Novan Provides Update on SB204 Development Program

Company to Host Conference Call and Webcast to Provide Additional Results of Phase 3 Clinical Trials

MORRISVILLE, N.C., March 06, 2017 -- Novan, Inc. (“the Company” or “Novan”) (NASDAQ:NOVN) today announced that, after further analysis of the results from the NI-AC301 and NI-AC302 pivotal clinical trials for the Company’s topical nitric oxide-releasing product candidate, SB204, it intends to proceed with the SB204 development program. Following announcement of the top-line results for NI-AC301 and NI-AC302 last month, Novan conducted an in-depth examination of the data sets and engaged consultants in biostatistics and regulatory affairs. Based on the results of this process and its ongoing analysis, Novan intends to pursue a pre-submission meeting with the U.S. Food and Drug Administration, or FDA, to discuss the entirety of the SB204 development program in the third quarter of 2017, which could lead to a new drug application, or NDA, submission targeted in the first quarter of 2018.

“The safety and tolerability of SB204 was evident from the trials conducted to date, and we look forward to moving ahead with the program,” said Nathan Stasko, PhD, President and CEO of Novan. “We remain committed to delivering the prescribing community a safe, non-antibiotic alternative to help combat the widespread overuse of antibiotics in the treatment of acne and look forward to working with regulatory bodies around the world in making this meaningful innovation available for patients.”

Novan continues to believe that the Company’s cash on hand is sufficient to fund operations at least through the end of 2017, advancing each of the Company’s development programs through its nearest-term milestone. Novan anticipates that additional funding will be required to support SB204 through the FDA process, including the cost of an additional well-controlled trial, as well as to fund operations beyond 2017. Management is reviewing a number of potential financing options, including non-dilutive partnership opportunities across the Company’s pipeline, as well as traditional private and public equity financings.

Conference Call and Webcast

Novan will host a conference call at 8 a.m. Eastern Time on Mar. 6, 2017, to provide additional information on the SB204 development program. Callers should dial in approximately 10 minutes prior to the start of the call. No reservation is necessary to participate on the call. The phone number to join the conference call is +1 (844) 707-0661 (toll-free in the United States and Canada) or +1 (703) 318-2240 (international). The conference ID for the live call is 77470993. A live webcast will be accessible from the Events page of the Company’s website at http://Events.Novan.com. The webcast will be archived on the Company’s website for 90 days following the live call.
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 related regulatory submissions, 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 the FDA is not amenable to our plan for SB204 or requires additional studies or information before we can submit our NDA; the risk that additional studies are inconsistent with our expectations; the risks that we are delayed in making an NDA submission, the FDA does not accept our submission for filing, disagrees with our analysis of endpoints or that the FDA requires us to conduct additional studies to support the submission; the risk that the FDA does not approve our NDA or approves our NDA with limitations or subject to additional studies; 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, or at all; 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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