Tourmaline Bio Announces FDA Clearance of Investigational New Drug (IND) Application for TOUR006, an anti-IL-6 antibody with a differentiated profile for the treatment of thyroid eye disease (TED)

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Phase 2b trial of TOUR006 is expected to report top-line clinical data in the first half of 2025

NEW YORK – August 28, 2023 – Tourmaline Bio, Inc. (Tourmaline), a late-stage clinical biotechnology company developing transformative medicines to dramatically improve the lives of patients with life-altering immune diseases, today announced U.S. Food and Drug Administration (FDA) clearance of Tourmaline's IND application for TOUR006.

TOUR006 is a fully-human, anti-IL-6 antibody with differentiated properties including high binding affinity to IL-6 and a naturally long half-life. TED, also known as Graves' ophthalmopathy, is an autoimmune disease characterized by inflammation and disfigurement around the eye, which can be sight-threatening in severe cases. Off-label use of IL-6 pathway inhibitors in TED has resulted in reduced inflammation and eye-bulging and has been shown to impact key biomarkers such as levels of pathogenic autoantibodies.

"We are excited to advance TOUR006 into late-stage development in TED. We believe TOUR006 could be an ideal treatment option for patients suffering from TED, in light of its anti-inflammatory mechanism of action, established tolerability profile, attractive dosing schedule, and convenient subcutaneous administration," said Sandeep Kulkarni, MD, Chief Executive Officer of Tourmaline. "We anticipate top-line data from this trial in the first half of 2025 and expect to further expand the development of TOUR006 into atherosclerotic cardiovascular disease (ASCVD) and other indications. We are also looking forward to the expected closing of our merger with Talaris Therapeutics and listing on Nasdaq in the fourth quarter of 2023."

The planned Phase 2b trial of TOUR006 in TED is expected to evaluate 20mg and 50mg doses against placebo given by a subcutaneous injection every eight weeks. The approximately 81 participants planned to be enrolled (27 in each arm) will be moderate to severe TED patients who are in the active phase of disease. The primary endpoint for this trial will be proptosis response, or reduction of abnormal eye protrusion, measured at week 20.

About Tourmaline Bio, Inc.

Tourmaline Bio 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 diseases. Tourmaline's lead program, TOUR006, is an anti-IL-6 antibody that exhibits differentiated properties including high binding affinity to IL-6 and a naturally long half-life. To date, TOUR006 has been studied in over 400 autoimmune patients across six clinical trials. Tourmaline plans to develop TOUR006 in thyroid eye disease (TED) and atherosclerotic cardiovascular disease (ASCVD) as its first two indications, with additional indications under consideration. In June 2023, Tourmaline announced it had entered into a definitive agreement with Talaris Therapeutics under which Tourmaline is expected to combine with Talaris. The combined company will operate under Tourmaline's name and be led by Tourmaline's current management team, focused on advancing the development of TOUR006.

Forward-Looking Statements

This communication 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 development and commercial potential and potential benefits of any product candidates or platform technologies of Tourmaline; anticipated preclinical and clinical drug development activities and related timelines, including the expected timing for data and other clinical results; and other statements that are not historical fact. All statements other than statements of historical fact contained in this communication 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. 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 these product candidates and its preclinical programs; (iii) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; and (iv) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market, among others. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section titled "Risk Factors" in Talaris Therapeutic, Inc.'s Registration Statement on S-4 filed with the SEC. 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. 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.

Participants in the Solicitation

This communication relates to the proposed merger transaction involving Talaris and Tourmaline and may be deemed to be solicitation material in respect of the proposed merger transaction. In connection with the proposed merger transaction, Talaris has filed relevant materials with the U.S. Securities and Exchange Commission (the "SEC"), including a registration statement on Form S-4 (the "Form S-4") that contains a proxy statement (the "Proxy Statement") and prospectus. This communication is not a substitute for the Form S-4, the Proxy Statement or for any other document that Talaris may file with the SEC and or send to Talaris' shareholders in connection with the proposed merger transaction. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS OF TALARIS ARE URGED TO READ THE FORM S-4, THE PROXY STATEMENT AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT TALARIS, THE PROPOSED MERGER TRANSACTION AND RELATED MATTERS.

Additional Information and Where to Find It

Investors and security holders will be able to obtain free copies of the Form S-4, the Proxy Statement and other documents filed by Talaris with the SEC through the website maintained by the SEC at http://www.sec.gov. Copies of the documents filed by Talaris with the SEC will also be available free of charge on Talaris' website at www.talaristx.com, or by contacting Talaris' Investor Relations at investors@talaristx.com. Talaris, Tourmaline, and their respective directors and certain of their executive officers may be considered participants in the solicitation of proxies from Talaris' shareholders with respect to the proposed merger transaction under the rules of the SEC. Information about the directors and executive officers of Talaris is set forth in its Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 31, 2023, and in subsequent documents filed with the SEC. Additional information regarding the persons who may be deemed participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, will also be included in the Form S-4, the Proxy Statement and other relevant materials to be filed with the SEC when they become available. You may obtain free copies of this document as described above.

No Offer or Solicitation

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities nor a solicitation of any vote or approval with respect to the proposed transaction or otherwise. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U S. Securities Act of 1933, as amended, and otherwise in accordance with applicable law.

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