# Tourmaline Bio Presents Phase 2 TRANQUILITY Study Design at American Society of Preventive Cardiology (ASPC) Congress 2024

August 2, 2024

- *Phase 2 TRANQUILITY trial is evaluating the high-sensitivity C-reactive protein (hs-CRP)-lowering effect, safety, tolerability, and pharmacokinetics (PK) of quarterly and monthly subcutaneous administration of TOUR006 in patients with chronic kidney disease and elevated hs-CRP —*
- *Dosing regimens are informed by six previous Phase 1 and Phase 2 clinical studies in healthy volunteers and patients with inflammatory autoimmune disorders, as well as PK/PD modeling —*
- *Topline data is expected first half of* 2025 *—*
- *Data from Phase 2 TRANQUILITY trial have the potential to advance TOUR006 toward Phase 3 readiness for atherosclerotic cardiovascular disease (ASCVD) and other cardiovascular diseases.*

NEW YORK, Aug. 02, 2024 (GLOBE NEWSWIRE) -- Tourmaline Bio, Inc. (Tourmaline) (NASDAQ: TRML), a late-stage clinical biotechnology company developing transformative medicines to dramatically improve the lives of patients with life-altering immune and inflammatory diseases, today presented a poster at the American Society of Preventive Cardiology (ASPC) Congress in Salt Lake City, Utah, detailing the rationale and design of the company's TRANQUILITY Phase 2 study examining the potential of its lead candidate, TOUR006, to reduce high-sensitivity C-reactive protein (hs-CRP), a key biomarker of residual inflammatory cardiovascular risk, in patients with chronic kidney disease (CKD) and elevated hs-CRP.

Patients with CKD and elevated hs-CRP are at heightened risk of atherosclerotic cardiovascular disease (ASCVD), including heart attack, stroke, and peripheral artery disease, despite current standard-of-care treatments. The IL-6 pathway has been identified as a significant contributor to ASCVD risk, particularly in CKD patients. TOUR006 has previously shown promise in reducing hs-CRP levels in patients with inflammatory autoimmune diseases.

"The TRANQUILITY study represents an important step in understanding the potential of TOUR006 to address unmet needs in patients with residual inflammatory cardiovascular risk, despite lifestyle changes and available therapeutic interventions," said Emil deGoma, MD, Senior Vice President of Medical Research at Tourmaline and former Medical Director of the Preventive Cardiovascular Program at the University of Pennsylvania. "With a robust clinical dataset from six previous trials involving 448 dosed study participants, comprised of healthy volunteers and patients with diseases other than cardiovascular disorders, as well as converging clinical evidence supporting the therapeutic potential of IL-6 inhibition, we are confident in our approach and the potential of TOUR006 and look forward to seeing the data from this study."

In the poster titled "**Evaluating TOUR006 in Participants with Chronic Kidney Disease and Elevated hs-CRP: Rationale and Design of the TRANQUILITY Phase 2 Study**," Tourmaline provided an overview of the study design and rationale behind investigating TOUR006 in patients with CKD and elevated hs-CRP, highlighting:

- **Objective:** To evaluate the hs-CRP-lowering effect, safety, tolerability, and pharmacokinetics of TOUR006 in patients with CKD and elevated hs-CRP.
- **Design**: A randomized, double-blind, placebo-controlled, multicenter trial involving approximately 120 patients with CKD stage 3 or 4 and hs-CRP ≥2 and <15 mg/L.
- **Methods:** Participants are stratified by CKD stage and randomized to receive subcutaneous TOUR006 at doses of 50 mg quarterly, 25 mg quarterly, 15 mg monthly, or placebo. The primary pharmacodynamic endpoint is the change in hs-CRP levels. Additional biomarkers being measured include IL-6, lipoprotein(a), oxidized low-density lipoprotein (LDL), and fibrinogen.
- **Timeline:** The treatment and follow-up periods are 180 days and 185 days, respectively, with the primary completion expected in May 2025.

The Phase 2 TRANQUILITY trial is expected to inform the dosing regimen and design of any future Phase 3 cardiovascular studies in high-risk patients.

Additional meeting information can be found at https://www.aspconline.org/2024congress

**About the Phase 2 TRANQUILITY Trial**
The Phase 2 TRANQUILITY trial is a randomized, double-blind, placebo-controlled study designed to evaluate the safety, pharmacokinetics (PK), and pharmacodynamics (PD), including CRP-lowering effect, of quarterly and monthly subcutaneous administration of TOUR006 in patients with elevated

high-sensitivity C-reactive protein (hs-CRP) and chronic kidney disease (CKD). The selection of dosing regimens being evaluated in TRANQUILITY was informed by six previously completed Phase 1 and Phase 2 trials of TOUR006 in healthy volunteers and patients with rheumatoid arthritis, Crohn's disease, or systemic lupus erythematosus as well as PK/PD modeling. For more information on the TRANQUILITY clinical trial, please visit clinicaltrials.gov (NCT06362759).

**About TOUR006**
TOUR006 is a long-acting, fully human, anti-IL-6 monoclonal antibody with differentiated properties, including a naturally long half-life, low immunogenicity, and high binding affinity to IL-6. TOUR006 has been previously studied in 448 participants, including patients with autoimmune disorders, across six completed clinical trials. Tourmaline is developing TOUR006 in thyroid eye disease and atherosclerotic cardiovascular disease as its first two indications, with additional diseases under consideration.

**About Tourmaline**
Tourmaline is a late-stage clinical biotechnology company driven by its mission to develop transformative medicines that dramatically improve the lives of patients with life-altering immune and inflammatory diseases. Tourmaline's lead asset is TOUR006.

**Cautionary Note Regarding Forward-Looking Statements:**
Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words and phrases such as "believe," "designed to," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on Tourmaline's current beliefs and expectations. These forward-looking statements include, but are not limited to, expectations regarding the development and potential therapeutic benefits of TOUR006, including the timing of initiation, progress and results of Tourmaline's current and future clinical trials for TOUR006, and reporting of data therefrom, including the anticipation that topline data from the Phase 2 TRANQUILITY trial will be available in the first half of 2025, and the expectation that such data, if successful, will position Tourmaline to be Phase 3-ready in 2025 for ASCVD and other cardiovascular diseases; and patient population and market opportunities. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the development of therapeutic product candidates, such as the risk that any one or more of Tourmaline's current or future product candidates will not be successfully developed or commercialized; the risk of delay or cessation of any planned clinical trials of Tourmaline's current or future product candidates, including the Phase 2 TRANQUILITY trial; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Tourmaline's current or future product candidates; the risk that Tourmaline's current or future product candidates or procedures in connection with the administration thereof will not have the safety or efficacy profile that Tourmaline anticipates; risks regarding the accuracy of Tourmaline's estimates of expenses, capital requirements and needs for additional financing; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; unexpected litigation or other disputes; the impacts of macroeconomic conditions Tourmaline's business, clinical trials and financial position; and other risks and uncertainties that are described in Tourmaline's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") on May 13, 2024 and other filings that Tourmaline makes with the SEC from time to time. Any forward-looking statements speak only as of the date of this press release and are based on information available to Tourmaline as of the date hereof, and Tourmaline assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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