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Dermata Therapeutics Completes Start-Up Activities to Support DMT310 Phase 3 STAR-1 Acne Trial

- Dermata is prepared to initiate DMT310 Phase 3 STAR-1 clinical trial by the end of 2023 -

- Investigational sites have been selected -

- Clinical trial materials are ready to be shipped to investigational sites -

SAN DIEGO, CA / ACCESSWIRE / October 26, 2023 [/Dermata Therapeutics.](#)

[Inc.](#) (NASDAQ:DRMA)(NASDAQ:DRMAW) ("Dermata" or the "Company"), a clinical-stage biotechnology company focusing on the treatment of medical and aesthetic skin conditions, today announced that it has completed start-up activities necessary to support its DMT310 Phase 3 STAR-1 trial in acne. Based on feedback from FDA on the Company's Type-C meeting package and End of Phase 2 meeting package, the Company completed the DMT310 Phase 3 manufacturing campaign and clinical start-up activities to prepare for the initiation of the STAR-1 Phase 3 study upon final approval from FDA.

"Our development team and partners have put forth a tremendous effort to prepare everything needed to start the STAR-1 Phase 3 acne study," said Gerry Proehl, Dermata's Chairman, President, and Chief Executive Officer. "We have amended the Phase 3 protocol as recommended by FDA, drug product kits are ready to be shipped, and clinical sites have been selected. Once we receive final approval of the amended STAR-1 protocol from FDA, we plan to quickly initiate the study and begin enrolling patients," concluded Mr. Proehl.

Dermata's lead product candidate, DMT310, is currently in late-phase development for the treatment of moderate-to-severe acne, with the Company prepared to initiate the DMT310 Phase 3 STAR-1 clinical trial. The STAR-1 trial is designed to evaluate the efficacy, safety, and tolerability of DMT310 in patients with moderate-to-severe facial acne. The STAR-1 trial will be a randomized (2:1), double-blind, placebo-controlled, enrolling over 500 acne patients ages 9 years and older in the United States and Latin America. The primary endpoints will include the mean change from baseline in inflammatory and noninflammatory lesion counts and the Investigator Global Assessment (IGA) response rate. IGA is measured on a 5-point scale (0-4), with a treatment response defined as a 2-grade improvement from baseline and an IGA score of 0 (clear) or 1 (almost clear). Patients will be treated once weekly for 12 weeks with either DMT310 or placebo and be evaluated monthly. This will be one of two pivotal Phase 3 trials that if positive, will be used to support the filing of a new drug application with FDA.

About Acne Vulgaris

Acne affects approximately 50 million people in the U.S., with about 85% of teenagers

experiencing some form of acne, and some individuals suffering from acne well into their 30s, 40s, and beyond. Acne is characterized by areas of scaly red skin, noninflammatory blackheads and whiteheads, inflammatory papules and pustules, and occasionally cysts and scarring, which occurs on the face, neck, chest, back, shoulders, and upper arms. While not life-threatening, acne can cause significant trauma for those suffering from it due to social stigmas, substantial risk of permanent facial scarring, lowered self-esteem, and social withdrawal.

About Dermata Therapeutics

Dermata Therapeutics is a clinical-stage biotechnology company focusing on the treatment of medical and aesthetic skin conditions. The Company's lead product candidate, DMT310, is the first product candidate being developed from its *Spongilla* technology platform. DMT310 is a once-weekly topical product candidate derived from a naturally sourced freshwater sponge with multiple unique mechanisms of action. In addition to acne, DMT310 has been studied for the treatment of psoriasis and rosacea. The Company's second product candidate, DMT410, uses its *Spongilla* technology as a new method for needle-free intradermal delivery of botulinum toxin for the treatment of multiple aesthetic and medical skin conditions. Dermata is headquartered in San Diego, California. For more information, please visit <http://www.dermatarx.com/>.

Forward-Looking Statements

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements are based on the Company's current beliefs and expectations and new risks may emerge from time to time. Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but are not limited to, statements related to: expectations with regard to the potential market acceptance of any of the Company's product candidates; timing of data events; expectations with regard to the timing and/or results from meetings with regulatory bodies; the Company's expectations with regard to current cash and the amount of time it will fund operations; the success, cost, and timing of its product candidate DMT310 development activities and ongoing and planned clinical trials; and whether the results of DMT310 will lead to future product development or approvals. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in drug development, approval and commercialization, and the fact that past results of clinical trials may not be indicative of future trial results. For a discussion of these and other factors, please refer to Dermata's filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and Dermata undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

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Company Update