



## Novan's Phase 3 Molluscum Pivotal Program Completes Enrollment

August 13, 2019

MORRISVILLE, N.C., Aug. 13, 2019 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced that the Company has recently completed patient recruitment in the Company's ongoing "B-SIMPLE" (Berdazimer Sodium In Molluscum Patients with Lesions) Phase 3 pivotal trials with SB206 for the treatment of molluscum contagiosum.

The trials enrolled approximately 680 patients with 3 to 70 molluscum lesions at Baseline. The primary efficacy endpoint of the trials is complete clearance of all treatable molluscum lesions at Week 12, and follow-up will include a Week 24 safety assessment.

The SB206 results from Phase 2, previously announced in December 2018, demonstrated a clear treatment effect on the complete clearance of all molluscum lesions at Week 12 for 12% once-daily SB206 gel. There were signs of efficacy as early as Week 2, and the Phase 2 trial showed a favorable safety profile. For the primary endpoint, 12% once-daily was the most effective dose with 38% (ITT,  $p < 0.05$ ) complete clearance rates compared to 18% for vehicle.

"The pace by which we fully enrolled these pivotal studies demonstrates the underlying demand and unmet medical need that exists for molluscum patients and their caregivers," commented Elizabeth Messersmith, Ph.D, Senior Vice President and Chief Development Officer. Dr. Messersmith further commented, "The Novan team, along with the investigators and program coordinators, have done an exceptional job in achieving this important milestone. We look forward to sharing the top line results at the appropriate time."

Novan reaffirms that top line results are expected 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% once daily 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; risks related to the manufacture of clinical trial materials and commercial supplies of any potentially approved product candidates, including the manufacture of our NVN1000 active pharmaceutical ingredient in our primary facility, our internal manufacturing capabilities and our ability to transfer technology and processes as contemplated by the manufacturing agreement; 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.

**CONTACT:**

(Investors & Media)

Cole Ikkala

Director, Investor Relations, Communications & Business Development

[cikkala@novan.com](mailto:cikkala@novan.com)



Source: Novan, Inc.