



Novan Publication Supports Women's Health Business Unit Initiative and Nitric Oxide's Potential Against HPV-Associated Diseases

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- Data from SB206 Phase 2 clinical trial in external genital warts have been published in the *Journal of Drugs in Dermatology*
- SB206 was efficacious and well tolerated in the trial
- Advancement of the late stage clinical asset for external genital warts will be a priority for the recently created Women's Health Business Unit

MORRISVILLE, N.C., Nov. 01, 2018 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced that data from the Company's Phase 2 clinical trial evaluating SB206, a topical nitric oxide-releasing product candidate for the treatment of external genital warts caused by human papillomavirus (HPV), have been published in the October 2018 issue of *Journal of Drugs in Dermatology*, a peer-reviewed journal in dermatology with high readership and exposure to approximately 14,500 dermatology healthcare professionals.

"The data generated in our Phase 2 trial with SB206 for the treatment of external genital warts are encouraging and support the potential for a nitric oxide-based therapy to treat a skin disorder with few treatment options, and possibly other HPV-associated diseases with significant unmet need," stated Tomoko Maeda-Chubachi, Novan's Vice President, Medical Dermatology. "The recognition of our data by industry associations and widely-respected peer-reviewed journals validates the high-quality of our science and innovative nature of the technology."

Results from the Phase 2 clinical trial conducted in 108 patients with external genital and/or perianal warts were initially announced in November 2016 and presented during a Late-breaking Research forum at the 2017 Annual Meeting of the American Academy of Dermatology (AAD). As detailed in the manuscript, the percentage of patients who experienced complete clearance was higher for SB206 treatment groups than for vehicle groups, with the greatest difference seen between SB206 12% once-daily (33.3%, $p=0.010$) and vehicle once-daily (4.3%). The most effective dose, SB206 12% once-daily, was well tolerated. None of these patients had recurrence during the trial period.

Novan recently announced the creation of a dedicated women's health business unit, which will leverage existing knowledge of the potential utility of nitric oxide-based products in the field of women's health, and, specifically, diseases caused by underlying high-risk HPV infections. The women's health business unit is being led by Paula Brown Stafford, Novan's Chief Development Officer, and is complemented by academic research collaborators at University of Alabama-Birmingham and clinical research collaborators at Health Decisions, Inc. This published data for SB206 as a treatment for external genital warts supports the translation of Novan's core nitric oxide technology into the women's health field and its therapeutic applicability to HPV-associated diseases, providing the business unit with a late stage asset for advancement.

Title: ["A Phase 2 Controlled Study of SB206, a Topical Nitric Oxide-Releasing Drug for Extragenital Wart Treatment"](#)

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About Human Papillomavirus (HPV) and Genital Warts

HPV refers to a large family of double-stranded DNA viruses that induce abnormal growths on the skin or mucosal surfaces. HPV affects nearly 80 million Americans, and an estimated 14 million new cases of the virus are reported each year, according to the Centers for Disease Control and Prevention, or CDC. There are over 100 subtypes of the virus, characterized as low-risk or high-risk based on their cancer-causing potential. The virus is typically transmitted via direct skin-to-skin contact through disruptions in the normal skin barrier. All warts are caused by HPV, including genital and perianal warts, common warts and plantar warts.

Genital warts, mainly caused by HPV, affect approximately 1% of sexually active adults in the United States and Europe, and are among the world's most common sexually transmitted diseases. Genital warts are usually flesh-colored growths that can be raised, flat or cauliflower-shaped and are typically found on the surface of the external genitalia or in and around the anus. In males, they can appear on the surface of the penis and scrotum, and in females inside the vagina or on the cervix. Genital warts carry a substantial psychosocial burden due to the shame and embarrassment related to having a sexually transmitted disease as well as the inconvenience and discomfort of current treatment modalities. Current treatment options for genital warts consist of ablative procedures that cut, burn or freeze the warts but do not address the underlying viral infection, and there are no currently approved oral or topical prescription products indicated for the treatment of genital warts with a direct anti-viral mechanism of action.

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 Statement

This press release contains forward-looking statements including, but not limited to, statements related to pharmaceutical development of nitric oxide-releasing product candidates 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 or trials related to our interpretation of data from preclinical studies or clinical trials, our ability to obtain substantial additional financing or enter into strategic

relationships to enable further advancement and development of our product candidates, including SB206, and other risks and uncertainties described in our annual report filed with the SEC on Form 10-K for the twelve months ended Dec. 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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