



## Novan to Present Clinical Data at Annual Meeting of the Society for Investigative Dermatology

May 7, 2019

MORRISVILLE, N.C., May 07, 2019 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced that recent data from the Company's Phase 1b trial with SB414 cream for the treatment of atopic dermatitis and Phase 2 trial with SB206 gel for the treatment of molluscum contagiosum will be presented at the 77th Annual Meeting of the Society for Investigative Dermatology. The meeting will be held May 8-11, 2019 in Chicago, Illinois.

Clinical and biomarker results from the Company's Phase 1b atopic dermatitis trial will be presented during an oral presentation on May 9, 2019 and during a poster session on May 11, 2019. In addition, clinical results from the Company's Phase 2 molluscum trial will be presented during a late-breaking poster session on May 9, 2019.

Top line results from Novan's Phase 1b clinical trial with SB414 for the treatment of atopic dermatitis were previously announced in the third quarter of 2018 and the Company intends to initiate non-clinical studies in the second quarter of 2019 to support the Phase 2 program launch, targeted for the fourth quarter of 2019. In addition, and as previously communicated, the Company's Phase 3 molluscum program will begin recruiting patients this month with top line results targeted early during the first quarter of 2020 or before.

### About the Presentations

**Title: "Topical Nitric Oxide Releasing Therapy with SB414 2% Cream Downregulated Major Gene Expressions in Patients with Atopic Dermatitis"**

Abstract and Poster Number: 586

Authors: Emma Guttman-Yassky, MD, PhD, Ana B. Pavel, PhD, Todd Durham, PhD, Tomoko Maeda-Chubachi, MD, PhD

Oral Presentation: Thursday, May 9, 2019 in "International Ballroom South" from 2:06 p.m. – 2:18 p.m. Central Daylight Time

Poster Presentation: Saturday, May 11, 2019 in "Stevens Salons B-D" between 12:45 p.m. – 2:45 p.m. Central Daylight Time

**Title: "Results of Phase 2 Study Evaluating the Efficacy and Safety of SB206, Topical Berdazimer Sodium Gel, in Subjects with Molluscum Contagiosum"**

Poster Number: LB1096

Authors: Tomoko Maeda-Chubachi, MD, PhD, David Hebert, PhD, Emily N. de León, Teresa Reams, Elizabeth Messersmith, PhD

Late-Breaking Poster Presentation: Thursday, May 9, 2019 in "Stevens Salons B-D" between 10:45 a.m. – 12:45 p.m. Central Daylight Time

### About Atopic Dermatitis

Atopic dermatitis, also known as atopic eczema, is the most common chronic relapsing inflammatory skin disease, affecting 18 million adults and nearly 10 million children in the United States according to the National Eczema Association.<sup>1,2</sup> 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.<sup>3</sup> 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.<sup>3</sup>

### References:

<sup>1</sup>Silverberg, J. I. (2017). Public Health Burden and Epidemiology of Atopic Dermatitis. *Dermatologic Clinics*, 35 (3), 283-289. doi:10.1016/j.det.2017.02.002

<sup>2</sup>Silverberg J, Simpson E. Associations of Childhood Eczema Severity. *Dermatitis*. 2014;25(3):107-114. doi:10.1097/der.000000000000034.

<sup>3</sup>Nakatsuji T., et al. *J Invest Dermatol*. 2016. 136(11):2192-2200.

### About Molluscum Contagiosum

Molluscum contagiosum is a common, contagious skin infection caused by the *molluscipoxvirus*, affecting approximately six million people in the U.S. annually, with the greatest incidence in children aged one to 14 years. Infected children typically present with 10 to 30 painless, yet unsightly lesions, and, in severe cases, they can have around 100 lesions. Due to the largely pediatric nature of the disease, parents are the caregivers for these children, in most cases, and tend to seek treatment. There are no FDA approved therapies for molluscum, and, upon seeking treatment, caregivers are faced with potentially painful in-office, dermatologist-administered physical procedures or cantharidin, or recommended off-label prescriptions and over-the-counter products. More than half of the patients diagnosed with molluscum are untreated and over 30% of those treated receive an off-label prescription with no molluscum indication or proven clinical efficacy. The average time to resolution is 13 months, however, some children experience lesions that may not resolve in 24 months. Further dissemination of this highly-contagious disease is common, and transmission to other children living in the household is reported to be 41%. There is a significant unmet need in the molluscum treatment landscape.

### About Novan

Novan, Inc. is a clinical development-stage biotechnology company focused on leveraging nitric oxide's naturally occurring anti-microbial and

immunomodulatory mechanisms of action to treat a range of diseases with significant unmet needs. We believe that our ability to deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to improve patient outcomes in a variety of dermatology, women's health and gastrointestinal 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, including SB206 for the treatment of molluscum and SB414 for the treatment of atopic dermatitis, 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, potential for delays 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, including the risk that products under development may not be approved or that additional studies may be required for approval or other delays may occur and that we may not obtain funding sufficient to complete the regulatory or development process, including with respect to the Phase 2 program launch for SB414; risks associated with relying on third parties for the manufacture of drug product for clinical trials; our ability to obtain additional funding or enter into strategic relationships or other business development necessary for the further advancement and development 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 December 31, 2018, 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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