Novan Announces First Patient Dosed in Phase 2 Molluscum Contagiosum Trial with SB206

MORRISVILLE, N.C., Jan. 25, 2018 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced that the first patient has been dosed in the Company's Phase 2 clinical trial to evaluate topical nitric oxide product candidate SB206 for the treatment of molluscum contagiosum, a contagious skin infection caused by the *molluscipoxvirus*. There is currently no FDA-approved treatment for the molluscum indication.

"Broadening Novan's clinical development pipeline to include the viral area within dermatology has been a significant focus of the team," stated Paula Brown Stafford, Novan's Chief Development Officer. "Our focus on execution and the application of nitric oxide across indications in the viral space is a high priority. The first patient dosed in the molluscum Phase 2 trial is an important step forward in that regard."

The Phase 2 multi-center, randomized, double-blind, vehicle-controlled, ascending dose clinical trial is designed to evaluate the efficacy, safety and tolerability of SB206 in 192, with an option to increase to 256, children and adolescents, 2 to 17 years of age, with molluscum. Patients will be treated with one of three concentrations of SB206 or vehicle for up to 12 weeks. The primary endpoint is the proportion of patients achieving complete clearance of all molluscum lesions at Week 12. Top line results are targeted for the fourth quarter of 2018.

About Molluscum

Molluscum contagiosum is a common skin disorder caused by the *molluscipoxvirus* and affects mainly healthy children[1]. Molluscum affects approximately six million people[2] in the U.S. annually and has the greatest incidence in individuals aged 1 to 14 years[3], with a 5% to 11% prevalence in children[4]. There is no FDA-approved treatment for molluscum. Commonly-used ablative treatment is painful and can interfere in physician-patient relationships. More than half of patients diagnosed with the infection are untreated, which increases further dissemination of the disease and leads to public health concern.

About Novan

Novan, Inc. is a clinical-stage biotechnology company focused on leveraging 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.

References

[1]Dohil M,; Lin P, Lee J, Lucky AW, Paller AS, Eichenfield LF. The epidemiology of molluscum contagiosum in children. J Am Acad Dermatol 2006; 54: 47-54.
[2]QuintilesIMS. Market Opportunity Assessment EGW, Common Warts and Molluscum, March 2017.
[3]Schofield JK, Fleming D, Grindlay D, Williams H. Skin conditions are the commonest new reason people present to general practitioners in England and Wales. Br J Dermatol 2011; 165: 1044–50.
[4]Olsen JR, Gallacher J, Finlay AY, Piguet V, Francis NA. Time to resolution and effect on quality of life of molluscum contagiosum in children in the UK: a prospective community cohort study.Lancet Infect Dis 2015; 15: 190–95.

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 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 or trials; the lengthy and unpredictable nature of the U.S. Food and Drug Administration's drug approval process, and other risks and uncertainties described in our annual report filed with the SEC on Form 10-K for the twelve months ended Dec. 31, 2016, 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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