



## **Novan Creates Dedicated Women’s Health Business Unit**

- Business unit will focus on Novan’s proprietary nitric oxide technology and its application to target high-risk human papillomavirus (HPV) and associated cancers affecting women such as cervical cancer where 70% of cases have been conclusively linked to HPV
- Novan partners with Health Decisions, a specialist CRO whose distinctive track record includes managing more than 150 trials in women-only indications
- Previously announced Phase 2 data for the treatment of external genital warts (EGW) provide a specific late stage clinical asset that targets HPV from which this dedicated development unit is launched
- Existing multi-year research collaboration with University of Alabama-Birmingham extended; recent ground-breaking findings presented at the 2018 International Papillomavirus Conference in Sydney, Australia, as well as the 49<sup>th</sup> DNA Tumor Virus Meeting in Madison, Wisconsin
- Exclusive worldwide rights obtained 12 months ago broadens the proprietary nitric oxide technology platform to target certain cancer-causing viruses

MORRISVILLE, N.C., Oct. 25, 2018 (GLOBE NEWSWIRE) -- Novan, Inc. (“the Company” or “Novan”) today announced the formation of a dedicated women’s health business unit as well as a foundational collaboration with Health Decisions, Inc. Health Decisions is a full-service contract research organization (CRO) specializing in clinical studies of therapeutics for women’s health indications. This therapeutically-focused unit will be led by Paula Brown Stafford, Chief Development Officer of Novan.

Over the past twelve months, Novan has progressed its knowledge on the potential to utilize nitric oxide-based products in the field of women’s health, with an emphasis on oncovirus (cancer-causing) applications. The Company’s initial focus has centered on persistent high-risk human papillomavirus (HPV). Significant clinical research on high-risk



HPV infections has demonstrated a conclusive link to the development of malignant lesions and neoplasias, including female cancers in the cervix, vagina, vulva, anus and oral cavity.

The collaboration with Health Decisions provides Novan with a differentiated opportunity to advance in the area of women's health. The combination of Novan's nitric oxide science and technology platform and the highly-experienced clinical expertise of Health Decisions creates a foundation for this approach.

Dr. Andrea Lukes, a board-certified OB/GYN and Chief Medical Officer of Health Decisions stated that, "The linkage of underlying high-risk HPV infection and its association with disease cascades across multiple pre-cancerous neoplasias and cancers affecting women is well documented." Dr. Lukes added, "The opportunity to work with Novan to develop localized antiviral nitric oxide-based therapies that can be self-administered by female patients to eliminate HPV infection and, therefore, inhibit disease progression is truly exciting. With success, it would be of significant benefit to patients."

Central to the Novan effort has been an ongoing, multi-year research collaboration with the University of Alabama-Birmingham studying the effects of nitric oxide-releasing compounds on HPV infections. The research team from the Department of Biochemistry and Molecular Genetics includes Drs. Louise Chow, a member of the Academy of Sciences, Tom Broker and Sanjib Banerjee.

Dr. Nathan Stasko, President and Chief Scientific Officer of Novan, commented on the work of Drs. Chow, Broker, and Banerjee by stating, "Our interactions with the University of Alabama-Birmingham team have been first rate in every way. Their recent work presented over the past few months found that nitric oxide inhibited HPV-18 viral replication and reduced the levels of cancer causing proteins in human tissue cultures. These findings provide us with the underlying scientific confirmation that we need to continue to move forward on this strategic initiative and as a result, over the course of 2018, we have been actively pursuing external grants as a means of utilizing non-dilutive capital to advance this area of scientific focus."

Given the global nature, extent and escalation of HPV, as well as the associated infection with a possible cascade to cancer, the interest in this initiative from a variety of sources is significant and emanates from specialized therapeutic and clinical participants, those within the public health sector, in addition to a broad array of non-U.S. countries where prophylactic vaccines are either not available, unaffordable or not permitted.



## **About Human Papillomavirus**

An oncovirus is virus that causes cancer. Approximately 20% of all human cancers, worldwide, are caused by oncoviruses. 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. The virus is typically transmitted via direct skin-to-skin contact through disruptions in the normal skin barrier. There are over 100 subtypes of the virus, characterized as low-risk or high-risk based on their cancer-causing potential. While low-risk variants of HPV typically are associated with two types of papilloma – common warts and genital warts – high-risk strains of the virus are associated with cervical intraepithelial neoplasia (CIN) and cervical cancers; high-grade anal intraepithelial neoplasia (HGAIN) and anal cancer; and, other cancers of the vagina, vulva, rectum and penis. High-risk strains 16 and 18 cause more than 90% of all oropharyngeal cancers and greater than 70% of cervical cancers.

## **About Novan**

Novan, Inc. is a clinical-stage biotechnology company aiming to leverage 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.

For more information, visit [www.Novan.com](http://www.Novan.com).

## **About Health Decisions**

Health Decisions is a full-service CRO specializing in women's health clinical development with a mission to improve healthcare outcomes for women worldwide. Health Decisions has partnered closely with biopharmaceutical companies over the past 29 years to successfully advance their products through the pipeline by leveraging the company's proven therapeutic and operational experience, high performing women's health site networks and deep relationships with Key Opinion Leaders. Recognizing that clinical research in women's health is both an art and a science, Health Decisions offers nimble, tailored solutions rooted in expertise and designed to drive meaningful outcomes for clients, investigators and patients alike.



For more information, visit [www.healthdec.com](http://www.healthdec.com)

### **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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