



## **Novan Receives Phase 2 NIH Federal Grant of Approximately \$1.0 Million**

February 20, 2020

- **Provides funds to evaluate the mechanistic antiviral activity of WH602**
- **Novan to progress IND-enabling toxicology and pharmacology studies for WH602**
- **Grant is additive to \$223,000 Phase 1 NIH grant received in August 2019**
- **Women's health initiative focused on potential HPV related onco-virus therapeutics**

MORRISVILLE, N.C., Feb. 20, 2020 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced that the Company has received approximately \$1.0 million funding from the National Institutes of Health (NIH) to cover the first year of a two-year Phase 2 federal grant. Novan is eligible to receive approximately \$500,000 of additional funding for the second year, subject to availability of NIH funds and satisfactory progress of the project. This grant is additive to the approximately \$223,000 Phase 1 NIH grant received in August 2019.

The grant will provide reimbursement for certain project expenses related to the advancement of WH602, a central focus of Novan's women's health business unit. WH602 is a nitric oxide-containing intravaginal gel product candidate for the treatment of cervical intraepithelial neoplasia (CIN). There are an estimated 250,000 to 1 million women newly diagnosed with CIN annually in the U.S., creating a significant patient care need.

The Company expects to use the grant to support the following objectives:

- Evaluate the intravaginal antiviral activity of WH602 in collaboration with Neil Christensen, Ph.D., Medical Director of the Jake Gittlen Laboratories for Cancer Research at Penn State College of Medicine. Dr. Christensen has developed a mouse model that enables evaluation of potential therapeutics in a preclinical setting that will inform clinical study design if the product candidate advances to human clinical trials. The specific focus of the work with Dr. Christensen is to ensure the nitric oxide delivery from the intravaginal gel replicates antiviral activity of nitric oxide previously demonstrated to be effective against papillomavirus in Novan's clinical and in vitro studies.
- Deepen the mechanistic understanding of the antiviral activity of Novan's proprietary nitric oxide delivery platform against human papillomavirus in collaboration with 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).
- Complete or advance certain investigational new drug (IND)-enabling toxicology and pharmacology studies and other preclinical activities required by the Food and Drug Administration (FDA) to advance product candidates to human clinical trials in antiviral indications.

The Company will continue to be supported through a collaboration with Health Decisions, Inc. ("Health Decisions"). Health Decisions is expected to provide consultation and insights for these initiatives and is expected to be involved in the first-in-human clinical studies, if the product candidates advance into the clinic.

The research will be supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R44AI143022.

### **About Cervical Intraepithelial Neoplasia (CIN)**

Cervical intraepithelial neoplasias (CIN), or precancerous lesions of the cervix caused by persistent high-risk human papillomavirus (HPV) infection, are categorized by HPV genotype and the depth of the infection within the epithelial tissue of the cervix. The CIN classifications include CIN 1 (low-grade neoplasia), CIN 2 (moderate) and CIN 3 (severe and carcinoma in situ). While there are an estimated 250,000 to 1 million women diagnosed with CIN annually in the U.S., there are no minimally invasive therapies with direct antiviral activity for the treatment of CIN and excisional procedures are often associated with pain, fertility issues and recurrence. Despite the availability of the prophylactic HPV vaccines, the incidence of HPV-induced cancer is steadily increasing, due to (a) the inability of the vaccine to cure preexisting infections; (b) a great majority of adolescent populations is not vaccinated; and (c) high rate of population growth. According to a survey on U.S. cervical cancer mortality rates, each year, nearly 12,000 women in the U.S. will be diagnosed with cervical cancer and more than 4,000 will die from the cancer.

### **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, the future prospects of additional grant funding and third-party cooperation 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 our ongoing or future product development activities and preclinical studies, which may not prove successful in demonstrating proof-of concept, or may show adverse toxicological findings, and even if successful may not necessarily predict that subsequent clinical trials will show the requisite safety and efficacy of our product candidates; 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 reliance on third parties; our ability to meet any of the requirements under the grants described above and the uncertainty involved with government grants, including the successful negotiation and availability of funding for the grants described above or any other grants to support funding for a women's health product candidate; our ability to obtain additional funding or enter into strategic relationships or other business development necessary for the further development 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, 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.

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