



Novan to Present Safety and Efficacy Data for SB204 Program in Adolescents at 13th World Congress of Pediatric Dermatology

MORRISVILLE, N.C., July 07, 2017 -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced that pharmacokinetic, safety and efficacy data for SB204, an investigational once-daily, topical monotherapy for the treatment of acne vulgaris, will be presented at the 13th World Congress of Pediatric Dermatology in Chicago, Illinois. New data from a post-hoc analysis of Novan's recently completed Phase 3 pivotal trials, conducted in a subset of only adolescent subjects, showed a statistically significant reduction ($p < 0.05$) in inflammatory, non-inflammatory and total lesion reductions with SB204 4% compared to vehicle, while maintaining a favorable safety and tolerability profile.

In two replicate, multi-center, randomized, double-blinded, vehicle-controlled, parallel group trials, a total of 2,639 patients ages 9 and older with moderate to severe acne were enrolled across 110 sites in the United States. In a post-hoc analysis of a subset of 905 adolescents ranging from ages 9 to under 17 years old, treated topically with SB204 Gel 4% once-daily ($n=439$) or vehicle gel once-daily ($n=466$) for 12 weeks, the Company found the following results (last observation carry forward methodology used for missing data).

- The percent change from baseline in the number of non-inflammatory lesions was -33.4% for SB204 and -24.2% for vehicle ($p=0.0013$).
- The percent change from baseline in the number of inflammatory lesions was -43.4% for SB204 and -36.4% for vehicle ($p=0.0113$).
- The percent change from baseline in the number of total lesions was -37.4% for SB204 and -29.1% for vehicle ($p < 0.001$).

In addition, a pharmacokinetic trial in adolescents with moderate to severe acne assessed systemic exposure following topical application of SB204. No systemic exposure to markers for nitric oxide exposure under maximal use conditions was detected.

"It is encouraging to see a potential new therapy, with positive data, in development for the treatment of acne in adolescents," said Diane Thiboutot, M.D., practicing dermatologist at The Milton S. Hersey Medical Center in Hersey, PA and professor of Dermatology at the Pennsylvania State University College of Medicine. "Acne is one of the most common skin conditions in children and teenagers, and its reach is far beyond the physical effects of the disease, extending to anxiety, depression and low self-esteem. A therapy that safely addresses the acne lesions without bothersome side effects is an unmet need for physicians, patients and parents."



These data in an adolescent population follow the recent presentation of new findings into the potential mechanism of action of SB204 at the Dermatology Summer Symposium of the Alabama Dermatology Society in Sandestin, Florida on June 23, 2017.

In an ex-vivo human skin model designed to assess the anti-inflammatory effects of topical treatments against a toll-like receptor-stimulated overexpression of cytokines in healthy, human skin biopsies, Novan observed that a single application of SB204 4% significantly inhibited the upregulation of IL-1 β by approximately 62% as compared to untreated controls (n of 6 donors, p=0.045). IL-1 β is an inflammatory cytokine known to be involved in the pathogenesis of acne, with a fifty-fold increased presence in papulopustular acne lesions versus normal human skin.¹ These findings support the hypothesis that the mechanism of anti-inflammatory effect of nitric oxide in acne prone skin is mediated by the inactivation of the NLRP3 inflammasome previously reported by Friedman and co-workers.²

Novan intends to request a follow up meeting with the U.S. Food and Drug Administration (“FDA”) in the third quarter of 2017 to discuss the path forward for the development of SB204 for the treatment of acne from both a clinical and regulatory perspective.

About the Posters

13th World Congress of Pediatric Dermatology

Title: “Pharmacokinetics and Safety of Nitric Oxide-Releasing SB204 Gel in Adolescents with Acne Vulgaris”

Authors: D Thiboutot, A Zaenglein, A Hebert, L Eichenfield

Abstract Number: LP-006

Presenter: Andrea Zaenglein, M.D.

Date and Time: Friday, July 7, 2017, 5:30 pm am – 1:30 p.m. Central Time

Dermatology Summer Symposium of the Alabama Dermatology Society

Title: “Effects of SB204 on LPS-induced Cytokine Release in an Ex-Vivo Human Skin Model”

Authors: K McHale, N Stasko and S Hollenbach

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, including the risk that the FDA is not amenable to our plan for SB204 or requires additional studies or information before we can submit our NDA, the risks that we are delayed in making an NDA submission, the FDA does not accept our submission for filing, disagrees with our analysis of endpoints or that the FDA requires additional studies to support the submission and the risk the FDA does not approve our NDA or approves our NDA with limitations or subject to additional studies; 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.

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