Novan Provides SB206 Program and Business Update

February 6, 2020

- **FDA grants Type C meeting for SB206 to be held on April 1, 2020**
- **Last subject completes last visit, Week 24 safety evaluation**
- **Additional 12-week efficacy and safety data provided**

MORRISVILLE, N.C., Feb. 06, 2020 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today provided an update on several aspects of its Phase 3 B-SIMPLE program (B-SIMPLE1 and B-SIMPLE2).

Novan has been granted a Type C meeting with the U.S. Food and Drug Administration ("FDA") on April 1, 2020. The Type C Meeting is to seek FDA feedback on the proposal to conduct one additional, well-controlled confirmatory study of SB206 to support a future New Drug Application ("NDA").

In the Company's Phase 3 B-SIMPLE program with SB206 for the treatment of molluscum contagiosum, the last subject completed their final visit as part of the ongoing safety evaluation through Week 24. Top-line efficacy results from this program were announced on January 2, 2020, and full efficacy and safety data, including data from the safety evaluation through Week 24, are targeted to be available in March 2020.

The safety profile of SB206 through the Week 12 visit was found to be favorable. Adverse events experienced in the B-SIMPLE program were primarily mild to moderate and the only treatment emergent adverse events (TEAE) reported in greater than 5% of subjects in the SB206 treatment arm were application site pain and application site erythema. There were no treatment-related serious adverse events reported in B-SIMPLE1 or B-SIMPLE2.

	B-SIMPLE1		**B-SIMPLE2**	
	SB206 (n=235)	**Vehicle (n=116)**	**SB206 (n=237)**	**Vehicle (n=117)**
Subjects with at least one…				
TEAE	115 (48.9%)	36 (31.0%)	120 (50.6%)	29 (24.8%)
TEAE leading to study drug discontinuation	7 (3.0%)	1 (0.9%)	17 (7.2%)	1 (0.9%)
Maximum severity of TEAE at any visit				
Mild	60 (25.5%)	25 (21.6%)	51 (21.5%)	18 (15.4%)
Moderate	50 (21.3%)	10 (8.6%)	64 (27.0%)	10 (8.5%)
Severe	5 (2.1%)	1 (0.9%)	5 (2.1%)	1 (0.9%)

Subjects treated with SB206 (n=472, integrated safety population) experienced a lower occurrence of scarring (3.8%), as determined by the investigator, through the Week 12 visit when compared to vehicle (n=233, integrated safety population; 7.3%). Final safety profile and scarring assessments will be updated through Week 24 and are targeted to be released in March 2020.

Additional post-hoc analyses of efficacy data were performed and identified discordant data in two-subject households (two subjects randomized to the same treatment arm within one household) in both studies. In two-subject households, a greater clearance response rate in vehicle was experienced when compared to SB206 in both B-SIMPLE1 and B-SIMPLE2. Both B-SIMPLE studies were stratified across treatment groups by household, two-subject or one-subject. The post-hoc analyses of the one-subject households are summarized below:

Complete Clearance of all Molluscum Lesions at Week 12 (ITT, One-Subject Households Only)			
Pivotal Study	**SB206**	**Vehicle**	**p-Value**
B-SIMPLE1	28.7% (n=181)	19.1% (n=89)	0.116
B-SIMPLE2	29.0% (n=193)	16.7% (n=96)	0.025

In the integrated primary analysis (combining data from B-SIMPLE1 and B-SIMPLE2), a treatment effect of 7.0% was observed, which includes subjects from one and two-subject households. When looking at one-subject households only (excluding the data from the discordant two-subject households), the treatment effect increases to 11.1%.

Primary Endpoint: Complete Clearance of all Molluscum Lesions at Week 12 (ITT)			
Integrated Analysis	**SB206**	**Vehicle**	**p-Value**

One and Two-Subject Households	27.9% (n=473)	20.9% (n=234)	0.049
One-Subject Households Only	28.9% (n=374)	17.8% (n=185)	0.005

Management, along with the Board of Directors, continues to explore both financial as well as strategic options in order to continue operations and to progress SB206 for the molluscum indication, subject to funding and FDA feedback. The Company intends to pursue financing, which may be dilutive, non-dilutive or both, in the near future and intends to engage one or more financial advisors to assist in this financial and strategic process.

About Novan

Novan, Inc. is a clinical development-stage biotechnology company focused on leveraging nitric oxide's naturally occurring anti-microbial and immunomodulatory mechanisms of action to treat a range of diseases with significant unmet needs. We believe that our ability to deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to improve patient outcomes in a variety of dermatology, women's health and gastrointestinal diseases.

Forward-Looking Statements

This press release contains forward-looking statements including, but not limited to, statements related to pharmaceutical development of nitric oxide-releasing product candidates and our intention to advance development of certain product candidates, including the timing of full results of our Phase 3 program to evaluate SB206 for the treatment of molluscum, the outcome of discussions with the FDA regarding our B-SIMPLE program, the timing for a third Phase 3 trial, the timing of potential regulatory submissions, our needs for funding and our intention to pursue financing and strategic alternatives. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from our expectations, including, but not limited to, the risk that full results of the Phase 3 program will not be received timely or will not be consistent with our expectations; the risk that the FDA will not agree with our position that the B-SIMPLE2 results can be used to support an NDA alongside results of a third confirmatory trial; the risk that results from a third Phase 3 trial will not be received timely or will not achieve significance sufficient to support an NDA; our ability to obtain funding or enter into strategic relationships on a timely basis, or at all, to enable or complete a third Phase 3 trial and to continue operations; our ability to reduce cash expenditures; our ability to utilize the stock purchase agreement previously entered with Aspire Capital Fund, LLC; risks and uncertainties in the clinical development process, including, among others, length, expense, ability to enroll patients, reliance on third parties, potential for delays 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 our product candidates may not be approved or that additional studies may be required for approval or other delays may occur and that we may not obtain funding sufficient to complete the regulatory or development process; risks related to the manufacture of clinical trial materials; our ability to obtain additional funding or complete other strategic alternatives necessary to continue our business and/or the further development of our product candidates; and other risks and uncertainties described in our annual report filed with the SEC on Form 10-K for the twelve months ended December 31, 2018, and in our subsequent filings with the SEC. These 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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