Novan Announces Positive Preclinical Data in SB019 COVID-19 Anti-Viral Therapy Program

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– Data indicate that berdazimer sodium prevents progression of SARS-CoV-2 infection in two independent in vivo transmission studies –

– Statistically significant, dose-dependent reduction in the amount of virus in the lung with doses as low as 2 mg/mL –

– Preliminary toxicology and pharmacology study results suggest intranasal administration is well-tolerated and safe –

DURHAM, N.C., June 10, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. (“the Company” or “Novan”) (Nasdaq: NOVN), today announced positive preclinical results with berdazimer sodium in a SARS-CoV-2 transmission model in golden Syrian hamsters. In light of these promising results, the Company is exploring opportunities to develop an anti-viral therapy against COVID-19, the disease caused by the SARS-CoV-2 virus, both internally and potentially through strategic partnerships for this program.

To further evaluate the potential of its NITRICIL™ platform technology as an intranasal treatment option for COVID-19, the Company initiated preclinical *in vivo* studies evaluating the efficacy of berdazimer sodium to reduce viral burden in infected animals and to deter viral transmission to uninfected animals. The work was conducted at the Institute for Antiviral Research at Utah State University. Results from two separate studies independently demonstrated the ability of berdazimer sodium to prevent progression of infection into the lungs after transmission, significantly limiting severity of disease in this model. The intranasal treatment was well-tolerated during the preclinical *in vivo* studies, and no treatment-related adverse events were observed.

“These preclinical data are encouraging and provide the basis that we were looking for to support continuing down the development path for SB019. We are exploring avenues to interact with the FDA to expedite or streamline a development program for a potential intranasal treatment option for COVID-19,” commented Paula Brown Stafford, President and Chief Executive Officer.

SARS-CoV-2 infected animals were co-housed with healthy animals to induce infection via animal-to-animal transmission. The effect of a repeat, once daily intranasal treatment regimen with berdazimer sodium at various doses was assessed versus placebo controls. The endpoints included nasal and lung tissue viral count, in addition to body weight changes, an indicator of disease severity.

The Company observed a dose-dependent, statistically significant reduction ($P<0.0001$) in the amount of virus in the lungs of animals treated with berdazimer sodium concentrations as low as 2 mg/mL compared to placebo-treated controls. The effect was observed after co-habitation with infected hamsters who were also treated with berdazimer sodium. The average amount of virus in the lungs was reduced by greater than 4 logs (>99.99%) with more than half of the animals having no detectable virus in lung tissue at all.

Catalent, a leading global provider of advanced delivery technologies, development and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products, continues to support Novan’s CMC efforts and development of an intranasal formulation, SB019, for use in the Company’s COVID-19 program.

Preclinical tolerability and toxicology studies were conducted at a third-party research organization to inform product development at Catalent. The initial studies support the established safety profile of berdazimer sodium and suggest favorable tolerability when administered intranasally after repeat dosing.

Further, preclinical dose-range finding studies are being conducted to inform potential human clinical trial design and dosing regimen.

Based on the scientific literature, the Company’s previously reported *in vitro* results and the *in vivo* results announced today, Novan believes that nitric oxide may inhibit viral replication by disrupting protein function critical for viral replication and infection through generation of reactive intermediates. The Company plans to submit a request to the FDA to determine an appropriate path to bring a new potential treatment option to patients, as quickly as possible. The Company is evaluating its strategy to submit an IND for the purposes of advancing its SB019 product candidate, subject to regulatory guidance, successful completion of IND-enabling toxicology studies and obtaining additional financing or strategic partnering.

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,” “intends” 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 potential for SB019 as an anti-viral therapy against COVID-19,the potential safety and tolerability of the Company’s product candidates, the Company’s plan to pursue discussions with the FDA regarding a regulatory pathway for SB019 and submit an IND, and the Company’s 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 the Company’s expectations, including, but not limited to, risks and uncertainties in the Company’s ongoing or future product development activities and preclinical studies, including the timing and outcome of discussions with the FDA, as well as completion of the additional preclinical studies described above; the Company’s ability to enter into arrangements with third parties to support its development efforts on terms that are acceptable to the Company or at all; 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; 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 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; any operational or other disruptions as a result of the COVID-19 pandemic; and other risks and uncertainties described in the Company's annual report filed with the Securities and Exchange Commission on Form 10-K for the twelve months ended December 31, 2020, and in the Company's subsequent filings with the Securities and Exchange Commission. 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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