

TOURMALINE

Tourmaline Bio Initiates Clinical Development of TOUR006 for Cardiovascular Diseases with First Patient Dosed in Phase 2 TRANQUILITY Trial

May 16, 2024

- First patient dosed in trial to evaluate the safety, pharmacokinetics and pharmacodynamics of TOUR006 in patients with inflammatory risk and chronic kidney disease –
- Topline data anticipated in the first half of 2025 with potential to advance TOUR006 toward Phase 3 readiness for atherosclerotic cardiovascular disease (ASCVD) and other cardiovascular diseases –
- TRANQUILITY trial intended to provide evidence of TOUR006's best-in-class potential for ASCVD, including the potential for quarterly subcutaneous dosing –

NEW YORK, May 16, 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 announced that the first patient has been dosed in its Phase 2 TRANQUILITY trial, marking the initiation of its clinical development program for TOUR006, a long-acting, fully human, anti-IL-6 monoclonal antibody, for the treatment of atherosclerotic cardiovascular disease (ASCVD) and other cardiovascular diseases. TRANQUILITY is a randomized, double-blind, placebo-controlled trial enrolling patients with inflammatory risk, manifesting as elevated high-sensitivity C-reactive protein (hs-CRP) at baseline, and chronic kidney disease (CKD).

"New treatments are sorely needed for the millions of patients who remain at very high risk of heart attack, stroke, acute limb ischemia, and death despite traditional risk factor modification," 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. "Converging evidence from IL-6 human genetic studies, epidemiological studies, and mechanistic experiments as well as analyses from clinical trials of upstream IL-6 inhibition supports the therapeutic potential of IL-6 inhibition for patients across the spectrum of ASCVD as well as for patients with other cardiovascular diseases, including heart failure."

The design of the TRANQUILITY clinical trial was informed by insights from six prior Phase 1 and Phase 2 studies of TOUR006. If successful, results from the Phase 2 TRANQUILITY trial are expected to position Tourmaline to be Phase 3-ready in 2025 for ASCVD and other cardiovascular diseases.

"TOUR006 is a true 'pipelines in a product' opportunity, seeking to address both serious cardiovascular diseases for which IL-6-driven inflammation plays a key role as well as serious autoimmune disorders, such as thyroid eye disease," continued Sandeep Kulkarni, MD, Co-Founder and Chief Executive Officer of Tourmaline. "We believe TRANQUILITY can showcase TOUR006's potential as a best-in-class treatment in these indications, offering ease of use and enabling consistent patient adherence, thanks to a potential quarterly dosing schedule. We look forward to sharing topline results from TRANQUILITY in the first half of 2025."

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 \(NCT06362759\)](https://clinicaltrials.gov/NCT06362759).

About TOUR006

TOUR006 is a long-acting, fully human, anti-IL-6 monoclonal antibody with best-in-class potential and 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 Bio

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 belief of TOUR006 being a pipelines in a product opportunity, seeking to address both cardiovascular diseases and autoimmune disorders; 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 on 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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