July 17, 2024

Dermata Announces Achievement of 50% Enrollment in Pivotal DMT310 Phase 3 STAR-1 Clinical Trial for Acne

- STAR-1 topline results expected in first quarter of 2025 -

- About 30 million acne patients seek treatment in the U.S. each year -

- DMT310, if approved, could be the first once-weekly topical product for the treatment of acne -

SAN DIEGO, CA / ACCESSWIRE / July 17, 2024 /Dermata Therapeutics, Inc. (Nasdaq:DRMA)(Nasdaq:DRMAW) ("Dermata" or the "Company"), a late-stage biotechnology company focusing on the treatment of medical and aesthetic skin conditions, today announced that it has successfully enrolled 50% of patients in its pivotal Phase 3 **S**pongilla **T**reatment for **A**cne **R**esearch (STAR-1) study of DMT310, a novel, once-weekly, topical product candidate for the treatment of moderate-to-severe acne. The STAR-1 study is the first of two Phase 3 studies that, if positive, would be used by the Company to support the filing of a new drug application (NDA) for DMT310 for the treatment of moderate-to-severe acne.

"We are excited by the enrollment progress seen in the STAR-1 study since enrolling our first patient in December 2023 and want to thank all those patients for their participation in the study," said Christopher Nardo, Ph.D., Dermata's Chief Development Officer. "With all clinical sites activated, we expect to continue our enrollment momentum in the coming months and expect to announce topline data from the STAR-1 study in the first quarter of 2025," Dr. Nardo continued. "Investigators continue to be enthusiastic about DMT310 and its potential to be the first approved once-weekly, topical product for the treatment of moderate-to-severe acne as there continues to be a need for safe and effective treatment options. We believe that if the DMT310 Phase 3 program confirms the safety and efficacy observed in our Phase 2b acne study, that if approved, DMT310 could become a first line therapy for the treatment of moderate-to-severe acne," concluded Dr. Nardo.

DMT310 Phase 3 Clinical Program 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 patients with moderate-to-severe acne, 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) treatment response. IGA is measured on a 5-point scale (0-4), with a treatment response defined as at least a 2-point improvement from baseline and an IGA score of 0 (clear) or 1 (almost clear). Patients will be treated once a week for 12 weeks with either

DMT310 or placebo and will be evaluated monthly. STAR-1 is the first of two pivotal Phase 3 trials, of which the second Phase 3 study will be followed by a long-term extension study. If positive, the results from the Phase 3 program would 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. DMT310 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

Over 30 million acne patients in the U.S. seek treatment each year, 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 late-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, funds available, 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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