Novan Reports Topline Results from SB204 Phase 3 Pivotal Trials

- *Topical Acne Product Candidate Achieves Statistical Significance on All Three Co-Primary Endpoints in One Trial, Demonstrates Statistical Significance on Only One of Three in the Second*
- *Company Continues to Analyze Trial Data to Better Understand These Results*

MORRISVILLE, N.C., Jan. 27, 2017 -- Novan, Inc. (NASDAQ:NOVN) today announced top-line results from the Company's two, replicate Phase 3 pivotal clinical trials for SB204 in the treatment of acne vulgaris. In the intent-to-treat analysis, Novan's topical nitric oxide-releasing product candidate SB204 demonstrated statistical significance ($p<0.05$) compared to vehicle on all three co-primary endpoints in NI-AC302, but demonstrated statistical significance on only one of three co-primary endpoints in NI-AC301. The three co-primary endpoints included the absolute changes in inflammatory and non-inflammatory lesion counts and proportion of patients achieving success on the Investigator Global Assessment, or IGA, at week 12. Success was defined as an improvement of at least two grades in the IGA score from baseline and an IGA score of 0 or 1, or "clear" or "almost clear."

In these two Phase 3 multi-center, randomized, double-blinded, vehicle-controlled, parallel group pivotal clinical trials, NI-AC301 and NI-AC302, a total of 2,639 patients ages 9 and older with moderate to severe acne were enrolled across a total of 110 sites in the United States, randomized in a 1:1 ratio to SB204 Gel 4% topically once-daily or vehicle gel topically once-daily and treated for 12 weeks. No new safety signals were observed and both treatments were generally safe and well tolerated, with less than 2% of patients discontinuing due to treatment-emergent adverse events in each trial. Summary statistics are based on the use of a multiple imputation methodology for missing data.

- The absolute change from baseline in the number of non-inflammatory lesions in NI-AC301 was -15.4 for SB204 and -13.4 for vehicle ($p=0.030$), and in NI-AC302 was -14.9 for SB204 and -12.3 for vehicle ($p=0.001$).
- The absolute change from baseline in the number of inflammatory lesions in NI-AC301 was -12.1 for SB204 and -11.1 for vehicle ($p=0.114$), and in NI-AC302 was -12.9 for SB204 and -10.6 for vehicle ($p<0.001$).
- The proportion of patients with IGA success in NI-AC301 was 13.4% for SB204 and 13.8% for vehicle ($p=0.866$), and in NI-AC302 was 18.9% for SB204 and 14.3% for vehicle ($p=0.032$).

The secondary endpoints for percent change in lesion counts are shown in the table below for each study along with the proportion of subjects achieving IGA success.

	NI-AC301	NI-AC302
Non-Inflammatory Lesion Reduction		
SB204, 4%	39%*	42%*
Vehicle	34%	34%
Inflammatory Lesion Reduction		
SB204, 4%	46%	51%*
Vehicle	43%	41%
IGA Success		
SB204, 4%	13.4%	18.6%*
Vehicle	13.8%	14.3%

*p<0.05

“While we are pleased with the results of the NI-AC302 trial that met the regulatory requirement for statistically significant efficacy of SB204, we are disappointed with the discordant results of NI-AC301. Our team has not yet received the full data set and we intend to provide an update on the SB204 program after our complete analysis,” said Nathan Stasko, PhD, President and CEO of Novan. “Despite these discordant results, we believe in the potential of nitric oxide’s multiple, well-documented mechanisms of action and the data we have recently generated for our SB206 anti-viral and SB414 anti-inflammatory product candidates. We continue to look forward to near term clinical results from our SB208 anti-fungal program in the second quarter of 2017 and advancing our pipeline of innovative therapies for patients suffering from skin diseases.”

The Company believes that its cash on hand is sufficient to fund operations at least through the end of 2017, of which the allocation of capital will be dependent upon further assessment of the SB204 Phase 3 trial results and data from other platform programs.

About Novan

Novan, Inc. is a late-stage pharmaceutical company focused on redefining the standard of care in dermatology through the development and commercialization of innovative therapies using the Company’s nitric oxide-releasing platform. Nitric oxide plays a vital role in the natural immune system response against microbial pathogens and is a critical regulator of inflammation. Our ability to harness nitric oxide and its multiple mechanisms of action has enabled us to create a platform with the potential to generate differentiated, first-in-class product candidates. We are rapidly advancing programs in five dermatological conditions with significant unmet medical need. We believe that our ability to conveniently deploy nitric oxide on demand in topical formulations allows us the

potential to significantly improve patient outcomes in a variety of skin diseases and positions us to be a commercially successful leader in the dermatology market.

For more information, visit the Company's website at www.Novan.com.

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, including further development of SB204, and future prospects of our business. 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 additional analyses of the data from the Phase 3 trial may be inconsistent with previously announced top-line results; uncertainties and risks in the clinical development process generally, including, among others, length, expense, ability to enroll patients, reliance on third parties and that results of earlier research and preclinical or clinical trials may not be predictive of results, conclusions or interpretations of later research or trials; the risk that we could incur additional expenses in connection with further analyses of any of our clinical-stage programs and whether we will be able to obtain additional funding when needed; and other risks and uncertainties described in our prospectus dated Sept. 20, 2016, filed with the Securities and Exchange Commission, or SEC, in our quarterly report filed with the SEC on Form 10-Q for the three months ended Sept. 30, 2016, and in any 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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