



Novan Advances Women's Health Business Unit with Non-Dilutive Funding

August 14, 2019

- **Company has received NIH federal grant of approximately \$223,000**
- **Anticipates additional federal grant of approximately \$1.0 million**
- **Women's health initiative to focus on potential HPV related onco-virus therapeutics**
- **Mechanistic rationale supported by recent University of Alabama at Birmingham publication**

MORRISVILLE, N.C., Aug. 14, 2019 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced that the Company has received a federal grant from the National Institutes of Health (NIH). In addition, the Company anticipates receiving an additional federal grant in the very near term. These grants will provide funding on a non-dilutive basis for specific initiatives within product advancement 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 two respective grants as follows:

- The NIH grant of approximately \$223,000 is a Phase 1 federal grant. The funds are to be used to advance formulation development of an intravaginal gel (WH504). The specific focus is to ensure the nitric oxide delivery from the gel replicates doses of nitric oxide previously demonstrated to be effective against human papilloma virus in Novan's clinical and *in vitro* studies. Prospectively, Novan expects to be eligible to receive additional grant dollars for Phase 2 and 3 extensions. The quantum of these awards could total approximately \$1.5 million. If awarded, Phase 2 and 3 would focus on the completion of investigational new drug (IND)-enabling toxicology and pharmacology studies and other preclinical activity.
- In addition to the NIH grant, the Company is in the final stages of securing a second federal grant. If awarded, this grant would total approximately \$1.0 million and these funds would be earmarked toward the development of an intravaginal suppository (WH602) that demonstrates potent anti-viral activity.

MedPharm Ltd ("MedPharm"), through the companies recently announced expanded strategic relationship, would take the lead on the intravaginal suppository formulation and associated drug delivery components. In so doing, MedPharm will work closely with Novan's product development team.

Both product candidates will represent the core to Novan's women's health business unit. This unit will continue to be supported through a collaboration with Health Decisions, Inc. ("Health Decisions"). Health Decisions will provide consultation and insights for these initiatives and would be involved in the first-in-human clinical studies, if the product candidates advance into the clinic.

About Cervical Intraepithelial Neoplasia (CIN)

Cervical intraepithelial neoplasias (CIN), or precancerous lesions of the cervix caused by persistent high risk-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, the anticipation of additional grant funding 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 secure the grants described above and any other grants, including

the amount and timing of any 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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