Novan's Phase 2 Molluscum Contagiosum Trial Fully Enrolled: Top Line Results Targeted in November

October 1, 2018

- **Trial enrollment completed meaningfully ahead of schedule**
- **Top line results targeted to be communicated no later than mid-November**
- **Favorable and consistent safety profile of SB206 enabled escalation to highest, 12% dose**

MORRISVILLE, N.C., Oct. 01, 2018 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced that enrollment in the Company's Phase 2 clinical trial to evaluate topical nitric oxide product candidate SB206 for the treatment of molluscum contagiosum has fully enrolled all cohorts. Cohorts 3 and 4, SB206 12% twice-daily (BID) and 12% once-daily (QD) respectively, were recruited meaningfully ahead of schedule with enrollment completed in August.

The trial was initiated in January of 2018; the Company previously communicated that top line results were targeted to be available in the fourth quarter of 2018. Based on the expedient enrollment, top line results for Cohorts 1 to 3 with SB206 4%, 8% and 12% twice-daily are now targeted to be communicated no later than mid-November, with Cohort 4, SB206 12% once-daily targeted to be reported in December.

"In addition to achieving the positive enrollment milestone, the favorable safety profile of our nitric oxide technology was reaffirmed with no significant safety concerns reported in the trial to date, allowing for escalation to the highest, 12% dose of SB206 for treatment in the trial," stated Paula Brown Stafford, Novan's Chief Development Officer. "In this largely pediatric population, a safe and efficacious product would greatly benefit the large majority of patients left untreated due to often painful, commonly-used ablative treatments."

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 up to 256 patients with molluscum contagiosum. The trial is being conducted in primarily pediatric patients and adults, 2 years of age and older. The first cohort of patients were randomized on a 3:1 basis to an initial dose of SB206 4% twice-daily, or placebo, for 12 weeks of treatment. If the dose in each cohort was determined to be safe and well tolerated by the Data Safety Monitoring Board, the dose was escalated up to 8% twice-daily in the second cohort, and then 12% twice-daily and once-daily for the ensuing cohorts of patients. The primary endpoint is the proportion of patients achieving complete clearance of all molluscum lesions at Week 12.

Pending results of the Phase 2 trial, Novan will request an end-of-Phase 2 meeting with the FDA as early as possible during the first quarter of 2019. This meeting would enable Novan to discuss and agree on a Phase 3 development plan for molluscum.

Currently, there is no FDA-approved therapy for the molluscum indication and patients are often treated with painful, ablative procedures. If the clinical and regulatory progression leads to an approval, Novan's SB206 would be a new chemical entity, or NCE, for the treatment and potential eradication of molluscum, that could offer a significant improvement in tolerability over current standard of care.

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[2], which increases further dissemination of the disease and leads to public health concern due to the highly contagious nature of the disease.

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, 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, other 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; 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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