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Dermata Therapeutics Announces Positive Feedback from FDA on the DMT310 Phase 3 Clinical Development Program in Moderate-to-Severe Acne

- FDA established key elements of the DMT310 Phase 3 clinical program and delineated a potential regulatory pathway for approval of DMT310 -

-The DMT310 Phase 3 program will consist of two pivotal trials, STAR-1 and STAR-2 (*Spongilla Treatment of Acne Research Study*)-

- The first patient in STAR-1 is planned to be enrolled in 2H of 2023 -

SAN DIEGO, CA / ACCESSWIRE / June 27, 2023/ Dermata Therapeutics, Inc. (Nasdaq:DRMA, DRMAW) ("Dermata" or the "Company"), a clinical-stage biotechnology company focusing on the treatment of medical and aesthetic skin conditions, today announced that following the Company's receipt of FDA responses to its End of Phase 2 meeting package, the Company's DMT310 Phase 3 clinical development program for the once-weekly topical treatment of patients with moderate-to-severe acne is on track to begin in the second half of 2023. The Company submitted data from its Phase 1 and 2 clinical trials, as well as a nonclinical data package supporting the efficacy, safety, and tolerability of DMT310 for the treatment of moderate-to-severe acne for its Phase 3 clinical development program.

FDA provided written responses to the Company's End of Phase 2 meeting package including an agreement that the Company's (1) nonclinical program appears reasonable to support Phase 3 clinical trials, (2) the overall Phase 3 clinical development program appears acceptable for filing a New Drug Application (NDA), (3) the three co-primary endpoints and secondary endpoints proposed in the Phase 3 clinical trial protocols are acceptable, and (4) the completed and planned nonclinical studies would be sufficient to support the submission of an NDA. Additionally, at the recommendation of FDA, the Company has agreed to include additional safety evaluations (laboratory measurements, electrocardiograms, and an extension study) in the Phase 3 clinical program and plans to submit final updated protocols to FDA shortly.

Based on FDA's feedback, the Company anticipates that the Phase 3 clinical program will consist of two independent pivotal trials and an extension study. Each pivotal trial will evaluate the efficacy, safety, and tolerability of DMT310 in patients with moderate-to-severe facial acne. Both pivotal Phase 3 trials will be randomized (2:1), double-blind, and placebo-controlled. 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). The pivotal Phase 3 trials will enroll patients as young as nine who will be treated once weekly with either DMT310 or placebo and be evaluated monthly for 12 weeks. The extension study will include patients from both the DMT310 and placebo arms of the *STAR-1* trial. Patients will be treated weekly with DMT310 and will be followed for 12 months to evaluate long-term safety.

"We appreciate the productive responses from FDA to our End of Phase 2 meeting package and believe we have a Phase 3 clinical development program that may provide us the clinical data to support filing an NDA with FDA," said Christopher Nardo, Ph.D., Dermata's Chief Development Officer. "We are also glad to have agreement from FDA on the three co-primary endpoints to be used in the Phase 3 program, which are the same endpoints used in our statistically significant Phase 2b trial in acne. If successful, the Phase 3 clinical development program should demonstrate the clinical effect and safety profile of DMT310, which could be the first once-weekly topical product for the treatment of acne."

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.

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 or responses from meetings with regulatory bodies, including the FDA; expectations with regard to any potential partnership opportunities for the Company's product candidates; 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.

Investors:
Sean Proehl
Senior Director, Legal and Business Development
info@dermatarx.com

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