Novan Announces Last Patient Visit at Week 24 in B-SIMPLE4 Pivotal Phase 3 Trial of SB206 in Patients with Molluscum Contagiosum

July 28, 2021

– Company previously reported positive topline efficacy and favorable safety data at Week 12 from B-SIMPLE4 in June 2021, with primary endpoint achieving statistical significance with p-value less than 0.0001 and no serious adverse events related to treatment with SB206 –

– Planned follow-up visit at week 24 is intended to further evaluate safety of SB206, 12 weeks following patient completion of treatment, with results expected in Q3 2021 –

– Novan intends to submit New Drug Application ("NDA") no later than the third quarter of 2022 –

– Currently no FDA-approved therapies for the treatment of molluscum –

DURHAM, N.C., July 28, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq: NOVN), today announced the last patient has completed their planned Week-24 follow-up visit in the B-SIMPLE4 pivotal Phase 3 clinical study of SB206, a topical gel with antiviral properties for the treatment of molluscum contagiosum ("molluscum").

Tomoko Maeda-Chubachi, M.D., Ph.D., M.B.A., Senior Vice President, Medical at Novan commented, "The completion of all Week-24 patient visits is an exciting step forward towards bringing a promising treatment option to molluscum patients. We continue to be encouraged by the positive topline results from this study and the potential benefit SB206 has for this contagious disease, which currently has no FDA-approved therapies. We look forward to reporting the full data set and importantly, potentially shifting the treatment landscape of molluscum for millions of people, primarily children, affected every year."

B-SIMPLE4 is a multi-center, double-blind, randomized, vehicle-controlled study that exceeded its enrollment target by randomizing 891 patients (1:1 randomization) in the study, across 55 clinical sites. Patients were treated for up to 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 lesion counts at Week 12 are considered treatment failures).

In June 2021, the Company reported positive topline results, including statistical significance for the primary endpoint with p-value less than 0.0001. Additionally, as was consistent with results from the Company's Phase 2 and earlier 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.

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

About Molluscum Contagiosum

Molluscum is a common, contagious skin infection caused by the *molluscipoxvirus*, affecting millions of people in the U.S. annually, with the greatest incidence in children. Approximately 70% of patients are below the age of 10. There are currently no U.S. Food and Drug Administration ("FDA") approved therapies for the treatment of molluscum. More than half of patients diagnosed with the infection are untreated.

About Novan

Novan, Inc. is a late clinical-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 various other medical conditions with significant unmet needs. The Company's lead product candidate is SB206, a topical gel with antiviral properties, 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 address an important unmet medical 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," "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, including SB206, the timing of follow-up safety results from B-SIMPLE4 and the potential timing of an NDA submission. 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, 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; the Company's ability to obtain additional funding or enter into strategic or other business relationships necessary or useful for the further development or, following regulatory approval, commercialization 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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