublituximab) in Patients with Multiple Sclerosis at the 7th JointECTRIMS – ACTRIMS Meeting

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Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely pleased by the data presented today showing not only rapid and near complete B-cell depletion at week 4, as previously presented, but that these levels of depletion are also sustained nearly 6 months later with no additional infusions of ublituximab. Today's data coupled with yesterday's presentations showing complete elimination of T1 Gd-enhancing lesions in the first 20 patients treated, a well-tolerated safety profile, and improvements in EDSS give us increased confidence in our currently enrolling Phase 3 program." Mr. Weiss continued, "With what we believe to be an appealing and differentiated profile in MS we look forward to strong enrollment into our Phase 3 program and future presentations from the Phase 2 study as the data continues to mature."

"This updated data presentation on the robust B-cell depletion occurring with ublituximab therapy is impressive in that the antibody appears to be extremely effective at rapidly depleting B-cells while maintaining those levels of depletion through 24 weeks. It is also very encouraging to see that the remainder of the immune system – NK cells, T-cells, and monocytes are able to return to a state of homeostasis shortly following ublituximab infusions. B-cell depleting agents have become an important treatment option for patients suffering from MS, and provided future data presentations and analysis continue to demonstrate the effects seen in the Phase 2 study, ublituximab could be an attractive treatment option for patients," stated Amy Lovett-Racke, PhD, Professor of the Department of Microbial Infection and Immunity at the Ohio State University Medical Center in Columbus, OH.

This Phase 2 trial is a 52-week randomized, placebo controlled, multi-center study evaluating the safety and efficacy of TG-1101 (ublituximab) at accelerated infusion times. Today's posters include data from 24 patients with RMS that were treated with TG-1101 across three dosing cohorts.

Poster Presentation Title: Placebo controlled, phase 2a multicenter study of ublituximab (UTX), a novel glycoengineered anti-CD20 monoclonal antibody (mAb), in patients with relapsing forms of multiple sclerosis (RMS): 6 months analysis of B cell subsets

Poster Highlights:

- TG-1101 was well tolerated and demonstrates rapid and robust B-cell depletion with rapid infusions, as low as a one hour for the 450mg Phase 3 dose
- B-cells are efficiently depleted in most patients within 24 hours of receiving the first dose of TG-1101, with 99% depletion observed at week 4 and maintained at week 24 (6 months) (n=24)
- The fluctuation in NK cells, T-cells and monocytes that occurred in response to B-cell depletion is corrected within 4 weeks post initial TG-1101 treatment
- No significant effect of TG-1101 treatment was observed at Week 24 on the NK cells, T-cells or monocytes, illustrating immune homeostasis in non-B cells

These data presentations support the recently announced international Phase 3 program evaluating TG-1101 (ublituximab) for the treatment of relapsing form of Multiple Sclerosis (RMS). The Phase 3 trials, entitled ULTIMATE I and ULTIMATE II, are being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) and will be led by Lawrence Steinman, MD, of Stanford University.

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