Novan’s NITRICIL™ Technology Shows In Vitro Antiviral Effect Against SARS-CoV-2 in Human Airway Infection Model

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- First demonstration of antiviral effect of nitric oxide-based medicine against SARS-CoV-2 in an in vitro model that mimics the human airway epithelium
- Company believes preclinical results demonstrate high potential for clinical translation
- Company plans to initiate Chemistry, Manufacturing, and Controls (CMC) work to develop intranasal formulation of berdazimer sodium for use in coronavirus program

MORRISVILLE, N.C., Oct. 14, 2020 (GLOBE NEWSWIRE) – Novan, Inc. (“the Company” or “Novan”) (Nasdaq: NOVN), today announced positive in vitro results showing the potential efficacy of its NITRICIL™ platform technology as an antiviral against SARS-CoV-2, the virus that causes COVID-19. To evaluate the ability of its NITRICIL™ platform technology as a potential nasal treatment option for COVID-19, the Company initiated in vitro assessments targeting the reduction of viral burden in differentiated normal human bronchial epithelial cells. The studies were conducted at the Institute for Antiviral Research at Utah State University and these results demonstrate the first instance of an antiviral effect from a nitric oxide-based medicine in a 3-D tissue model that has similar structure to the human airway epithelium.

The results from the in vitro assessment of concentrations as low as 0.75 mg/mL demonstrated that berdazimer sodium reduced 90% of virus after repeat dosing, once daily.

“COVID-19 continues to have a major ongoing impact on global health and there remains a direct need for a safe and effective antiviral therapy. The naturally occurring antiviral effects of nitric oxide and the results we have generated from this assessment, provide us with confidence that our NITRICIL™ platform technology may be an effective treatment for COVID-19. We also believe the data from this sophisticated model of the human respiratory tract demonstrate a high potential for clinical translation,” commented Paula Brown Stafford, Chairman and Chief Executive Officer of Novan.

Novan plans to initiate Chemistry, Manufacturing, and Controls (CMC) work with a global leader in providing integrated services, superior delivery technologies and manufacturing solutions to develop an intranasal formulation of berdazimer sodium for use in the Company’s COVID-19 program.

Dr. Carri Geer, Senior Vice President and Chief Technology Officer added, “With these encouraging in vitro results in hand, the next step is to advance our program into preclinical IND-enabling studies to further confirm the safety of our NITRICIL™ technology when administered intranasally. We are in the process of finalizing arrangements with a global leader in drug development to assist in our development activities as we work toward a potential IND filing targeted in 2021.”

Based on the scientific literature and data available to-date with berdazimer sodium and Novan’s product candidate SB206, Novan believes that nitric oxide may inhibit viral replication by disrupting protein function critical for viral replication and infection through generation of reactive intermediates.

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
This press release contains forward-looking statements including, but not limited to, statements related to the potential therapeutic value of our NITRICIL™ platform technology, our pharmaceutical development of nitric oxide-releasing product candidates, our intention to advance development of certain product candidates, and our intention to partner with third parties. 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 our ongoing or future product development activities and preclinical studies, which may not prove successful in demonstrating proof-of-concept, or may show adverse toxicological findings, and even if successful may not necessarily predict that subsequent clinical trials will show the requisite safety and efficacy of our product candidates; our ability to enter arrangements with third parties to support our development efforts on terms that are acceptable to us or at all; risks and uncertainties in the clinical development process, including, among others, length, expense, ability to enroll patients, reliance on third parties, 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 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 or other business relationships necessary or useful for the further development of our 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 our regulatory submissions, all of which could have a material adverse effect on our business; risks related to the
manufacture of clinical trial materials; 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 Phase 3 trial; 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, 2019, as amended, 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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