Novan Announces Strategic Priorities and Outlines Key Milestones

September 9, 2021

– Company planning for three potential New Drug Application (NDA) filings in three years with the first submission expected in Q3 2022 for lead program SB206 in molluscum contagiosum –

– Late-stage product candidate, SB204 for the treatment of acne vulgaris, selected to advance as second lead program toward pivotal Phase 3 study –

– SB019 SARS-CoV-2 development program advancing toward Phase 1 study in healthy volunteers, targeted for 1H 2022 –

– Company to host conference call and webcast today at 8:30 AM ET –

DURHAM, N.C., Sept. 09, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. (the “Company” or “Novan”) (Nasdaq: NOVN), today announced its key strategic priorities including its decision to advance late-stage asset, SB204, for the treatment of acne vulgaris as its second lead program. The Company provided a general update and outlined key milestones for its priority pipeline programs in development for the treatment of dermatology and infectious diseases. Novan management will host a conference call and webcast to discuss the updates today, September 9, 2021, at 8:30 a.m. ET (details below).

“This year has been transformational for Novan. Our proprietary and innovative platform, NITRICIL™, has continued to demonstrate robust clinical data and support our confidence in our ability to deliver therapeutic amounts of topical nitric oxide with an attractive safety profile across a number of dermatology and infectious disease indications, in addition to potential applications in animal health. Our recently completed B-SIMPLE4 study of SB206 for the treatment of molluscum has provided validation of our platform technology, demonstrated our ability to execute our clinical development programs effectively and has helped to guide prioritization of our pipeline programs,” stated Paula Brown Stafford, President and Chief Executive Officer.

“We are confident and excited to be advancing SB204 for the treatment of acne vulgaris. As our second lead program, we believe that SB204 has the potential to address an unmet medical need and address a significant market opportunity. We believe Novan is well-positioned to be the world leader in nitric oxide-based science, technology, and clinical development in support of delivering safe and efficacious therapies to patients. We remain committed to leveraging our core synergies of science, human and capital resources and medical need to create value by bringing new nitric oxide-based medicines to market. We believe that our strategic priorities are aligned to help us realize the full potential of Novan,” added Ms. Brown Stafford.

SB206 – A Topical Antiviral Treatment for Molluscum Contagiosum

In June 2021, Novan reported statistically significant positive topline results for the primary endpoint (p-value <0.0001) of complete clearance of all treatable lesions in its B-SIMPLE4 pivotal Phase 3 clinical study of SB206 for the treatment of molluscum. Additionally, and consistent with results from the Company’s prior Phase 2 and Phase 3 studies, SB206 was found to be safe and well tolerated in the B-SIMPLE4 study. No treatment-related serious adverse events were reported. In July 2021, the Company announced that the last patient had completed their planned Week-24 follow-up visit in the B-SIMPLE4 study. This follow-up visit at Week-24 is intended to further evaluate the safety of SB206, 12-weeks following completion of treatment.

The Company recently announced it has engaged Syneos Health (Nasdaq: SYNH), a fully integrated biopharmaceutical solutions organization, as its commercial solutions provider for SB206 prelaunch strategy and commercial preparation, in addition to sales and marketing support of SB206, if approved by the U.S. Food and Drug Administration (FDA).

Upcoming Targeted Milestones:

- Full data readout from the B-SIMPLE4 study, including Week-24 safety, within the next several weeks.
- Pre-NDA meeting with the FDA, as well as conduct of stability testing, targeted for 1H 2022.
- Potential submission of an NDA targeted for Q3 2022.

The Company believes that SB206 as a topical, at-home administered therapy, with a rapid treatment benefit would address 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.

SB204 – A Novel Multi-factorial Mechanism of Action for the Treatment of Acne Vulgaris

Novan is developing SB204 as a topical monotherapy for the treatment of acne vulgaris. This form of acne represents a multi-factorial disease with varying disease pathology (inflammatory and bacterial). SB204 utilizes the same active pharmaceutical ingredient used in the Company’s lead product candidate, SB206, and it is formulated specifically to address acne via an anti-inflammatory and anti-bacterial mechanism.

In two previous Phase 3 studies, AC301 and AC302, SB204 demonstrated consistent and promising results across two of three co-primary endpoints. In addition, AC302 was a successful pivotal trial with respect to all three co-primary endpoints, including non-inflammatory lesions, inflammatory lesions, and Investigator’s Global Assessment (IGA). Based on the recent positive pivotal Phase 3 results in the SB206 molluscum development program, the Company believes it can optimize the trial design of a pivotal Phase 3 study for SB204 that has the potential to serve as a second pivotal

trial to support an NDA submission.

