Novan Provides Enrollment Update and Announces New Corporate Headquarters

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– B-SIMPLE4 pivotal Phase 3 study in molluscum contagiosum reaches 90% enrollment with topline data targeted for Q2 2021 –

– Company secures new location to serve as corporate headquarters and to support various cGMP activities, including research and development and small-scale manufacturing capabilities –

MORRISVILLE, N.C., Jan. 19, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. (“the Company” or “Novan”) (Nasdaq: NOVN), today provided an update that enrollment for its B-SIMPLE4 pivotal Phase 3 study evaluating SB206, a topical antiviral gel for the treatment of molluscum contagiosum (“molluscum”), has reached 90% of the approximately 850 subjects targeted for enrollment in the study.

In addition, the Company has entered into a lease agreement for approximately 15,000 square feet at a new location in Durham, North Carolina, to serve as the Company’s corporate headquarters, and the Company expects to move into the new facility during the second quarter of 2021. The Company is building out the newly leased location to support various cGMP activities, including research and development and small-scale manufacturing capabilities.

“This is an exciting time for the Company. With enrollment into our B-SIMPLE4 pivotal Phase 3 study, initiated in September of last year, we are encouraged by the progress that has been made in such a short period of time. We are grateful to all the investigators and staff who are driving enrollment for this important program forward, as well as the molluscum patients for their ongoing support. If approved, we believe that SB206 would help meet the need for patient care with an at-home treatment,” commented Paula Brown Stafford, President and Chief Executive Officer of Novan. “As we look forward to the readout of B-SIMPLE4, in addition to advancing our priority pipeline and NITRICIL platform technology, equipping the Company with a new location to support potential future activities was a key decision for us. We believe these steps position us to build momentum and enter the next phase of growth for the Company.”

Patient enrollment in the B-SIMPLE4 pivotal Phase 3 study commenced in September 2020 and is expected to enroll approximately 850 patients (1:1 randomization), across 55 clinical sites, who will be treated for 12 weeks with a follow-up visit at Week 24. To-date the study has enrolled approximately 90% of patients for the study.

Completion of patient enrollment is targeted for the first quarter of 2021. Topline efficacy results from the B-SIMPLE4 trial are targeted for 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. For more information about the B-SIMPLE4 trial, 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, enrollment demand and progress of our Phase 3 program to evaluate SB206 for the treatment of molluscum and the timing of anticipated topline results and the Company’s plans regarding its new facility. 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, the Company’s reliance on arrangements with third parties to support its operations, including the lease agreement described herein, and development efforts and the

risk that such parties will not successfully carry out their contractual duties or meet expected deadlines; 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; any operational or other disruptions as a result of the COVID-19 pandemic, including any delays or disruptions to the enrollment in and conduct of the B-SIMPLE4 pivotal Phase 3 study; 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.

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