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Dermata Therapeutics Announces Positive Results from a Phase 1 Clinical Trial of DMT410, A New Topical Delivery Mechanism for Botulinum Toxin

SAN DIEGO, July 9, 2019 /PRNewswire/ -- Dermata Therapeutics, LLC, today announces positive results from a Phase 1 POC clinical trial of DMT410 (DMT310 + botulinum toxin (BTX)) for the treatment of primary axillary hyperhidrosis. These results provide evidence of Dermata's newly developed combination regimen, DMT400, a mechanism for topically delivering biologics into the dermis using DMT310 sponge powder.



"This study provides convincing evidence that DMT310, our *Spongilla lacustris* powder with millions of microscopic needle-like spicules, is effective in creating channels through the stratum corneum for biologics to enter the dermis, resulting in effects similar to injections," said Gerry Proehl, President and CEO of Dermata Therapeutics, LLC.

DMT410 is a combination regimen for the treatment of skin diseases and aesthetic conditions, by first topically applying DMT310 to the skin, followed by topical application of botulinum toxin.

Study Detail: In the Phase 1 DMT410 Hyperhidrosis trial, 10 patients were enrolled at one site, in an open label, 2-arm, 4-week study. Each patient had a baseline of at least 50mg of sweat production in each axilla. Each axilla received topical application of DMT310 powder reconstituted with either hydrogen peroxide or sterile saline massaged onto the skin. After application of the DMT310 was washed off, both axillae then received topical application of BTX, reconstituted per its label, by massaging it into the same treatment area of each axilla.

Efficacy Results: The primary endpoints were the percent of patients with greater than 50% reduction in gravimetrically measured sweat production from baseline; the percent of patients with gravimetric sweat production less than 50mg; and the mean absolute change from baseline in gravimetrically measured sweat production. At Day 29, 80% of patients achieved an overall decrease in gravimetric sweat production of greater than 50%; 85% of patients achieved a gravimetric sweat production of less than 50mg; and the mean absolute change in gravimetric sweat production was -114.64mg.

DMT410 was well tolerated with only two adverse events, and only one being related to treatment. These results demonstrate DMT410's clinically meaningful effects in reducing hyperhidrosis symptoms similar to results from BOTOX® injections for hyperhidrosis.

"We are very encouraged with these results and the multiple other biologic combination therapy opportunities this presents for DMT400," stated Christopher Nardo, Ph. D, Senior VP of Development. "There are many potential benefits of using DMT310 as a dermal delivery mechanism for not only botulinum toxin but also other biologics. We believe this provides the potential for lower systemic drug exposure, greater patient acceptance due to the injection-free delivery, and the possibility to expand the use of biologics to patients with milder disease."

About Dermata: Dermata is a development-stage biotechnology company focused on making major advancements in the treatment of serious diseases treated by dermatologists, including acne vulgaris, acne rosacea, and hyperhidrosis. To learn more about Dermata and its pipeline of treatments, please visit www.dermatarx.com.

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