



Novan Reports Positive Topline Results with SB208 in Phase 2 Trial

Clinical Evidence of Antifungal Activity Supports Antimicrobial Breadth of Nitric Oxide Platform

MORRISVILLE, N.C., April 12, 2017 -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced positive topline results from the Company's Phase 2 clinical trial with SB208, a topical, silicone based-gel under development for the treatment of infections caused by dermatophytes such as *Trichophyton rubrum*, or *T. rubrum*. Novan is developing SB208 as a broad-spectrum antifungal gel for the treatment of superficial cutaneous fungal infections of the skin and nails, including tinea pedis and onychomycosis. Novan's SB208 Gel, at both the 4% and 16% concentrations, demonstrated a statistically significant effect ($p < 0.05$) compared to vehicle in a clinical trial in patients with tinea pedis, or athlete's foot. Clinical activity against dermatophytes was measured by incidence of a negative fungal culture after two weeks of treatment.

"The results from this Phase 2 trial with SB208 confirm the fungicidal activity of nitric oxide observed in our preclinical studies," said Nathan Stasko, Ph.D., President and Chief Executive Officer of Novan. "We have now seen clinical evidence of antibacterial, antiviral and antifungal activity with product candidates from our nitric oxide platform. Our ability to deploy antimicrobial doses of nitric oxide in this trial gives us confidence to move forward in the development of a potential treatment for hard-to-treat infections like onychomycosis."

In this double-blind, randomized, vehicle-controlled, dose-ranging clinical trial, the tolerability, safety and antifungal activity of SB208 was evaluated in 222 patients with clinical signs and symptoms of tinea pedis. Patients were randomized evenly to one of three active or vehicle treatment arms, applying either SB208 Gel (2%, 4% or 16%) or vehicle once-daily for two weeks, followed by a four-week post-treatment observation period. Efficacy assessments were made on a modified intent-to-treat population (mITT) comprised of patients who had a positive baseline culture for dermatophytes such as *T. rubrum*. The primary endpoint in this study was the proportion of patients in each treatment group achieving negative fungal culture at day 14.

In the primary efficacy analysis of patients with evaluable culture results, 80.6% ($p = 0.002$) of patients treated with SB208 4% and 74.2% ($p = 0.016$) of patients treated with SB208 16% achieved negative fungal culture at day 14 versus 45.5% of patients treated with vehicle. Similar results were observed in the per-protocol analysis, with both SB208 4% and 16% demonstrating statistical superiority to vehicle treated subjects ($p < 0.05$).

Mycological cure, defined as both a negative fungal culture and a negative skin scraping for the presence of fungus, was assessed at day 14 and after a four week follow up period at day 42 as two of the secondary endpoints. The percentage of patients achieving mycological cure at the day 14 visit was 50.0% ($p = 0.009$) of the patients treated with SB208 4% and 53.1% ($p = 0.010$) of patients treated with SB208 16% versus 23.5% of patients treated with vehicle. Mycological cure was maintained at day 42 in both dose groups; 58.8% of patients treated with SB208 16% demonstrated a mycological cure compared to vehicle ($p < 0.05$).

"Fungal infections of the skin and nails are persistent, in part because there are no currently-approved therapies that treat both with a single topical product," said Dr. Leon Kircik, board-



certified dermatologist, associate clinical professor of dermatology at Indiana University Medical Center in Indianapolis and Icahn School of Medicine at Mount Sinai Medical Center in New York and medical director of DermResearch, PLLC and Physicians Skin Care, PLLC. “These clinical trial results in patients with tinea pedis, paired with the previously released preclinical rapid nail penetration data, suggest that Novan’s SB208 may provide an effective topical alternative to simultaneously treat the nail plate, the interdigital space and the surrounding cutaneous tissue, thereby potentially improving initial efficacy while decreasing relapse or reinfection.”

Based on the data generated in this SB208 Phase 2 dose-ranging trial, Novan will evaluate late stage development opportunities in superficial cutaneous fungal infections, such as a Phase 2 trial in patients with onychomycosis, to be initiated as early as the second half of 2017.

About Onychomycosis

Onychomycosis is a chronic fungal infection of the nails, and Novan estimates that it affects more than 40 million people in the United States.¹ The prevalence of disease increases with age, and more than 50% of patients are 70 years or older.² The dermatophytes *T. rubrum* and *Trichophyton mentagrophytes* are causative agents for the majority of infections and often result in a painful thickening, deformation and discoloration of the nail and sometimes splitting, separation of the nail plate from the nail bed and an inability of the nail to perform its natural protective function. Because the fungi that cause onychomycosis are present in many common locations such as floors, the soil, socks and shoes, the nail can become re-infected and additional courses of treatment are frequently required after successful treatment.²

About Novan

Novan, Inc. is a late-stage pharmaceutical company focused on redefining the standard of care in dermatology through the development and commercialization of innovative therapies using the Company’s nitric oxide-releasing platform. Nitric oxide plays a vital role in the natural immune system response against microbial pathogens and is a critical regulator of inflammation. Our ability to harness nitric oxide and its multiple mechanisms of action has enabled us to create a platform with the potential to generate differentiated, first-in-class product candidates. We are rapidly advancing programs in five dermatological conditions with significant unmet medical need. We believe that our ability to conveniently deploy nitric oxide on demand in topical formulations allows us the potential to significantly improve patient outcomes in a variety of skin diseases and positions us to be a commercially successful leader in the dermatology market.

For more information, visit the Company’s website at www.Novan.com.

Forward-Looking Statements

This press release contains forward-looking statements including, but not limited to, pharmaceutical development of nitric oxide-releasing product candidates and future prospects of our business and our product candidates. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from our expectations, including, but not limited to, uncertainties and risks in the clinical development process, including, among others, length, expense, ability to enroll patients, reliance on third parties, and that results of earlier research and preclinical or clinical trials may not be predictive of results, conclusions or interpretations of later research or trials; the lengthy and unpredictable nature of the U.S. Food and Drug Administration’s drug approval process; whether we will be able to obtain additional



funding when needed; and other risks and uncertainties described in our annual report filed with the Securities and Exchange Commission, or SEC, on Form 10-K for the twelve months ended Dec. 31, 2016, and in any subsequent filings with the SEC. These forward-looking statements speak only as of the date of this press release, and Novan disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements, except as may be required by law.

References

- ¹ Ghannoum MA, Hajjeh RA, Scher R, Konnikov N, Gupta AK, Summerbell R, Sullivan S, Daniel R, Krusinski P, Fleckman P, Rich P, Odom R, Aly R, Pariser D, Zaiac M, Rebell G, Leshner J, Gerlach B, Ponce-De-Leon GF, Ghannoum A, Warner J, Isham N, Elewski B. A large-scale North American study of fungal isolates from nails: the frequency of onychomycosis, fungal distribution, and antifungal susceptibility patterns. *J Am Acad Dermatol.* 2000 Oct; 43(4):641-8.
- ² Westerberg D, Voyack M. Onychomycosis: current trends in diagnosis and treatment. *Am Fam Physician.* 2013 Dec 1; 88(11):762-70.

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