



Novan Extends Technical Production Capacity and Reaches Agreement with Orion Corporation

October 16, 2018

- **External manufacturing agreement reached to enable production of clinical trial materials for SB204 and the acne indication, with the potential to include additional product candidates**
- **Extension of capacity complements existing internal operations, proprietary technological knowledge, intellectual property strategy and production skills**
- **Agreement aligns with and supports global business development strategy**

MORRISVILLE, N.C., Oct. 16, 2018 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced that the Company has established a strategic alliance with Orion Corporation ("Orion"), a Finnish full-scale pharmaceutical company with broad experience in manufacturing.

The alliance enables Orion to manufacture Novan's topical nitric oxide-releasing product candidates on behalf of Novan and Novan's global strategic partners. The companies have executed a master contract manufacturing agreement to enable technology transfer and manufacturing of clinical trial materials for future clinical trials with Novan's product candidates. Novan plans to transfer the technology for the manufacture of SB204, currently in Phase 3 development for the treatment of acne, and intends for Orion to be able to manufacture the drug product, or the finished dosage form of the gel, in accordance with Novan's established manufacturing processes, in compliance with applicable regulatory guidelines, as appropriate for clinical trials and alongside Novan's current manufacturing capabilities.

"This alliance with Orion allows us to expand our technical production capacity," stated Jeff Hunter, Novan's Chief Business Officer. Commenting further, Mr. Hunter added, "Developing additive and modular capabilities for manufacturing our product candidates gives us the opportunity to expand our business, including and beyond the United States, as or when those opportunities may arise." Regarding the choice of Orion, Mr. Hunter commented, "Orion has an impressive profile with over 100 years in the pharmaceutical business and a manufacturing reputation that precedes itself. We are delighted with our decision to include them as an extension of our global business network." An interdisciplinary team of Jeff Hunter, Carri Geer, Vice President of Pharmaceutical Development, Andrew Novak, Chief Accounting Officer, and Johannes Roebbers, Chief Executive Officer of Cilatus BioPharma AG, were responsible for conducting a multi-month assessment of potential partners.

While the initial framework of the agreement enables the manufacture of SB204, the companies plan to evaluate expanding the agreement to include other product candidates for the manufacture of clinical trial materials and, potentially, commercial quantities. Importantly, this alliance is intended to support major global markets in which Novan and its partners pursue regulatory approvals for Novan's product candidates and complements existing Novan internal capabilities.

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.

About Orion

Orion is a globally operating Finnish pharmaceutical company - a builder of well-being. Orion develops, manufactures and markets human and veterinary pharmaceuticals and active pharmaceutical ingredients. The company is continuously developing new drugs and treatment methods. The core therapy areas of Orion's pharmaceutical R&D are central nervous system (CNS) disorders, oncology and respiratory diseases for which Orion develops inhaled Easyhaler® pulmonary drugs. Orion's adjusted net sales in 2017 amounted to EUR 1,034 million and the company had about 3,200 employees. Orion's A and B shares are listed on Nasdaq Helsinki.

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; risks related to the regulatory approval process, which is lengthy, time-consuming and inherently unpredictable; risks related to the manufacture of clinical trial materials and commercial supplies of any potentially approved product candidates, including the manufacture of our NVN1000 active pharmaceutical ingredient in our primary facility, our internal manufacturing capabilities and our ability to transfer technology and processes as contemplated by the manufacturing agreement; 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; 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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