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Dermata's XYNGARI(TM) Phase 3 Trial Hits Statistically Significant Difference at 4 Weeks

- Dermata previously announced XYNGARI(TM) produced highly statistically significant topline data for all primary endpoints at week 12 in Phase 3 trial -

- Additional data analysis revealed that XYNGARI(TM) separated from placebo after just four once-weekly treatments -

- XYNGARI(TM) could be the first once-weekly topical product candidate for moderate-to-severe acne -

SAN DIEGO, CA / ACCESS Newswire / April 15, 2025 /Dermata Therapeutics, Inc. (Nasdaq:DRMA)(Nasdaq:DRMAW) ("Dermata" or the "Company"), a late-stage biotechnology company focusing on the treatment of medical skin diseases and aesthetic applications, today announced that additional analysis of topline data from its Phase 3 STAR-1 trial showed that XYNGARI™ had a statistically significant difference from placebo on three efficacy endpoints as early as week 4, which occurred after just four treatments with XYNGARI™.

XYNGARI™ Phase 3 STAR-1 Topline Week 4 Efficacy Results

In the intent to treat analysis, Dermata saw statistically significant differences in IGA treatment success, inflammatory lesion count, and non-inflammatory lesion count at week 4 (earliest measured timepoint) when compared to placebo.

Investigator Global Assessment: Patients achieving a 2-point reduction AND score of 0 or 1 ("clear" or "almost clear")

	Week 4
XYNGARI™ (n=342)	11.9%
Placebo (n=178)	6.2%
p-value	$p < 0.05$

Mean change from baseline in inflammatory lesion count

	Week 4
XYNGARI™ (n=342)	-11.4
Placebo (n=178)	-8.6
p-value	p < 0.001

Mean change from baseline in non-inflammatory lesion count

	Week 4
XYNGARI™ (n=342)	-12.4
Placebo (n=178)	-8.8
p-value	p < 0.001

"We are very excited to see such great separation from placebo as early as week 4, after just four once-weekly treatments, which we believe shows how quickly XYNGARI™ can work for some patients," commented Christopher Nardo, Ph.D., Chief Development Officer of Dermata. "We believe acne patients are looking for a product that can reduce their inflammatory lesions as quickly as possible, which reduces the appearance of acne, and we think XYNGARI's™ early efficacy could be a strong driver of patient compliance. We expect these data, coupled with the fact that XYNGARI™ only needs to be applied once per week, will help differentiate XYNGARI™ from other products currently on the market," concluded Dr. Nardo.

XYNGARI™ Phase 3 STAR-1 Clinical Study Design

The XYNGARI™ Phase 3 STAR-1 clinical study evaluated the efficacy, safety, and tolerability of XYNGARI™ in patients with moderate-to-severe facial acne. The STAR-1 study was a randomized (2:1), double-blind, and placebo-controlled 12 week study which enrolled 520 patients with moderate-to-severe acne, ages 9 years and older in the United States and Latin America. The primary endpoints include 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 were treated once-a-week for 12 weeks with either XYNGARI™ or placebo and were evaluated monthly. The STAR-1 study is the first of two pivotal Phase 3 studies, with the second Phase 3 study to be followed by an extension

study. If positive, the results of the Phase 3 program would be used to support the filing of a new drug application with the U.S. Food and Drug Administration.

About XYNGARI™ (formerly DMT310)

XYNGARI™ is a novel, once-weekly, topical product candidate derived from a freshwater sponge being developed for the treatment of multiple skin diseases. XYNGARI™ has multiple mechanisms of action that includemechanical 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.

About Dermata Therapeutics

Dermata Therapeutics is a late-stage biotechnology company focusing on the treatment of medical skin diseases and aesthetic applications. The Company's lead product candidate, XYNGARI™, is currently in Phase 3 and is the Company's first product candidate being developed from its *Spongilla* technology platform. XYNGARI™ is a once-weekly, topical product candidate derived from a naturally sourced freshwater sponge with multiple unique mechanisms of action. In addition to acne, XYNGARI™ is being studied for the treatment of psoriasis and rosacea. The Company's second product candidate, DMT410, uses its XYNGARI™ product candidate as a new method for needle-free intradermal delivery of botulinum toxin for the treatment of multiple aesthetic applications and medical skin diseases. 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, including the initiation of a Phase 3 STAR-2 trial and extension study; expectations with regard to the timing and/or results or responses from meetings with regulatory bodies, including the FDA; expectations with regard to the timing of a New Drug Application with the FDA; the success, cost, funds available, and timing of its product candidate XYNGARI™ development activities and ongoing and planned clinical trials; and whether the results of XYNGARI™ will lead to future product development, partnerships, 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, 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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