Novan Reports First Quarter 2021 Financial Results and Provides Corporate Update

May 11, 2021

– Topline efficacy results for ongoing Phase 3 study evaluating SB206 as a treatment for molluscum on track for targeted readout before the end of Q2 2021 –

– Preclinical program underway evaluating SB019 with berdazimer sodium as a potential intranasal therapy for COVID-19, with results targeted for readout in Q2 2021 –

– Proof-of-concept results from companion animal health program, NVN4100, targeted for Q2 2021 –

– Company expects current cash balance, plus expected contractual payments, to provide adequate liquidity to fund its operations into the first quarter of 2022 –

DURHAM, N.C., May 11, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. (“the Company” or “Novan”) (Nasdaq: NOVN), today announced its financial and operating results for the quarter ended March 31, 2021 and provided a corporate update.

“We continued to make progress across our priority pipeline development programs over the course of the first quarter. With the final Week-12 patient visit completed in our pivotal Phase 3 study for molluscum, B-SIMPLE4, we continue to work toward the targeted readout of our topline efficacy and safety data before the end of June. Additionally, we continue to advance our preclinical program for COVID-19 and our animal health program, both targeting data readouts in the second quarter,” commented Paula Brown Stafford, President and Chief Executive Officer of Novan. “With a number of near- and long-term milestones ahead, we believe we are well positioned for an exciting year ahead.”

Recent Highlights

- Announced the final patient completed their last Week-12 visit in the B-SIMPLE4 pivotal Phase 3 trial for SB206 as a treatment for molluscum contagiosum;
- Appointed Steven D. Skolsky to Board of Directors, a recognized healthcare and life science industry leader with over 35 years of international product development, strategy and commercialization experience; and
- Secured new location to serve as corporate headquarters and to support various cGMP activities, including research and development and small-scale manufacturing capabilities for drug substance and drug product.

Priority Development Pipeline Update

SB206 – A Topical Antiviral Treatment for Viral Skin Infections (Molluscum Contagiosum)

The Company announced on May 3, 2021 that the final patient had completed their last Week-12 visit in the B-SIMPLE4 trial. 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).

Upcoming Targeted Milestones:

- Topline efficacy and safety results from the B-SIMPLE4 study continue to be targeted for reporting before the end of the second quarter of 2021.
- Potential filing of new drug application (“NDA”) targeted no later than Q3 2022.

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.

SB019 – Infectious Disease, Coronaviridae (COVID-19)

In the fourth quarter of 2020, Novan announced positive *in vitro* results showing the potential efficacy of the Company's NITRICIL™ platform technology, berdazimer sodium (NVN1000), as an anti-viral against SARS-CoV-2, the virus that causes COVID-19. The Company initiated *in vitro* assessments targeting the reduction of viral burden in differentiated normal human bronchial epithelial cells. The studies were conducted at the Institute for Antiviral Research at Utah State University, and these results demonstrate the first instance of an anti-viral effect from a nitric oxide-based medicine in a 3-D tissue model that has similar structure to the human airway epithelium. The results from the *in vitro* assessment of concentrations as

low as 0.75 mg/mL demonstrated that berdazimer sodium reduced 90% of virus after repeat dosing, once daily.

Based on the scientific literature and data available to-date related to berdazimer sodium and Novan's product candidate SB206, Novan believes that nitric oxide may inhibit viral replication by disrupting protein function critical for viral replication and infection through generation of reactive intermediates.

Upcoming Targeted Milestones:

- Ongoing preclinical program with results targeted in the second quarter of 2021.
- Pending results of preclinical studies, the Company anticipates exploring possible strategic partners and filing a potential investigational new drug ("IND") application with the FDA in 2021.
- Targeting initiating human clinical trials in the second half of 2021, subject to regulatory guidance and obtaining additional financing or strategic partnering.

NVN4100 – Companion Animal Health

Novan has initiated exploratory work to evaluate the Company's new chemical entity, NVN4100, as a potential product candidate for antimicrobial indications in companion animal health. The Company has progressed efforts for initial formulation development to assess viability and has engaged animal health experts to assess technical feasibility and market potential.

