# Tourmaline Bio Announces Expected Upcoming Key Milestones for the Clinical Development of TOUR006, a Long-Acting Subcutaneous Inhibitor of IL-6 with Best-in-Class Potential, in Thyroid Eye Disease (TED) and Atherosclerotic Cardiovascular Disease (ASCVD)

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*Tourmaline plans to accelerate the initiation of a pivotal Phase 3 trial in 2024 evaluating subcutaneous TOUR006 every 8 weeks as first-line treatment for TED, with topline data expected in 2026*

*Alignment has been reached with the FDA on the clinical development program in ASCVD, including a Phase 2 trial evaluating quarterly dosing of TOUR006 in patients with elevated cardiovascular risk*

*Topline data from the ongoing pivotal Phase 2b trial in TED (spiriTED) and the Phase 2 trial in patients with elevated cardiovascular risk are both expected in the first half of 2025*

*Tourmaline continues to expect cash runway through 2026, including key TOUR006 data readouts in TED and cardiovascular disease*

NEW YORK, Jan. 08, 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, announced today that:

- It is planning to commence a pivotal Phase 3 trial for TOUR006 in TED in 2024. This second pivotal trial will replace the previously planned TED basket trial and does not impact Tourmaline's expected cash runway through 2026. Topline data from the ongoing Phase 2b spiriTED trial are expected in the first half of 2025 and topline data from the planned Phase 3 trial in TED are expected in 2026.
- Alignment has been reached with the U.S. Food & Drug Administration (FDA) on the ASCVD clinical development program, including a Phase 2 trial evaluating the reduction of C-reactive protein (CRP), a validated biomarker for inflammation, with quarterly dosing of TOUR006 in patients with elevated cardiovascular risk. This trial is targeted to commence in the first half of 2024, with topline data expected in the first half of 2025. Pending success, the results from the Phase 2 trial are expected to position Tourmaline to be ready in 2025 to commence a pivotal Phase 3 trial in cardiovascular disease.

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. To date, TOUR006 has been studied in 448 participants, including patients with autoimmune disorders, across six clinical trials.

*"It is an exciting time in the IL-6 field, as new insights and evidence emerge identifying a central role for this validated drug target in TED and across many autoantibody and inflammation-driven diseases,"* said **Sandeep Kulkarni, MD, Co-Founder and Chief Executive Officer of Tourmaline**. *"We believe TOUR006 offers the potential to fulfill the promise of this IL-6 renaissance as we are aiming to achieve a best-in-class and best-in-disease profile by addressing IL-6 mediated autoantibody production and inflammation, while providing a patient-friendly treatment through long-acting, low-volume subcutaneous injections."*

**Planned TED Development**

Tourmaline's pivotal Phase 3 trial is expected to evaluate first-line use of TOUR006 in patients with TED. Subject to FDA and other regulatory feedback, this trial is planned to be a randomized, double-masked, placebo-controlled trial evaluating TOUR006 administration on an eight-week dosing schedule. The primary endpoint is expected to be proptosis response, or reduction of abnormal eye protrusion, as measured at week 20 following three subcutaneous (SC) administrations. Other efficacy endpoints are anticipated to include additional measures such as clinical activity score (CAS), diplopia and quality of life (QoL).

The ongoing spiriTED Phase 2b trial is the first of two pivotal trials in TED evaluating TOUR006. This randomized, double-masked, placebo-controlled trial is evaluating 20 mg and 50 mg doses versus placebo given by low-volume SC injections every eight weeks. The study is enrolling a planned 81 participants with moderate-to-severe TED who are in the active (inflammatory) phase of disease. The primary endpoint is proptosis response as measured at week 20 following three SC administrations. Other endpoints include important additional efficacy measures such as CAS, diplopia and QoL, as well as safety, pharmacokinetics, pharmacodynamics, and immunogenicity.

**Planned ASCVD Development**

TOUR006 is also being developed for ASCVD using quarterly, low-volume, SC administrations, in contrast to other IL-6 pathway inhibitors that are in development that have more frequent dosing regimens. The Phase 2 clinical trial of TOUR006 in patients with elevated cardiovascular risk is expected to be a randomized, double-blind, placebo-controlled trial with 120 patients across four different SC treatment arms: 50 mg quarterly, 25 mg quarterly, 15 mg monthly, and placebo. The primary endpoint for this trial is change from baseline in high-sensitivity C-reactive protein (hsCRP), a validated marker of IL-6 mediated inflammation in ASCVD. The study will also evaluate other biomarkers of IL-6 pathway activation as well as safety,

pharmacokinetics, and immunogenicity.

*"Despite important advances in the management of atherosclerotic cardiovascular disease, there continues to be a large number of patients worldwide who remain at high risk for major adverse cardiovascular events",* said **Yung Chyung, MD, Chief Medical Officer of Tourmaline**. *"We believe TOUR006 has the potential to address this significant unmet medical need by targeting the IL-6 pathway as well as by offering a patient-friendly, quarterly, low-volume subcutaneous dosing regimen."*

**About Tourmaline Bio, Inc.**

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.

**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. To date, TOUR006 has been studied in 448 participants, including patients with autoimmune disorders, across six clinical trials. Tourmaline is developing TOUR006 in TED and ASCVD as its first two indications, with additional diseases under consideration.

**Forward-Looking Statements**

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including but not limited to, express or implied statements regarding the potential of, and expectations regarding, Tourmaline's product candidates, including TOUR006; the timing, initiation and success of ongoing and new clinical trials for TOUR006 in TED and ASCVD; expectations concerning decisions of regulatory bodies, including the FDA, and the timing thereof; other drug candidates in development; expectations regarding the sufficiency of Tourmaline's capital resources and cash runway; and other statements that are not historical fact. All statements other than statements of historical fact contained in this press release are forward-looking statements. These forward-looking statements are made as of the date they were first issued, and were based on the then-current expectations, estimates, forecasts, and projections, as well as the beliefs and assumptions of management. There can be no assurance that future developments affecting Tourmaline will be those that have been anticipated.

Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Tourmaline's control. Tourmaline's actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to (i) the uncertainties associated with Tourmaline's platform technologies, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; (ii) risks related to the inability of Tourmaline to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (iii) uncertainties in obtaining successful clinical results for product candidates of Tourmaline and unexpected costs that may result therefrom; (iv) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed by Tourmaline in light of inherent risks and difficulties involved in successfully bringing product candidates to market; and (v) the impacts of general macroeconomic and geopolitical conditions, rising inflation, and uncertain credit and financial markets on Tourmaline's business, clinical trials and financial position. These and other risks and uncertainties are more fully described in periodic filings with the Securities and Exchange Commission (the "SEC"), including the factors described in the section titled "Risk Factors" in Tourmaline's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. Except as may be required under applicable law, Tourmaline expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based. This press release does not purport to summarize all of the conditions, risks and other attributes of an investment in Tourmaline.

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