American Academy of Dermatology 2019 Annual Meeting <u>S034 - Late-breaking Research: Clinical Trials</u> 11328 – Successful Treatment of Common Warts with Candida Extract - a Phase II study Saturday, March 02 1:00 PM — 4:00 PM in Ballroom A

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Background:

Common warts, *Verruca vulgaris*, remain a clinical condition without a definitive therapy. The commonly used treatments are non-specific and destructive. Non-destructive therapies are not well-characterized. A specific, effective therapy is needed.

Type of Study:

A Phase IIa, randomized, double-blind, placebo-controlled study

Methods:

Adult subjects with multiple warts from 3-20 mm in size were randomized to four cohorts of investigational treatment with *Candida albicans* Skin Test Antigen for Cellular Hypersensitivity [Nielsen Biosciences]: 0.3 ml to one wart, 0.5 ml to one wart, 0.3 ml to up to four warts or placebo. Treatments were given every other week for 10 treatments. Warts were assessed by diameter. Safety was assessed via subject diaries and adverse event reporting.

Results:

169 subjects received at least one injection, 125 subjects completed 10 treatments or achieved resolution. Three active cohorts demonstrated statistically significant wart clearance compared to placebo. Clearance rates were 66% (P=0.0329), 79% (P=0.0007), 73% (P=0.0052) and 37% for the 0.3 ml one wart, 0.5 ml one wart, 0.3 ml multiple wart and placebo groups, respectively. Subjects in each of the active treatment groups cleared ALL warts more commonly than the placebo group (0.3 ml – 32%, 0.5 ml – 53%, placebo – 21%). Local reactions included tenderness, pain, itching, swelling, and redness, were generally mild and modestly more prevalent in the active groups versus placebo.

Conclusions:

Treatment of common warts with intralesional *candida* antigen appears safe and effective. Further studies are warranted to confirm the dosing scheme and demonstrate safety and effectiveness for FDA licensure.