Upcoming Targeted Milestones:

- Proof-of-concept results from exploratory *in vivo* and *in vitro* assessments targeted for the second quarter of 2021.
- Pending results of the exploratory assessment, the Company anticipates engaging with a potential collaborator or strategic partner to advance development in this area.

Financial Update

Summary of Financial Results for First Quarter 2021

- As of March 31, 2021, Novan had a total cash and cash equivalents balance of $32.7 million and positive working capital of $32.6 million.
- The Company believes that its existing cash and cash equivalents balance as of March 31, 2021, plus expected contractual payments to be received in connection with existing licensing agreements, will provide it with adequate liquidity to fund its operating needs into the first quarter of 2022, based on management's projections and planned priority development activities described in the Company's quarterly report on Form 10-Q for the three month period ended March 31, 2021.
- Novan reported a net loss of $9.0 million for the three months ended March 31, 2021, compared to a $6.2 million net loss for the same period in 2020.
- License and collaboration revenue was $0.7 million for the three months ended March 31, 2021, compared to $1.0 million for the same period in 2020. The decrease from the prior year related to the change in the Company's estimated performance period related to the non-refundable upfront and expected milestone payments under one of the Company's license agreements, which was extended during the fourth quarter of 2020.
- Research and development expenses were $6.4 million for the three months ended March 31, 2021, compared to $4.9 million for the same period in 2020. The increase was primarily attributable to (i) net increased costs of $3.3 million related to Novan's ongoing conduct, active enrollment and treatment phase activities of the B-SIMPLE4 Phase 3 trial during the first quarter of 2021, compared to relatively lower cost of B-SIMPLE1 and B-SIMPLE2 Phase 3 trials wind down activities during the comparative period in 2020; and (ii) a decrease of $1.5 million in other research and development expenses, primarily related to (i) a $1.0 million decrease in research and development personnel costs, (ii) a $0.4 million decrease in rent and depreciation expense and (iii) a $0.1 million decrease in material costs associated with manufacturing.
- General and administrative expenses were $2.7 million for the three months ended March 31, 2021, compared to $2.5 million for the same period in 2020. The increase was primarily due to (i) a $0.3 million increase in insurance premium expenses associated with the renewal of the Company's directors' and officers' liability policies in 2020 and (ii) a $0.2 million increase in other administrative expenses, including investor and public relations expense, partially offset by (i) a $0.1 million net decrease in general and administrative personnel and related costs and (ii) a $0.2 million decrease in rent and depreciation expense.

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," 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 timing and progress of the Company's Phase 3 program to evaluate SB206 for the treatment of molluscum, the timing of anticipated topline results, the Company's expected cash runway, the timing of anticipated results of the Company's preclinical development programs, 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, 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, including any delays or disruptions to the conduct of the B-SIMPLE4 Phase 3 trial; 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, 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, 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 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; 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.

NOVAN, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	**2020**
License and collaboration revenue	$ 747	$ 1,024
Government research contracts and grants revenue	72	189
Total revenue	819	1,213
Operating expenses:		
Research and development	6,418	4,916
General and administrative	2,686	2,507
Total operating expenses	9,104	7,423
Operating loss	(8,285)	(6,210)
Other (expense) income, net:		
Interest income	3	35
Other (expense) income	(670)	8
Total other (expense) income, net	(667)	43
Net loss and comprehensive loss	$ (8,952)	$ (6,167)
Net loss per share, basic and diluted	$ (0.06)	$ (0.17)
Weighted-average common shares outstanding, basic and diluted	150,028,864	37,043,876

NOVAN, INC.
Selected Condensed Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 32,661	$ 35,879
Total current assets	41,178	44,007
Total assets	46,983	46,829
Total current liabilities	8,585	8,700
Total liabilities	46,133	43,852
Total stockholders' equity	850	2,977
Total liabilities and stockholders' equity	$ 46,983	$ 46,829

INVESTOR AND MEDIA CONTACT:
Jenene Thomas
JTC Team, LLC
833-475-8247
NOVN@jtcir.com