

SHAREHOLDER ALERT: The Law Offices of Timothy L. Miles Reminds Investors of a Lawsuit Against TG Therapeutics, Inc.

Class action lawsuit charges TG Therapeutics and certain of its top executive officers with violations of the Securities Exchange Act of 1934.

NASHVILLE, TENNESSEE, UNITED STATES, September 9, 2022

/EINPresswire.com/ -- The Law Offices of [Timothy L. Miles](#), who has been leading the fight to protect shareholder rights for over 20 years, reminds investors that a purchaser of TG Therapeutics, Inc. (NASDAQ: TGTX) who suffered losses in TG Therapeutics, filed a class action complaint against the Company for alleged violations of

the Securities Exchange Act of 1934. The TG Therapeutics class action lawsuit seeks to represent purchasers or acquirers of TG Therapeutics securities between January 15, 2020 and May 31, 2022, inclusive (the "Class Period"). The TG Therapeutics class action lawsuit is captioned Shapiro v. TG Therapeutics, Inc., No. 22-cv-06106 (S.D.N.Y.).



TG Therapeutics
Shareholders Urged to
Contact the Firm (24/7) for
Additional Information or
Questions"

Timothy L. Miles

If you suffered losses in TG Therapeutics stock or would like additional information, please [visit us here](#).

Allegations in the TG Therapeutics Class Action Lawsuit

TG Therapeutics' therapeutic product candidates include Ublituximab, an investigational glycoengineered

monoclonal antibody for the treatment of B-cell Non-Hodgkin lymphoma, chronic lymphocytic leukemia ("CLL"), and relapsing forms of multiple sclerosis; and Umbralisib, or UKONIQ, an oral inhibitor of PI3K-delta and CK1-epsilon for the treatment of CLL, marginal zone lymphoma, and follicular lymphoma. In January 2020, TG Therapeutics initiated a rolling submission of a New



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FIRM ANNOUNCEMENT

**The Law Offices of Timothy L. Miles Reminds
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Timothy L. Miles Informs Investors of a Lawsuit
Against TG Therapeutics, Inc.**

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Nationally Recognized Shareholder Rights Attorney
Timothy L. Miles

Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”), requesting accelerated approval of Umbralisib as a treatment for patients with previously treated marginal zone lymphoma (“MZL”) and follicular lymphoma (“FL”) (the “Umbralisib MZL/FL NDA”).

In December 2020, TG Therapeutics initiated a rolling submission of a Biologics License Application (“BLA”) to the FDA for Ublituximab in combination with Umbralisib (together, “U2”), as a treatment for patients with CLL (the “U2 BLA”). In May 2021, TG Therapeutics submitted a supplemental New Drug Application (“sNDA”) for Umbralisib to add an indication for CLL and small lymphocytic lymphoma (“SLL”) in combination with Ublituximab (the “U2 sNDA”). And in September 2021, TG Therapeutics submitted a BLA to the FDA for Ublituximab as a treatment for patients with relapsing forms of multiple sclerosis (“RMS”) (the “Ublituximab RMS BLA”).

The TG Therapeutics class action lawsuit alleges that, throughout the Class Period, defendants made false and misleading statements and failed to disclose that: (i) clinical trials revealed significant concerns related to the benefit-risk ratio and overall survival data of Ublituximab and Umbralisib; (ii) accordingly, it was unlikely that TG Therapeutics would be able to obtain FDA approval of the Umbralisib MZL/FL NDA, the U2 BLA, the U2 sNDA, or the Ublituximab RMS BLA in their current forms; and (iii) as a result, TG Therapeutics had significantly overstated Ublituximab and Umbralisib’s clinical and/or commercial prospects.

On November 30, 2021, TG Therapeutics issued a press release “announc[ing] the [FDA] has notified [TG Therapeutics] that it plans to host a meeting of the Oncologic Drugs Advisory Committee (ODAC) in connection with its review of the pending Biologics License Application (BLA)/supplemental New Drug Application (sNDA) for the combination of ublituximab and UKONIQ® (umbralisib) (combination referred to as U2) for the treatment of adult patients with



Timothy L. Miles, a nationally recognized shareholder rights attorney



[CLL] and [SLL].” TG Therapeutics advised that “[t]he FDA has notified [TG Therapeutics] that potential questions and discussion topics for the ODAC include: the benefit-risk of the U2 combination in the treatment of CLL or SLL, and the benefit-risk of UKONIQ in relapsed/refractory [MZL] or [FL]. In addition, as part of the benefit-risk analysis, the overall safety profile of the U2 regimen, including adverse events (serious and Grade 3-4), discontinuations due to adverse events, and dose modifications, is expected to be reviewed.” The release also stated that “[t]he FDA’s concern giving rise to the ODAC meeting appears to stem from an early analysis of overall survival from the UNITY-CLL trial.” On this news, TG Therapeutics’ stock price fell by nearly 35%.

