



Novan Completes End-of-Phase 2 Meeting and Provides Additional Business Updates

March 11, 2019

- **Completed end-of-Phase 2 FDA meeting for molluscum contagiosum**
- **Meeting minutes received and support second quarter 2019 pivotal Phase 3 initiation**
- **Finalizing establishment of Irish entity to enable EU regulatory and partnering progress**
- **Shareholder class action lawsuit has been dismissed**
- **Letter of intent signed with partner to outsource drug substance manufacturing**
- **Phase 1b atopic dermatitis and Phase 2 molluscum abstracts selected for oral presentations**

MORRISVILLE, N.C., March 11, 2019 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced a number of recent business advancements.

Novan concluded an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding SB206 for the treatment of molluscum. The Company has also received the written minutes from that meeting. Based on guidance from both the meeting and minutes received, the Company believes that pivotal Phase 3 clinical trials for molluscum are positioned to be initiated in the second quarter of 2019, subject to securing additional financing or partnering. Novan has engaged a contract research organization (CRO) for the execution of the pivotal trials and, if the trial is initiated on this timetable, top-line results would be expected in late 2019 or during the first quarter of 2020.

"We are pleased with our clinical, operational and regulatory progress with SB206 for molluscum," commented Paula Brown Stafford, Novan's President and Chief Operating Officer. "The feedback from both investigators and clinical sites regarding the progression of the molecule has been positive."

To support European regulatory and business development expansion activities, Novan is in the final stages of establishing an Ireland-based business entity. Once organization of the entity is complete, Novan, through its Irish entity, intends to establish itself as a small- and medium-sized enterprise (SME) and then apply for Priority Medicines (PRIME) status. PRIME is a scheme launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need, with the goal of bringing therapies to patients earlier. With the support of a CRO, the company intends to focus initial EU regulatory efforts on SB206 for molluscum and utilize the PRIME process to work with the EMA for this unmet medical need.

The Company previously reported that it was subject to putative stockholder class action lawsuits that were filed in November 2017, in connection with statements related to its Phase 3 clinical trials of SB204. In January of 2019, the district court adopted the magistrate judge's recommendation to grant the Company's motion to dismiss, and as such, the case was dismissed with prejudice and judgment entered in favor of the Company and against the plaintiff. The plaintiff did not appeal this dismissal and judgment, and therefore, the Company has concluded that this matter is closed.

In addition, Novan has signed a letter of intent with a full-scale active pharmaceutical ingredient (API) manufacturer, for the production of Novan's proprietary berdazimer sodium drug substance. Upon entering a master service agreement, this would enable the production of Novan's drug substance by the partner for clinical trials and, upon approval of any of the Company's drug product candidates, for commercial purposes. This evolving relationship reinforces continued adjustments to the business model intended to allow the Company to transition away from a fixed internal infrastructure to a flexible external network of partners and follows on from the previously announced relationship with Orion Corporation for drug product manufacturing.

Lastly, Novan announces that clinical results from the Company's Phase 1b clinical trial in atopic dermatitis and Phase 2 clinical trial in molluscum contagiosum will be presented at upcoming medical conferences.

Novan's Phase 1b trial with SB414 cream for the treatment of atopic dermatitis will be presented at the 77th Annual Society for Investigative Dermatology Meeting in Chicago, IL to be held May 8-11, 2019. Dr. Emma Guttman, M.D., Ph.D., the Sol and Clara Kest Professor of Dermatology, Vice Chair of Research and Director of the Center for Excellence in Eczema, Icahn School of Medicine at Mount Sinai Medical Center, New York, will present the results on behalf of Novan.

The clinical results from the Company's Phase 2 trial with SB206 gel for the treatment of molluscum contagiosum will be presented at the 118th Annual Meeting of the Japanese Dermatological Association (JDA) in Nagoya, Japan to be held June 6-9, 2019. Dr. Tomoko Maeda-Chubachi, Novan's Vice President of Medical Dermatology, will present the results.

About Molluscum Contagiosum

Molluscum contagiosum is a common, contagious skin infection caused by the *molluscipoxvirus*, affecting approximately six million people in the U.S. annually, with the greatest incidence in children aged one to 14 years. Infected children typically present with 10 to 30 painless, yet unsightly lesions, and, in severe cases, they can have around 100 lesions. Due to the largely pediatric nature of the disease, parents are the caregivers for these children, in most cases, and tend to seek treatment. There are no FDA approved therapies for molluscum, and, upon seeking treatment, caregivers are faced with potentially painful in-office, dermatologist-administered physical procedures or cantharidin, or recommended off-label prescriptions and over-the-counter products. More than half of the patients diagnosed with molluscum are untreated and over 30% of those treated receive an off-label prescription with no molluscum indication or proven clinical efficacy. The average time to resolution is 13 months, however, some children experience lesions that may not resolve in 24 months. Further dissemination of this highly-contagious disease is common, and transmission to other children living in the household is reported to be 41%. There is a significant unmet need in the molluscum treatment landscape.

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, including SB206 for the treatment of molluscum, which is subject to our ability to obtain additional financing or enter into strategic relationships to enable such development, potential business development opportunities for the Company's late-stage dermatology assets, expansion of our business 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, our ability to obtain substantial additional funding on a timely basis in order to sustain operations and for the further advancement and development of our product candidates; our ability to identify and enter into strategic relationships or other business development opportunities for the further development and potential commercialization of our product candidates and support thereof; 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 relating to our ability to complete an agreement for the manufacture of our API; risks related to the manufacture of clinical trial materials and commercial supplies of any potentially approved product candidates, including the manufacture of our API and our ability to transfer technology and processes to a third party effectively; risks associated with relying on third parties for the manufacture of drug product for clinical trials; 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.

CONTACT:

(Investors & Media)
Cole Ikkala
Director, Investor Relations, Communications & Business Development
cikkala@novan.com



Novan, Inc.