Novan Conducts Guidance Meeting with FDA on SB204 Development Program

MORRISVILLE, N.C., Sept. 25, 2017 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced that it has concluded a guidance meeting with the U.S. Food and Drug Administration (FDA) regarding SB204 for the treatment of acne vulgaris. The FDA advised that an additional pivotal trial should be conducted. Given the need for the additional clinical study, the agency treated this meeting as a guidance meeting rather than a pre-NDA meeting. The Company anticipates receiving written minutes of the meeting within the next 30 days.

"We had a productive guidance meeting with the FDA regarding SB204. The meeting provided important clarity with regard to design for any future pivotal trial," stated Kelly Martin, Novan's interim Chief Executive Officer. "We intend to update the marketplace as to the next steps for SB204 after having had the chance to review and verify the final FDA minutes and incorporate that input into the overall Novan plan."

About Novan

Novan, Inc. is a 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 have advanced programs with four product candidates for 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.

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, our potential financing opportunities and partners, as well as our expected uses of cash and cost-savings initiatives, and the future prospects of our business, including management succession, operating activities and our product candidates. 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, uncertainties and risks in the clinical development process, including specifically with respect to SB204 and the uncertainties regarding the FDA approval requirements, whether an additional study would be successful or additional requirements are imposed which we may be unable to meet and other clinical development process risk 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 lengthy and unpredictable nature of the U.S. Food and Drug Administration's drug approval process; whether we will be able to enter into strategic arrangements or obtain adequate funding to support our operations and initiatives on acceptable terms, or at all; our ability to implement and realize anticipated benefits from any adjustments to our business, including headcount reductions and other cost-saving measures; our ability to modify, streamline or reposition our manufacturing infrastructure and associated capabilities on financial and operational terms that are acceptable; the ability to attract and retain senior management and key employees and other risks and uncertainties described in our annual report filed with the Securities and Exchange Commission, or SEC, on Form 10-K for the twelve months ended Dec. 31, 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.

CONTACT:

(Investors)
Novan, Inc.
919-627-6847
investors@novan.com

(Media)
Deb Holliday
Pascale Communications, LLC
412-877-4519
deb@pascalecommunications.com