



Novan's Drug Substance Demonstrates Inhibition of HPV-18 Virus Production

- | **Preclinical data published in *Antiviral Research***
- | **Study conducted by Drs. N.S. Banerjee, L.T. Chow and T.R. Broker at The University of Alabama at Birmingham**
- | **Findings reinforce anti-viral mechanism of action for Novan's nitric oxide-based drug substance**
- | **HPV-related clinical applications remain an area of focus for the Company**

MORRISVILLE, N.C., July 24, 2019 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced that independently generated preclinical data which demonstrated the antiviral effects of the Company's nitric oxide-releasing macromolecule, NVN1000, on human papillomavirus (HPV) infections has been published in *Antiviral Research*. The study was conducted by a research team from the Department of Biochemistry and Molecular Genetics at the University of Alabama at Birmingham led by N. Sanjib Banerjee, Ph.D., Thomas R. Broker, Ph.D., Founding President of the International Papillomavirus Society, and Louise T. Chow, PhD, Member of the U.S. National Academy of Sciences and of Academia Sinica (Taiwan).

The preclinical work published in the manuscript demonstrates NVN1000's durable inhibition of high-risk HPV-18 DNA replication in a three-dimensional human skin culture model. More specifically, the output from the study shows reduction of both the E6 and E7 viral oncoprotein levels.

"The observations published are exciting and highlight both NVN1000's strong inhibitory effect against HPV when topically delivered to the infected epithelium and its broader anti-viral mechanism of action," commented the authors of the study. Drs. Broker and Chow further noted, "while there are treatments available today in the HPV arena, none comprise a complete and reliable solution for patients and most have tolerability issues. The *in vitro* NVN1000 efficacy data that our laboratory has generated provide compelling evidence to invest the effort and resources to pursue additional clinical development activities which target premalignant HPV lesions.

Title: ["NVN1000, a novel nitric oxide-releasing compound, inhibits HPV-18 virus production by interfering with E6 and E7 oncoprotein functions"](#)

Authors: N. Sanjib Banerjee, Dianne W. Moore, Hsu-Kun Wang, Thomas R. Broker, Louise T. Chow

Publication: *Antiviral Research*: Jul 15:104559. doi: 10.1016/j.antiviral.2019.104559. [Epub ahead of print] PMID: 31319090

The *in vitro* results suggest that the positive results seen during the Phase 2 clinical trial with SB206 for the treatment of external genital warts caused by HPV could be due to the direct antiviral activity of NVN1000 against HPV proteins. Novan intends to advance a women's health product candidate to IND-enabling studies, subject to receiving the funding of grant-related dollars. The Company aims to be in a position to advance this initiative in the near future.

About Human Papillomavirus (HPV)

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. Cervical cancer and other carcinomas of anogenital mucosa in women and in men are driven by high-risk HPV types. While the HPV vaccines are safe and effective, the reality is that global vaccination rates are low. Accordingly, there remains an unmet need for novel topical antiviral therapies to treat HPV lesions in order to prevent infectious transmission and to eliminate the risk of lesions progressing to dysplasias and cancers.

About Novan

Novan, Inc. is a clinical development-stage biotechnology company focused on leveraging nitric oxide's naturally occurring anti-microbial and immunomodulatory mechanisms of action to treat a range of diseases with significant unmet needs. We believe that our ability to deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to improve patient outcomes in a variety of dermatology, women's health and gastrointestinal 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 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, potential for delays 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, including the risk that our product candidates may not be approved or that additional studies may be required for approval or other delays may occur and that we may not obtain funding sufficient to complete the regulatory or development process; our ability to obtain additional funding or enter into strategic relationships or other business development necessary for the further development of our product candidates, including the amount and timing of any grants to support funding for a women's health product candidate; 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, 2018, 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