Novan Announces Final Week-12 Visit for Last Patient in B-SIMPLE4 Pivotal Phase 3 Study of SB206 for Treatment of Molluscum

May 3, 2021

– Topline data on track for readout before the end of Q2 2021 –

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

– Potential for NDA filing no later than Q3 2022 –

DURHAM, N.C., May 03, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq: NOVN), today announced the final patient has completed their last Week-12 visit in the B-SIMPLE4 pivotal Phase 3 clinical study of SB206, a topical antiviral gel, for the treatment of molluscum contagiosum ("molluscum"). Topline efficacy and safety results from the B-SIMPLE4 study are targeted to be reported before the end of the second quarter of 2021.

"We are incredibly pleased with the progress we have continued to make as we advance our lead program. We remain focused on executing our remaining steps according to plan and reporting topline efficacy and safety data in June. On behalf of Novan, I would like to extend our sincere gratitude to the patients, families and clinical staff that have participated in the study," commented Paula Brown Stafford, President and Chief Executive Officer of Novan. "Each patient will visit their physician one more time, at Week 24, and the study is expected to fully complete in the third quarter, although no additional efficacy data will be collected at that time."

Molluscum contagiosum is a common, contagious skin infection caused by the *molluscipoxvirus*, affecting up to six million people in the U.S. annually, with the greatest incidence in children aged one to 14 years. Infected children typically present with 10-30 painless, yet unsightly lesions, and, in severe cases, patients present with around 100 lesions.

"There remains an unmet need in the treatment landscape of molluscum, which affects millions of people each year and primarily children under the age of 10. Our product candidate, SB206, represents a promising opportunity to provide patients with treatment benefit and address the unmet needs in the treatment landscape for molluscum. Depending on the results of the B-SIMPLE4 Phase 3 trial, we are targeting a potential NDA filing no later than the third quarter of 2022," stated Tomoko Maeda-Chubachi, M.D., Ph. D., M.B.A., Senior Vice President, Medical at Novan.

B-SIMPLE4 is a multi-center, double-blind, randomized, vehicle-controlled study. The Company exceeded its enrollment target by randomizing 891 patients (1:1 randomization) in the study, across 55 clinical sites, due to the number of patients in screening at the time of achieving the planned enrollment goal. Patients have been 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 data at Week 12 are considered treatment failures).

There are currently no U.S. Food and Drug Administration ("FDA") approved therapies for the treatment of molluscum. The Company believes that SB206 as a topical, at-home, self or caregiver-applied therapy with a rapid treatment benefit, if approved, would satisfy 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.

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 or in the announced presentation 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," "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 and the Company's intention to advance development of certain product candidates. 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; any operational or other disruptions as a result of the COVID-19 pandemic, including any delays or disruptions to the conduct of the B-SIMPLE4 study; 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 SEC on Form 10-K for the twelve months ended December 31, 2020, and in the Company's subsequent filings with the SEC. Such forward-looking statements speak only as of the date of this press release or the announced presentation, as applicable, 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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