Novan Phase 2 Molluscum Contagiosum Trial Achieves Statistical Significance in Preliminary Top Line Results

- **Higher rates of complete clearance of all molluscum lesions at Week 12 for the two highest doses, SB206 8% and 12% twice-daily, more than double the rate observed in the vehicle group**
- **Clear treatment effect observed as early as Week 4 in the percent reduction of molluscum lesions**
- **Attractive safety and tolerability profile, a critical and highly appealing feature for a predominantly childhood disease**
- **SB206 as a topical, at-home, caregiver-applied therapy with a rapid treatment benefit, if approved, would satisfy an important patient-care need for the treatment of molluscum**
- **End-of-Phase 2 meeting to be requested in 4Q 2018 and Phase 3 program expected to begin in 1H 2019**

MORRISVILLE, N.C., Nov. 14, 2018 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced positive preliminary top line results for three full cohorts of four from the Company's Phase 2 clinical trial to evaluate topical nitric oxide product candidate SB206 for the treatment of molluscum contagiosum. SB206 gel demonstrated a clear treatment effect on the complete clearance of all molluscum lesions at Week 12, with signs of efficacy evident as early as Week 4 for the two highest doses, 8% and 12% twice-daily. The safety and tolerability profiles were favorable overall with no serious adverse events reported. Results for Cohort 4, SB206 12% once-daily, are targeted to be announced in December.

Novan conducted a 12-week, randomized, double-blind, vehicle-controlled, ascending dose Phase 2 trial to evaluate four treatment groups of 4%, 8% and 12% twice-daily and 12% once-daily, and vehicle as a treatment for molluscum. Key characteristics of this trial include:

- Number of patients: 256 total; 192 in Cohorts 1 through 3; 64 in Cohort 4.
- Inclusion criteria: Ages 2 years and older, with 3 to 70 molluscum lesions.
- Primary endpoint: Complete clearance of all molluscum lesions at Week 12.

- Primary statistical analysis population: Prespecified as Modified Intent-to-Treat (mITT), consisting of all patients who were randomized and completed the study treatment. A sensitivity analysis of the primary endpoint was repeated using the ITT population.

The totality of the primary and secondary endpoint analyses received to date indicates a clear dose response, in both the mITT and ITT populations. The preliminary top line results include:

- The 4% twice-daily dose showed a modest biological signal across all endpoints.
- In the primary endpoint, 8% twice-daily was the most effective dose with 41% complete clearance compared to 17% for vehicle (mITT, $p<0.05$).
- There was no further treatment benefit from the additional nitric oxide delivered by 12% twice-daily with complete clearance rates of 35%.
- At Week 12, 0% of patients reported severe burning, stinging and itching and less than 3% of patients reported moderate.

Full trial results including data from the fourth cohort, 12% once-daily, are targeted to be announced in December. The purpose of this cohort is to evaluate the potential for a once-daily treatment option that would be attractive from a commercial perspective.

“The trial was designed to evaluate the efficacy, safety and tolerability of SB206 across a range of doses and identify a dose to carry forward in clinical development,” stated Paula Brown Stafford, Novan’s Chief Development Officer. “While the trial was not powered for formal statistical comparisons, we are encouraged by the higher rates of complete clearance of all molluscum lesions at Week 12, with clearance as early as Week 4, in the 8% and 12% twice-daily treatment groups. In addition, our secondary endpoints received to date are supportive of and consistent in direction with the primary endpoint of complete clearance. We look forward to receiving the results of Cohort 4 and discussing these data with the FDA as soon as possible.”

Molluscum contagiosum is a common, contagious skin infection affecting 6 million people in the U.S. annually, with the greatest incidence in children aged one to 14 years. Infected children typically present with 10 to 30 painless, yet unsightly lesions, and, in severe cases, they can have up to 100 lesions. Due to the largely pediatric nature of the disease, in most cases, parents are the caregivers for these children and tend to seek treatment. There are currently no FDA approved therapies for the treatment of molluscum.

"It is important to remember that this disease is largely present in children and the average age in our clinical trial was seven years," commented Tomoko Maeda-Chubachi, M.D., Novan's Vice President of Medical Dermatology. "Upon seeking treatment, caregivers are faced with potentially painful in-office, physician-administered scraping, freezing, burning and blistering treatments or off-label prescriptions with no molluscum indication, no proven clinical efficacy and tolerability issues. As a result of the inadequate treatment paradigm, over 50% of patients diagnosed with molluscum are untreated. There is a clear unmet need for an at-home, caregiver-applied therapy that would not require multiple physician visits and is safe and well tolerated with a potential early onset of efficacy."

Based on the data generated in this Phase 2 trial, the Science and Technology Committee of Novan's Board of Directors has recommended that the Company proceed expeditiously, and by the end of the fourth quarter, with a request to the FDA for an end-of-Phase 2 meeting. This meeting would enable Novan and the FDA to agree on a Phase 3 development plan for molluscum. Following a successful end-of-Phase 2 meeting with the FDA, the Company plans to initiate a Phase 3 program of SB206 for molluscum in the first half of 2019 with top line results possible by the end of 2019 or early in 2020.

Novan will host a corporate update conference call and webcast today at 8:30 am Eastern Time. The phone number to join the conference call is +1 (844) 707-0661 (toll-free in the United States and Canada) or +1 (703) 318-2240 (international). The conference ID for the live call is 958218. A live webcast will be accessible from the Events page of the Company's website at http://Events.Novan.com.

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.

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 the development of SB206 for the treatment of molluscum, 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, 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; risks that data from the fourth cohort impact our assessment of SB206 for the treatment of molluscum; 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 Dec. 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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