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Dermata Receives Approval from FDA for the Proprietary Name Xyngari(TM)

- Xyngari (formerly DMT310) is currently being studied in Phase 3 for the treatment of acne, with topline results from the first Phase 3 STAR-1 study expected in March 2025 -

SAN DIEGO, CA / ACCESSWIRE / December 16, 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 diseases and conditions, today announced that it received approval from U.S. Food and Drug Administration (FDA) of the proprietary name, Xyngari (pronounced zin-gar-ee) (formerly DMT310), for its Phase 3 clinical drug candidate in acne. The proprietary name, Xyngari, is approved pending the successful submission and acceptance of a new drug application (NDA).

"The FDA approving the Xyngari name is just one more successful step our team has completed in the development program for this unique product candidate," commented Gerry Proehl, Dermata's Chairman, President, and Chief Executive Officer. "Having an approved proprietary name with the approaching Phase 3 acne topline results expected in March 2025, and recent notice of allowance of a US patent covering Xyngari for the treatment of acne, we believe, positions Dermata well to complete this development program and eventually file an NDA. Our team is excited about the prospect of making Xyngari available to patients, if approved, as we see great commercial opportunity for Xyngari, as it is potentially the first safe, effective, once-weekly, topical product to treat acne," concluded Mr. Proehl.

Xyngari Phase 3 STAR-1 Clinical Study Design

The Xyngari Phase 3 **S**pongilla **T**reatment of **A**cne **R**esearch (STAR-1) clinical study will evaluate the efficacy, safety, and tolerability of Xyngari in patients with moderate-to-severe facial acne. The STAR-1 study is a randomized (2:1), double-blind, and placebo-controlled study with 520 patients enrolled 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 are treated once-a-week for 12 weeks with either Xyngari or placebo and are evaluated monthly. The STAR-1 study is the first of two pivotal Phase 3 studies required by the FDA, of which the second Phase 3 study will be

followed by an extension study. If positive, the results from both Phase 3 studies would be used to support the filing of an NDA with FDA.

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 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. Xyngari has previously shown its treatment effect in moderate-to-severe acne in a Phase 2b study where once weekly applications achieved statistically significant results at all timepoints for all primary and secondary endpoints. Xyngari also saw almost 45% of patients achieving an IGA score of clear or almost clear compared with less than 18% for placebo patients.

About Dermata Therapeutics

Dermata Therapeutics is a late-stage biotechnology company focusing on the treatment of medical and aesthetic skin diseases and conditions. The Company's lead product candidate, Xyngari (formerly DMT310), is the 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 has been studied for the treatment of psoriasis and rosacea. The Company's second product candidate, DMT410, uses Xyngari as a new method for needle-free intradermal delivery of botulinum toxin for the treatment of multiple aesthetic and medical skin diseases and 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 Xyngari development activities and ongoing and planned clinical trials; and whether the results of Xyngari 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, 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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