Novan Completes Enrollment in B-SIMPLE4 Pivotal Phase 3 Study of SB206 for Treatment of Molluscum

February 1, 2021

– Topline data on track for targeted readout before the end of Q2 2021 –

– SB206, if approved, has the potential to meet an important need for the treatment of molluscum, an area with no current FDA-approved treatment –

MORRISVILLE, N.C., Feb. 01, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. (“the Company” or “Novan”) (Nasdaq: NOVN), today announced it has completed patient enrollment in the B-SIMPLE4 pivotal Phase 3 clinical study of SB206, a topical antiviral gel, for the treatment of molluscum contagiosum (“molluscum”).

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.

B-SIMPLE4 is a multi-center, double-blind, randomized, vehicle-controlled study. The Company exceeded its enrollment target of 850 patients (1:1 randomization) in the study, across 55 clinical sites, due to the number of patients in screening at the time of achieving the trial’s stated goal. Patients will be treated for 12 weeks with a follow-up visit at Week 24. The primary endpoint for the study is the proportion of patients with complete clearance of all treatable molluscum lesions at Week 12 (Intent-to-Treat or “ITT” population, where the analysis assumes that patients with missing data at Week 12 are assessed as treatment failures).

“We are excited about the response from patients for this study and to have completed enrollment, amidst a challenging time with the current coronavirus pandemic. I believe SB206 has the potential to be an important choice in the treatment landscape of molluscum, which affects millions of people each year, and importantly, can provide a much-needed treatment benefit to patients. We look forward to seeing the clinical efficacy results from the B-SIMPLE4 study and SB206’s ability to address the unmet need in this indication,” stated John Browning, M.D., F.A.A.D, F.A.A.P., MBA, Adjunct Associate Professor of Pediatrics and Dermatology at UT Health San Antonio and the Chief of Staff of Pediatric Dermatology at Texas Dermatology and Laser Specialists, and a Principal Investigator in the B-SIMPLE4 study.

Topline efficacy results from the B-SIMPLE4 study are anticipated before the end of the second quarter of 2021, subject to the targeted timing and trial execution plan which have been and may be further impacted by the COVID-19 pandemic.

“This is a significant milestone for the Company and our molluscum program. We are very pleased with the enthusiasm we have seen across the molluscum patient population and the over-enrollment that our team was able to accomplish in such a short period of time. Our team is now keenly focused on bringing the study to completion and working to minimize the potential risk for missing data. We aim to report the topline efficacy data before the end of the second quarter and look forward to ultimately advancing this important product candidate toward potential approval,” commented Elizabeth Messersmith, Ph.D, Chief Development Officer of Novan.

There are currently no FDA-approved therapies for the treatment of molluscum. The Company believes that SB206 as a topical, at-home, caregiver-applied therapy with a rapid treatment benefit, if approved, would satisfy an important patient-care need for the treatment of molluscum.

For more information about the B-SIMPLE4 study, please visit clinicaltrials.gov and reference identifier: NCT04535531.

About Molluscum

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 U.S. Food and Drug Administration (“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 its proprietary nitric oxide (NO) based technology platform, NITRICIL™ to generate macromolecular New Chemical Entities (NCEs) to treat multiple indications in dermatology, men’s and women’s health, infectious diseases and gastroenterology conditions with significant unmet needs. The Company’s lead product candidate, SB206, a topical antiviral gel, for the treatment of molluscum contagiosum, is currently being evaluated in the B-SIMPLE4 pivotal Phase 3 clinical study. The Company believes that SB206 as a topical, at-home, caregiver-applied therapy with a rapid treatment benefit, if approved, would address an important patient-care need for the treatment of molluscum.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe,” “expect,” “target,” “anticipate,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on the Company’s current beliefs and expectations. These forward-looking statements include, but are not limited to, statements related to the potential therapeutic value of the Company's NITRICIL™ platform technology, the Company’s pharmaceutical development of nitric oxide-releasing product candidates, the Company’s intention to advance development of certain product candidates, including the timing and progress of our Phase 3 program to evaluate SB206 for the treatment of molluscum and the timing of anticipated topline results. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from the Company’s expectations, including, but not limited to, any operational or other disruptions as a result of the COVID-19 pandemic, including any delays or disruptions to the conduct of the B-SIMPLE4 study; risks and uncertainties in the clinical development process, including, among others, length, expense, ability to enroll patients, potential for delays or other impacts, whether as a result of the COVID-19 pandemic or other factors, 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 the Company’s product candidates may not be approved or that additional studies may be required for approval or other delays may occur and that the Company may not obtain funding sufficient to complete the regulatory or development process; the Company’s ability to obtain additional funding or enter into strategic or other business relationships necessary or useful for the further development of the Company’s product candidates; the risk that disruptions at the FDA or other agencies could cause such agencies to cancel or postpone meetings or otherwise impact the ability of such agencies to provide regulatory guidance or feedback or timely review and process the Company’s regulatory submissions, all of which could have a material adverse effect on the Company’s business; risks related to the manufacture of raw materials, including the Company’s active pharmaceutical ingredient, and drug product components utilized in clinical trial materials, including failure to transfer technology and processes to third parties effectively or failure of those third parties to obtain approval of and maintain compliance with the FDA or comparable regulatory authorities; the Company’s reliance on arrangements with third parties to support its operations and development efforts and the risk that such parties will not successfully carry out their contractual duties or meet expected deadlines; and other risks and uncertainties described in the Company’s annual report filed with the SEC on Form 10-K for the twelve months ended December 31, 2019, as amended, and in the Company’s subsequent filings with the SEC, including the Company’s quarterly report on Form 10-Q for the three months ended September 30, 2020. Such 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.

INVESTOR AND MEDIA CONTACT:

Jenene Thomas
JTC Team, LLC
833-475-8247
NOVN@jtcir.com