Novan Reports Full Year 2020 Financial Results and Provides Corporate Update

February 25, 2021

– B-SIMPLE4 pivotal Phase 3 trial evaluating SB206 as a treatment for molluscum contagiosum progressing with top-line efficacy results targeted before the end of Q2 2021 –

– Company targeting initiating preclinical studies for intranasal formulation of berdazimer sodium for COVID-19 program, SB019, in Q1 2021 –

– Ongoing evaluations for strategic partnering opportunities to leverage broader pipeline to secure next phase of growth –

MORRISVILLE, N.C., Feb. 25, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. (“the Company” or “Novan”) (Nasdaq: NOVN), today announced its financial and operating results for the year ended December 31, 2020 and provided a corporate update.

“With our accomplishments achieved over the course of 2020 and our near-term milestones ahead of us this year, we believe we are well-positioned for an exciting 2021. As enrollment has been completed in our pivotal Phase 3 study for molluscum, B-SIMPLE4, we are quickly approaching the expected readout of our top-line efficacy data, targeted before the end of the second quarter and are working to advance this important product candidate toward potential approval,” commented Paula Brown Stafford, President and Chief Executive Officer of Novan. “As we continue to grow and build momentum advancing our priority development pipeline and the NITRICIL platform technology, we are focused on preparing for success and equipping the Company with the necessary resources and capital.”

Recent Highlights

- Completed enrollment for B-SIMPLE4 pivotal Phase 3 trial for SB206 as a treatment for molluscum with top-line efficacy results targeted before the end of the second quarter of 2021;
- 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; and
- Announced Master Services Agreement with Catalent, Inc. to support chemistry, manufacturing and control activities and development of an intranasal formulation of berdazimer sodium for the Company’s COVID-19 program, SB019.

Priority Development Pipeline Update

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

The Company announced the completion of patient enrollment for B-SIMPLE4 on February 1, 2021. B-SIMPLE4 is a multi-center, double-blind, randomized, vehicle-controlled study to evaluate the efficacy and safety of SB206 12% once-daily in approximately 850 total patients (1:1 active:vehicle randomization), ages 6 months and above, with molluscum. The Company exceeded its enrollment target of 850 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 trial’s stated goal. Patients will be treated for 12 weeks with a safety follow-up visit at Week 24. The primary endpoint for the study is the proportion of patients achieving 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 assessed as treatment failures).

Upcoming Targeted Milestones:

- Top-line efficacy results targeted before the end of the second quarter of 2021, if the trial is not further impacted by the COVID-19 pandemic.

For more information about the B-SIMPLE4 trial, 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 our NITRICIL™ platform technology, berdazimer sodium (NVN10000), 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:

- Advancing this program through preliminary preclinical studies, which Novan targets to have results in the second quarter of 2021;

- Pending the results of the preclinical studies, anticipates filing a potential IND application with the U.S. Food and Drug Administration in 2021; and

- Targeting initiating human clinical trials in the second half of 2021, subject to 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 internal efforts for initial formulation development to assess viability and has engaged animal health experts to assess technical feasibility and market potential.

Upcoming Targeted Milestones:

- Engaging with a potential collaborator or strategic partner to advance development in this area upon positive proof-of-concept work.

Financial Update

Summary of Full Year 2020 Financial Results

- As of December 31, 2020, Novan had a total cash and cash equivalents balance of $35.9 million and positive working capital of $35.3 million.

- As of December 31, 2020, the Company had an accumulated deficit of $249.3 million and there is substantial doubt about its ability to continue as a going concern. The Company believes that its existing cash and cash equivalents balance, plus expected contractual payments to be received in connection with existing licensing agreements, will provide it with adequate liquidity to fund its planned operating needs into the first quarter of 2022, based on management's projections and planned development and operating activities described in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

- Novan incurred net losses of $29.3 million and $30.4 million in the years ended December 31, 2020 and 2019, respectively.

- License and collaboration revenue of $4.2 million and $4.5 million for the years ended December 31, 2020 and 2019, respectively, was associated with the Company's performance during the period and the related amortization of non-refundable upfront and expected milestone payments under one of the Company's license agreements.

