Novan Reports Positive Topline Results from Pivotal Phase 3 Trial of SB206 in Patients with Molluscum Contagiosum

June 11, 2021

– B-SIMPLE4 achieves statistical significance for the primary endpoint with p-value less than 0.0001 –

– No serious adverse events related to treatment with SB206 –

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

– Management to host video webcast today at 8:00 a.m. ET –

DURHAM, N.C., June 11, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq: NOVN), today announced positive topline efficacy and safety results for the B-SIMPLE4 pivotal Phase 3 clinical study of SB206, a topical antiviral gel, for the treatment of molluscum contagiosum ("molluscum"). Molluscum is a common, contagious skin infection caused by the *molluscipoxvirus*, affecting approximately six million people in the U.S. annually, with the greatest incidence in children aged one to 14 years. The Company will host a video webcast, today, June 11, 2021, at 8:00 a.m. ET (details below) to discuss the results of the study.

"The positive results from B-SIMPLE4 represent a transformational milestone for our employees, investors and most importantly, people living with molluscum. The strong safety and statistically significant efficacy results give us confidence as we move forward in preparing a New Drug Application to potentially bring SB206 to market and to patients in need of an effective therapy," commented Paula Brown Stafford, President and Chief Executive Officer of Novan. "We owe a great deal of gratitude to the collaborative efforts of our employees, partners, CROs, study investigators and participating patients who have contributed or participated in B-SIMPLE4."

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 data at Week 12 are considered treatment failures).

Summary of the primary and secondary endpoint results are as follows:

	B-SIMPLE4		
	SB206 (N=444)	**Vehicle (N=447)**	**p-value**
Primary Endpoint: Complete Clearance of All Lesions at Week 12	32.4%	19.7%	p<0.0001
Secondary Endpoint: Proportion Achieving a Lesion Count of 0 or 1 at Week 12	43.5%	24.6%	p<0.0001
Secondary Endpoint: Proportion Achieving ≥90% Clearance of Lesions at Week 12	43.0%	23.9%	p<0.0001
Secondary Endpoint: Complete Clearance of All Lesions at Week 8	19.6%	11.6%	p=0.0014

Consistent with results from the Company's Phase 2 and earlier Phase 3 studies, SB206 was found to be safe and well tolerated. No treatment-related serious adverse events ("TEAE") were reported.

Tomoko Maeda-Chubachi, M.D., Ph.D., M.B.A., Senior Vice President, Medical at Novan added, "This is an exciting day for both Novan, the treatment landscape of molluscum and the millions of people, primarily children, affected every year. These results are a testament to Novan's solid execution of the SB206 clinical program and strategy, and our belief in the potential of SB206 to provide patients with treatment benefit. With 32% of patients experiencing total clearance at Week 12 and 43% of patients with total clearance or one remaining lesion at Week 12, I am pleased to say the data demonstrate SB206 can be a powerful treatment option to shorten the duration of this contagious disease with visible skin lesions that worry parents and caregivers."

"I am proud to have been an investigator in this pivotal study. The results are better than I could have imagined. I am excited to potentially have a topical treatment that is safe and effective in treating molluscum for my patients," stated John Browning, M.D., F.A.A.D, F.A.A.P., MBA, Adjunct Associate Professor of Pediatrics and Dermatology at UT Health San Antonio and Baylor College of Medicine, and a Principal Investigator in the B-SIMPLE4 study.

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.

Conference Call and Webcast Details

The Novan management will host a video webcast presentation for investors, analysts, and other interested parties today, Friday, June 11, 2021, at 8:00 a.m. ET. 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 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 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, 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 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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