Novan to Present Data from SB414 Phase 1b Atopic Dermatitis Clinical Trial at 3rd Inflammatory Skin Disease Summit

- Clinical efficacy, as measured by EASI (Eczema Area and Severity Index) changes, was numerically greater for SB414 treated groups compared to vehicle
- Strong anti-pruritic (itch) effect as measured by improvement on the pruritus (itch) numeric rating scale (NRS) compared to vehicle
- Clinical data additive to established non-clinical results supporting nitric oxide’s role in affecting the underlying immunology of atopic dermatitis

MORRISVILLE, N.C., Dec. 11, 2018 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced that clinical results from the Company’s Phase 1b trial with SB414 cream for the treatment of atopic dermatitis will be presented at the 3rd Inflammatory Skin Disease Summit in Vienna, Austria.

Tomoko Maeda-Chubachi, M.D., Novan’s Vice President of Medical Dermatology, is scheduled to present “A Topical Nitric Oxide-Releasing Cream SB414: Results of a Phase 1b Double-Blind, Randomized, Vehicle-Controlled Study in Patients with Mild-to-Moderate Atopic Dermatitis” during a poster session on December 12, 2018 and an oral presentation on December 15, 2018.

“We are excited by the data we are presenting with SB414 as it demonstrated trends suggestive of clinical efficacy within only 2 weeks of treatment,” said Tomoko Maeda-Chubachi, M.D., Novan’s Vice President of Medical Dermatology. “Nitric oxide has the potential to impact multiple mechanisms of atopic dermatitis and the results from this trial give us the confidence to move forward with a more robust Phase 2 program.”

Top line results from Novan’s Phase 1b clinical trial with SB414 for the treatment of atopic dermatitis were previously announced in August and the Company intends to conduct a Phase 2 trial.

About the Presentations

Title: “A Topical Nitric Oxide-Releasing Cream SB414: Results of a Phase 1b Double-Blind, Randomized, Vehicle-Controlled Study in Patients with Mild-to-Moderate Atopic Dermatitis”
Authors: Tomoko Maeda-Chubachi, Todd Durham, Stephen Schleicher, Phoebe Rich, Emma Guttman-Yassky
Presenting Author: Tomoko Maeda-Chubachi, M.D., Novan’s Vice President of Medical Dermatology
Poster Presentation: Wednesday, December 12, 2018 at the “Säulenhalle” (Level 1) and the “Science Café” (Level 0) between 6:00 p.m. – 9:00 p.m. Central European Standard Time
Oral Presentation: Saturday, December 15, 2018 from 1:00 p.m. – 1:30 p.m. Central European Standard Time

About Atopic Dermatitis

Atopic dermatitis, also known as atopic eczema, is the most common chronic relapsing inflammatory skin disease, affecting nearly 18 million people in the United States.¹ Nearly eighty percent of the atopic dermatitis population suffers from mild-to-moderate disease and are treated with first-line monotherapies, however, corticosteroids and calcineurin inhibitors have side effects and are not well-suited for chronic use.² Recently, the first biologic treatment for atopic dermatitis targeting IL-4 and IL-13 was approved, but it is reserved for patients with moderate-to-severe disease.

Stabilizing the disease and reducing the number and severity of flares are the primary goals of current treatment. The disease is characterized by intense itching, dry skin with red papules and plaques, “weeping” clear fluid, crust and scaling. Immune cells in the deep layers of skin release inflammatory signals, causing an itchy rash. Scratching leads to defects in the skin barrier function, allowing environmental triggers, such as the bacteria Staphylococcus aureus, to penetrate the skin barrier and further exacerbate the condition, triggering the “itch-scratch” cycle. The density of S. aureus colonization has been correlated with both the severity of atopic dermatitis lesions and the degree of cutaneous inflammation.²

References

About Novan

Novan, Inc. is a clinical-stage biotechnology company focused on leveraging nitric oxide’s natural antiviral and immunomodulatory mechanisms of action to treat dermatological and oncovirus-mediated diseases. We believe that our ability to conveniently deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to significantly improve patient outcomes in a variety of diseases.

Forward-Looking Statements

This press release contains forward-looking statements including, but not limited to, statements related to pharmaceutical development of nitric oxide-releasing product candidates, our intention to advance development of certain product candidates, which is subject to our ability to obtain additional financing or enter into strategic relationships to enable such development, and the 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, risks and uncertainties 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 activities or additional trials; risks related to the regulatory approval process, which is lengthy, time-consuming and inherently unpredictable; our ability to obtain substantial additional funding for the further advancement and development of our product candidates, including the SB414 anti-inflammatory program; our ability to identify and enter into strategic relationships for the further development and potential commercialization of our product candidates; and other risks and uncertainties described in our annual report filed with the SEC on Form 10-K for the twelve months ended Dec. 31, 2017, and in our 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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