Novan believes that acne has continued to be characterized as an unmet medical need due to the difficulty of balancing efficacy, systemic safety and cutaneous tolerability, as well as growing concerns with anti-bacterial resistance with existing therapies.

Upcoming Targeted Milestones:

- Prepare for pivotal Phase 3 study during 2022.
- Conduct planned pivotal Phase 3 trial targeted for 2023, subject to obtaining additional financing or strategic partnering.
- Potential submission of an NDA targeted for 2024.

SB019 – An Intranasal Formulation for the Treatment of Infectious Disease, COVID-19

In June 2021, Novan announced positive preclinical results demonstrating the anti-viral effect of the Company's NITRICIL™ platform technology, berdazimer sodium, against SARS-CoV-2, the virus that causes COVID-19. To evaluate SB019 as a potential intranasal treatment option for COVID-19, the Company completed preclinical *in vivo* studies evaluating the effect of berdazimer sodium to reduce viral load in infected animals and to deter viral transmission to uninfected animals. Results from two separate studies independently demonstrated the ability of berdazimer sodium to prevent progression of infection into the lungs following transmission, significantly limiting severity of disease, with statistically significant reduction ($p<0.0001$) in the amount of virus in the lungs of animals treated with berdazimer sodium at concentrations as low as 2 mg/mL, as compared to placebo-treated control animals. This intranasal treatment was well-tolerated during the preclinical *in vivo* studies, and no treatment-related adverse events were observed. Additional studies assessing the preclinical toxicology of SB019 in another species have been conducted at a third-party research organization and support the overall safety profile and favorable tolerability of intranasally administered SB019.

Based on the strong preclinical and clinical data demonstrating anti-viral effect of berdazimer sodium against multiple viruses, as well as increasing public health need to reduce breakthrough infections and transmission, the Company plans to advance its SB019 product candidate.

Upcoming Targeted Milestones:

- Initiation of Phase 1 study in healthy volunteers targeted for 2022.
- Phase 2/3 study(s) targeted for 2023, subject to obtaining additional financing or strategic partnering.
- Potential submission of an NDA targeted for 2024.

Conference Call and Webcast Details

As previously announced, Novan will host a corporate update conference call and webcast today, Thursday, September 9th at 8:30 a.m. ET. The call will be led by Paula Brown Stafford, President and Chief Executive Officer of Novan, who will be joined by additional members of the Novan management team. Interested participants and investors may access the conference call by dialing (844) 707-0661 (domestic) or (703) 318-2240 (international) and referencing conference ID: 6243828. The live webcast will be accessible on the Events page of the Investors section of the Novan website, novan.com, and will be archived for 90 days.

About Novan

Novan, Inc. is a pre-commercial nitric oxide-based pharmaceutical company focused on dermatology and anti-infective therapies. We leverage our core synergies of science, capital, resources and patient needs to create value by bringing new nitric oxide-based medicines to market. Our goal is to create the world's leader in nitric oxide-based science, technology, and clinical translation in support of delivering safe and efficacious therapies using our proprietary nitric oxide-based technology platform, NITRICIL™ to generate macromolecular New Chemical Entities (NCEs) to treat multiple indications.

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, including SB206, SB204 and SB019, the potential timing of clinical trials and FDA submission(s), the potential market opportunity for the Company’s product candidates, plans for launch and commercialization of SB206, if approved, 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 related to the regulatory approval process, which is lengthy, time-consuming and inherently unpredictable, including the risk that the FDA will not agree with the Company’s approach to a potential NDA submission, that the Company’s product candidates may not be approved or that additional studies may be required for approval or other delays may occur, that the Company may not have sufficient quantities of drug substance and/or drug product to support regulatory submissions and that the Company may not obtain funding sufficient to complete the regulatory or development process; the Company’s limited experience as a company in obtaining regulatory approvals and commercializing pharmaceutical products; changes in the size and nature of the market for our product candidates, including potential competition; risks and uncertainties in the Company’s 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 the Company’s product candidates; any operational or other disruptions as a result of the COVID-19 pandemic; the Company’s ability to obtain additional funding or enter into strategic or other business relationships necessary or useful for the further development or commercialization of the Company’s product candidates; 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 supply chain disruptions or delays, failure to transfer technology and processes to third parties effectively or failure of those third parties (or the Company in connection with the upfit of the Company’s new facility) 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 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.

INVESTOR AND MEDIA CONTACT:

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