Then, on April 15, 2022, TG Therapeutics issued a press release “announc[ing] that [TG Therapeutics] has voluntarily withdrawn the pending [BLA]/sNDA] for the combination of ublituximab and UKONIQ® (umbralisib) (combination referred to as U2) for the treatment of adult patients with [CLL] and [SLL].” The press release stated that “[t]he decision to withdraw was based on recently updated overall survival (OS) data from the UNITY-CLL Phase 3 trial that showed an increasing imbalance in OS.” On this news, TG Therapeutics’ stock price fell by nearly 22%.

Thereafter, on May 31, 2022, TG Therapeutics issued a press release announcing that the FDA extended the Prescription Drug User Fee Act date for Ublituximab to December 28, 2022 “to allow time to review a submission provided by [TG Therapeutics] in response to an FDA information request, which the FDA deemed a major amendment.” On this news, TG Therapeutics’ stock price fell by more than 14%.



Nationally Recognized Shareholder Rights Attorney Timothy L. Miles Has Achieved the Recognition of American's Mo



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Finally, on June 1, 2022, the FDA announced that, due to safety concerns, it had withdrawn its approval for Umbralisib for the treatment of MZL and FL. Specifically, the FDA provided that “[u]pdated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving [UKONIQ]. As a result, we determined the risks of treatment with [UKONIQ] outweigh its benefits.” On this news, TG Therapeutics’ stock price fell by an additional 11.5%, further damaging investors who suffered losses in TG Therapeutics stock.

TG Therapeutics Shareholders Urged to Contact the Firm

If you purchased TG Therapeutics securities, have information, or have any questions concerning this announcement or your rights or interests with respect to these matters, please [click here](#) for more information or contact Timothy L. Miles, Esquire, at 615-587-7384, Toll-Free at 855-846-6529, or by email to tmiles@timmileslaw.com. If you inquire by email please include your mailing address, telephone number, and the number shares owned.

About Timothy L. Miles

Timothy L. Miles is a nationally recognized shareholder rights attorney raised in Nashville, Tennessee. Mr. Miles was recently selected by Martindale-Hubbell® and ALM as a 2022 Top Ranked Lawyer and a 2022 Top Rated Litigator. Mr. Miles also maintains the AV Preeminent Rating by Martindale-Hubbell®, their highest rating for both legal ability and ethics. Mr. Miles is a member of the prestigious Top 100 Civil Plaintiff Trial Lawyers: The National Trial Lawyers Association, a superb rated attorney by Avvo, a recipient of the Lifetime Achievement Award by Premier Lawyers of America (2019) and recognized as a Distinguished Lawyer, Recognizing Excellence in Securities Law, by Lawyers of Distinction (2019).

Awards: Top Rated Litigator by Martindale-Hubbell® and ALM (2019); 2019 Elite Lawyer of The South by Martindale-Hubbell® and ALM (2019); Member of the Top 100 Civil Plaintiff Trial Lawyers: The National Trial Lawyers Association (2017-2019); AV® Preeminent™ Rating by Martindale-Hubbell® (2014-2020); PRR AV Preeminent Rating on Lawyers.com (2017 & 2019); The Top-Rated Lawyer in Litigation™ for Ethical Standards and Legal Ability (Martindale-Hubbell® 2015); Lifetime Achievement Award by Premier Lawyers of America (2019); Superb Rated Attorney (Avvo); Avvo Top Rated Lawyer for (Avvo 2017-2020). Mr. Miles has authored numerous publications advocating for shareholdings including most recently: Free Portfolio Monitoring Services Offered by Plaintiff Securities Firms Provides Significant Benefits To Investors (Timothy L. Miles, Dec. 3, 2019).

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