November 16, 2023

Dermata to Begin Enrolling Patients in DMT310 Phase 3 Acne Clinical Program in December 2023 based on Agreement with FDA on the Phase 3 Protocols

- DMT310 Phase 3 STAR-1 (Spongilla Treatment of Acne Research) clinical trial will evaluate the efficacy and safety of once-weekly treatments of DMT310 for 12 weeks in moderate-to-severe acne patients -

- Topline results from STAR-1 clinical trial expected in Q1 2025 -

- DMT310, if approved, may be the first once-weekly, topical acne treatment -

SAN DIEGO, CA / ACCESSWIRE / November 16, 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, announces agreement with the U.S. Food and Drug Administration (FDA) on the DMT310 Phase 3 clinical protocols for the treatment of acne. This agreement allows the Company to initiate the Phase 3 clinical trial program, with plans to begin enrolling patients in the first Phase 3 clinical trial in December 2023.

"Our team is thrilled to have received positive feedback and agreement from FDA to allow us to initiate the pivotal DMT310 Phase 3 clinical program, as this is an important milestone for Dermata," said Gerry Proehl, Dermata's Chairman, President, and Chief Executive Officer. "We look forward to enrolling the first patients in the STAR-1 trial by the end of this year, which we believe may provide further evidence of the significant efficacy of DMT310 seen in

moderate-to-severe acne patients. We believe patients and physicians are eagerly awaiting a novel product like DMT310 that only requires once-weekly applications with a demonstrated 45% reduction in inflammatory lesions after only 4 treatments as seen in our Phase 2b acne study. If approved, we believe DMT310 has the potential to cause a paradigm shift in the treatment of moderate-to-severe acne, becoming a first in class treatment option for the approximately 50 million patients suffering with acne in the US," concluded Mr. Proehl.

DMT310 Phase 3 Clinical Trial Design

The DMT310 Phase 3 clinical program will include two Phase 3 clinical trials to evaluate the efficacy, safety, and tolerability of DMT310 in patients with moderate-to-severe facial acne. Each Phase 3 trial will be randomized (2:1), double-blind, and placebo-controlled, enrolling approximately 550 acne patients ages 9 years and older in the United States and Latin America. The primary endpoints are 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-point 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 will be evaluated monthly. The first of two pivotal Phase 3 trials, STAR-1, is planned to begin enrolling patients by the end of 2023. If positive, the results from both Phase 3 clinical trials will be used to support the filing of an NDA with FDA.

About DMT310

DMT310 is a novel, once-weekly, topical product candidate derived from a freshwater sponge being developed for the treatment of multiple skin diseases. It has multiple mechanisms of action that include mechanical components and chemical compounds to help treat inflammatory skin diseases, like acne. After processing, the sponge powder contains precisely sized and shaped silica spicules that upon application may help exfoliate the skin, promote collagen production, open closed comedones (creating an aerobic environment to help kill *C. acne* bacteria), and create microchannels to facilitate penetration of the sponge's naturally occurring chemical compounds. These chemical compounds have been shown, in-vitro, to have both antimicrobial and anti-inflammatory properties, which may play a significant role in the treatment of inflammatory skin diseases. DMT310 has previously shown its treatment effect in moderate-to-severe acne in a Phase 2b study where DMT310 applied once weekly, achieved statistically significant results at all timepoints for all primary and secondary endpoints. DMT310 also observed almost 45% of patients achieve an IGA score of clear or almost clear compared with less than 18% of placebo patients achieving the same at the end of 12 weeks.

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 can present 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 trials and data events; expectations with regard to the timing and/or results or responses from meetings with regulatory bodies, including the FDA; 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 forward-looking statements are generally identified by the use of such words as "may," "could," "should," "would," "believe," "anticipate," "forecast," "estimate," "expect," "intend," "plan," "continue," "outlook," "will," "potential" and similar statements of a future or forward-looking nature. 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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SOURCE: Dermata Therapeutics

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https://www.accesswire.com/804113/dermata-to-begin-enrolling-patients-in-dmt310-phase-3-acne-clinical-program-in-december-2023-based-on-agreement-with-fda-on-the-phase-3-protocols