- Research and development expenses were $19.8 million for the year ended December 31, 2020, compared to $25.2 million for the year ended December 31, 2019. The net decrease of $5.4 million was primarily related to (i) a net $0.7 million increase in the SB206 program, (ii) a $4.3 million decrease in other research and development expenses, and (iii) a $1.6 million decrease in the SB414 program. The $4.3 million decrease in other research and development expenses was primarily driven by (i) a $1.3 million net decrease in research and development personnel costs, (ii) a $1.6 million decrease in costs associated with Novan's manufacturing technology transfer projects to third-party manufacturers, (iii) a $0.7 million decrease in depreciation expense and (iv) a $1.0 million decrease in manufacturing materials and support costs at the Company's previous primary facility, partially offset by $0.3 million of discrete costs incurred during the second and third quarters of 2020 related to decommissioning manufacturing capabilities at the Company's previous primary facility.

- General and administrative expenses were $11.3 million for the year ended December 31, 2020, compared to $10.4 million during the year ended December 31, 2019. The increase was primarily due to $1.7 million of aggregate non-cash expense related to the issuance of commitment shares as consideration for entering into common stock purchase arrangements with Aspire Capital Fund, LLC, partially offset by a $0.5 million decrease in general and administrative personnel and related costs and a $0.3 million decrease in other general and administrative expenses.

- For the year ended December 31, 2020, the Company recognized $2.3 million of non-cash impairment charges related to the July 2020 termination of its previous primary facility lease and a $1.8 million loss on the disposition of related assets, of which $0.8 million was a non-cash charge.

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.

About Molluscum

Molluscum contagiosum 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. Infected children typically present with 10 to 30 painless, yet unsightly lesions, and, in severe cases, they can have around 100 lesions. Due to the largely pediatric nature of the disease, parents are the caregivers for these children, in most cases, and tend to seek treatment. There are no U.S. Food and Drug Administration approved therapies for molluscum, and, upon seeking treatment, caregivers are faced with potentially painful in-office, dermatologist-administered physical procedures or cantharidin, or recommended off-label prescriptions and over-the-counter products. More than half of the patients diagnosed with molluscum are untreated and over 30% of those treated receive an off-label prescription with no molluscum indication or proven clinical efficacy. The average time to resolution is 13 months, however, some children experience lesions that may not resolve in 24 months. Further dissemination of this highly-contagious disease is common, and transmission to other children living in the household is reported to be 41%. There is a significant unmet need in the molluscum treatment landscape.

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 our Phase 3 program to evaluate SB206 for the treatment of molluscum, the timing of anticipated topline results, the Company's expected cash runway 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, 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; 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 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 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)

	Year Ended December 31,	
	2020	**2019**
License and collaboration revenue	$ 4,208	$ 4,477
Government research contracts and grants revenue	712	419
Total revenue	4,920	4,896
Operating expenses:		
Research and development	19,814	25,172
General and administrative	11,271	10,412
Impairment loss on long-lived assets	2,277	—
Loss on facility asset group disposition	1,772	—
Total operating expenses	35,134	35,584
Operating loss	(30,214)	(30,688)
Other (expense) income, net:		
Interest income	51	177

Interest expense	—	(2)
Other income, net	870	136
Total other income (expense), net	921	311
Net loss and comprehensive loss	$ (29,293)	$ (30,377)
Net loss per share, basic and diluted	$ (0.30)	$ (1.16)
Weighted-average common shares outstanding, basic and diluted	98,808,114	26,254,119

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

	Year Ended December 31,	
	2020	**2019**
Cash and cash equivalents	$ 35,879	$ 13,711
Total current assets	44,007	15,724
Total assets	46,829	29,097
Total current liabilities	8,700	12,899
Total liabilities	43,852	51,380
Total stockholders' equity (deficit)	2,977	(22,283)
Total liabilities and stockholders' equity (deficit)	$ 46,829	$ 29,097

INVESTOR AND MEDIA CONTACT:

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