



First Patient Enrolled and Dosed in Novan's SB206 Phase 3 Molluscum Program

June 4, 2019

- **Phase 3 pivotal program commences and underway**
- **Investigative sites now activated and enrollment activities actioned**
- **Anticipated patient demand managed with a highly disciplined approach to trial execution**
- **Top line results targeted to be no later than early in the first quarter of 2020**

MORRISVILLE, N.C., June 04, 2019 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced that the first patient has been dosed in the Company's "B-SIMPLE" (**B**erdazimer **S**odium **I**n **M**olluscum **P**atients with **L**esions) Phase 3 program. The study is designed to evaluate topical nitric oxide product candidate SB206 for the treatment of molluscum contagiosum.

The B-SIMPLE Phase 3 program consists of two multi-center, randomized, double-blind, vehicle-controlled studies, B-SIMPLE1 and B-SIMPLE2. Each study will enroll approximately 340 patients. The program will evaluate the efficacy and safety of SB206 12% QD (once daily) compared to vehicle (placebo) for the treatment of molluscum.

"Molluscum contagiosum is a terribly frustrating condition for affected children and their parents. Despite the self-limited nature of the skin infection, spontaneous resolution can take quite a while. Fears regarding potential viral transmission to others, secondary infection of lesions and scarring can create a sense of treatment urgency," stated Dr. Robert A. Clifford, MD, FAAP, Managing Partner, Coastal Pediatric Associates. Dr. Clifford, an investigator in the B-SIMPLE program, further commented, "because of this, I am delighted to be participating in the B-SIMPLE program and am eager to offer this study to patients seeking a potential solution for their molluscum lesions."

Currently there are no FDA approved therapies for the treatment of molluscum. Treatment choices for patients, the majority of whom are children, include in-office and often painful, physician-administered scraping, freezing, burning and blistering treatments. The only other choice appears to be prescriptions with no clinical data that would support a molluscum indication and therefore have no proven clinical efficacy and an unknown safety profile. Novan's SB206 product candidate demonstrated clinical efficacy with a favorable safety profile in the Phase 2 trial conducted in 2018.

"Novan is committed to swiftly advancing SB206 in a high quality and disciplined manner. With success, our aim is to provide patients with a simple topical treatment for this contagious condition that can be administered in the home setting," stated Elizabeth Messersmith, PhD, Senior Vice President and Chief Development Officer of Novan. Dr. Messersmith commented further that, "the enthusiasm and interest from the medical community for SB206 has been exceptional and we look forward to working closely with them on all aspects of the SB206 program as it progresses."

Novan is targeting top line efficacy and safety results no later than early in the first quarter of 2020.

About B-SIMPLE Phase 3 Program

The B-SIMPLE Phase 3 program consists of two multi-center, randomized, double-blind, vehicle-controlled studies, B-SIMPLE1 and B-SIMPLE2, to evaluate the efficacy and safety of SB206 12% QD for the treatment of molluscum. Each pivotal study will enroll approximately 340 patients aged 6 months and older, with a 2:1 (active:vehicle) randomization. Subjects or their caregivers will apply SB206 12% or Vehicle Gel once daily for a minimum of 4 weeks and up to 12 weeks to all treatable lesions (baseline and new). There will be visits at Screening/Baseline, Week 2, Week 4, Week 8, Week 12 and safety follow-up at Week 24. The primary endpoint of these studies is the proportion of patients with complete clearance of all treatable molluscum lesions at Week 12.

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 and our intention to advance development of certain product candidates, including the timing, enrollment demand and progress of our Phase 3 program to evaluate SB206 for the treatment of molluscum. 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 our product candidates 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; our ability to obtain additional funding or enter into strategic relationships or other business development necessary for the further 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.

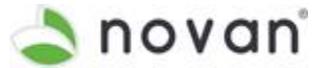
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