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Dermata Announces Positive Results from its Phase 2b Clinical Trial of Once Weekly Topical Application of DMT310 for the Treatment of Moderate to Severe Acne Vulgaris

- DMT310 achieved IGA success (2-point change & 0 or 1) in 44.4% of patients versus 17.8% of placebo patients (p=0.0003)

- DMT310 saw a -15.6 mean change from baseline in inflammatory lesion count versus a -10.8 mean change from baseline for placebo (p=0.0017)

- Additionally, DMT310 saw a -18.3 mean change from baseline in non-inflammatory lesion count versus -12.4 mean change from baseline for placebo (p=0.0027)

SAN DIEGO, June 10, 2020 /PRNewswire/ -- Dermata Therapeutics' lead clinical candidate, DMT310, produced statistically significant results at week 4, 8 and 12 for all its primary and secondary endpoints in its Phase 2b clinical trial evaluating the safety, tolerability and efficacy of DMT310 in moderate to severe acne patients. DMT310 also appeared to be safe and well tolerated by patients with minimal treatment related adverse events and no serious adverse events related to treatment.

"A big problem with treating acne is patient compliance, so having an effective product with an excellent safety profile that is only applied once weekly would be a great option for acne patients," states Chris Nardo, PhD, SVP, Development of Dermata. "Also, patients are seeking more natural ways to treat their acne, which could position DMT310 as a very attractive product for many patients."

DMT310-003 Trial Design:
DMT310-003, was a 12-week, 14-center, double-blind, randomized, placebo controlled trial designed to evaluate the safety, tolerability and efficacy of once weekly application of DMT310 in 181 moderate to severe acne patients, defined as a grade 3 or 4 on the Investigator Global Assessment (IGA) five-point scale and at least 20 inflammatory and 20 non-inflammatory lesions on the face at baseline. The trial contained two arms: (1) DMT310 + H_2O_2; and (2) Placebo + H_2O_2. The primary endpoint was the mean change from baseline

in inflammatory lesion count at week 12. Other endpoints included IGA treatment success, defined as the percentage of patients with at least a two-point reduction and a score 0 or 1 ("clear" or "almost clear") on IGA scale at week 12 and the mean change from baseline in non-inflammatory lesion count at week 12. The trial also used a HIPAA compliant smartphone application on patients' mobile devices to document patient treatment compliance. During the study, patients recorded a ten second video, which was reviewed by clinic staff to ensure complete and timely application of the product.

DMT310-003 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 as early as week 4 and continuing to week 12 (study end) 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	Week 8	Week 12
DMT310	14.3%	21.1%	44.4%
Placebo	2.4%	7.1%	17.8%
p-value	0.0035	0.0177	0.0003

Mean change from baseline in inflammatory lesion count

	Week 4	Week 8	Week 12
DMT310	-11.3	-13.6	-15.6
Placebo	-5.9	-8.9	-10.8
p-value	<0.0001	0.0004	0.0017

Mean change from baseline in non-Inflammatory lesion count

	Week 4	Week 8	Week 12
DMT310	-10.7	-12.7	-18.3
Placebo	-4.4	-8.5	-12.4
p-value	0.0001	0.0236	0.0027

"The substantial clinical response observed in our DMT310-003 trial gives us confidence that DMT310 could alter the current treatment paradigm in acne by providing patients with a novel, once weekly treatment option with minimal side effects and quicker time to treatment effect," states Gerry Proehl, President, CEO and co-Founder of Dermata. "We believe the multiple mechanisms of action of DMT310 are crucial to its treatment success and will be a significant market differentiator for acne and other inflammatory skin diseases."

Based on these results, Dermata plans to hold an end of Phase 2 meeting with the FDA and initiate two Phase 3 trials in moderate to severe acne patients to evaluate the safety and efficacy of DMT310. Dermata also plans to initiate a Phase 2 clinical trial of DMT310 in patients with papulopustular rosacea starting in early 2021.

About Dermata: Dermata is a development-stage biotechnology company focused on making a paradigm shift in the treatment of inflammatory diseases treated by dermatologists. Dermata has a team of experienced professionals who are currently focused on progressing multiple programs for the treatment of acne, rosacea and aesthetic skin conditions. To learn more about Dermata and its pipeline of treatments, please visit www.dermatarx.com.

DERMATA CONTACT:
Sean Proehl
Investor Relations and Business Development
858.208.6766
sproehl@dermatarx.com

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