Novan Awarded Approximately $1.1 Million Grant by Department of Defense

September 20, 2019

- Funds to progress women’s health product candidate, WH504
- Additive to recently announced NIH grant for WH602
- Women’s health initiative to focus on potential HPV related onco-virus therapeutics

MORRISVILLE, N.C., Sept. 20, 2019 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq: NOVN) today announced that the Company has received a grant from the U.S. Department of Defense's (DoD) Congressionally Directed Medical Research Programs (CDMRP) of approximately $1.1 million as part of its Peer Reviewed Cancer Research Program.

The grant will support the development of a product candidate (WH504) for the treatment of cervical intraepithelial neoplasia (CIN), with well-characterized physical chemical properties suitable for intravaginal administration. In addition, the grant will support the evaluation of the effect of varying concentrations and treatment durations of berdazimer sodium (NVN1000) against HPV-18 in human raft cell culture \textit{in vitro} studies. There are, currently, no FDA-approved therapeutics indicated to treat CIN. The current standard of care is “watch and wait” or in-office procedures depending on severity. This targeted research aims to create a disease-altering treatment that could be used upon detection and the early signs of high-risk HPV infection to intervene before progression to cervical cancer.

This grant is in addition to the previously announced National Institute of Health (NIH) Phase 1 grant of approximately $223,000 for the development of a separate product candidate (WH602). Both product candidates will represent core initiatives within the previously announced Novan women’s health business unit.

The views expressed in this press release are those of the Company and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.

About Cervical Intraepithelial Neoplasia (CIN)

Cervical intraepithelial neoplasias (CIN), or precancerous lesions of the cervix caused by persistent high-risk human papilloma virus (HPV) infection, are categorized by HPV genotype and the depth of the infection within the epithelial tissue of the cervix, with grades 1 and 2 considered precancerous and grade 3, 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 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; 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 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.

CONTACT:

(Investors & Media)
Cole Ikkala