



Novan Receives FDA Guidance for SB204 and Acne Indication

- **Written minutes received from Type C meeting with FDA**
- **Moderate-to-severe patient pathway re-affirmed**
- **Additional insights gained around the severe patient sub-population**

MORRISVILLE, N.C., Sept. 24, 2018 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced receipt of written meeting minutes from a Type C meeting held with the U.S. Food and Drug Administration (FDA) in the second quarter of 2018. As previously communicated, receipt of the meeting minutes is a necessary and critical step in the Company's assessment and consideration around the advancement of SB204 in acne vulgaris for the U.S. market.

"We now have clarity around the FDA's expectations and necessary steps for acne and are working to incorporate this specific and important guidance into a potential clinical development plan," stated Paula Brown Stafford, Novan's Chief Development Officer. "Our constructive dialogue with the agency was based on actual patient data from our previous pivotal trials, as well as interactions with key opinion leaders in the field of dermatology."

Including the Type C meeting, Novan has had several interactions with the FDA over the past 12 months regarding SB204 and the acne indication. In September 2017, Novan conducted a guidance meeting with the FDA to obtain clinical and regulatory guidance by reviewing the previously completed parallel Phase 3 pivotal trials in patients with moderate-to-severe acne. The FDA's specific feedback noted that there were no additional safety requirements and that one additional pivotal trial – in moderate-to-severe acne – would be required for registration.

In the second quarter of 2018, Novan conducted a Type C meeting to further discuss the Phase 3 program with the FDA and the potential for proceeding with a more narrowly defined patient segmentation. In that dialogue, Novan's focus was centered specifically on the severe patient population. The FDA provided feedback in their minutes on two paths forward for the acne indication, confirming the need for one additional pivotal trial for moderate-to-severe acne or, as an alternative, additional preliminary trials for a severe-only patient population.



Based on the most recent FDA feedback, as well as on-going dialogue with the agency, Novan is finalizing clinical development plans for SB204 and the acne indication for the U.S. market. These plans focus on acne, both as a specific and singular indication, as well as its incorporation into the Company's overall clinical portfolio. With the receipt of these minutes, Novan has continued discussions with the third party with which the Company entered into a non-binding term sheet in the fourth quarter of 2017 and is considering business structures and constructs with any one or more third party investors or business partners that could provide a favorable path forward with SB204.

About Novan

Novan, Inc. is a clinical-stage biotechnology company focused on leveraging nitric oxide's natural antiviral and immunomodulatory mechanisms of action to treat dermatological and oncovirus-mediated diseases. We believe that our ability to conveniently deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to significantly improve patient outcomes in a variety of 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, our intention to advance development of certain product candidates, which is subject to our ability to obtain additional financing or enter into strategic relationships to enable such development, and the future prospects of our business 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: risks and uncertainties in the clinical development process, 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 activities or additional trials, specifically including with respect to any new trials related to SB204; risks related to the regulatory approval process, which is lengthy, time-consuming and inherently unpredictable; our ability to obtain substantial additional funding for the further advancement and development of our product candidates; our ability to identify and enter into strategic relationships for the further development and potential commercialization of our product candidates, including our ability to complete a business construct that will provide funding



to enable the further development of SB204 relating to acne vulgaris and our other programs and objectives; 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, 2017, 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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