



## **Novan Announces Full Top Line Results from Phase 2 Molluscum Contagiosum Clinical Trial and Decision to Move Forward with SB206 12% Once-Daily**

- **SB206 12% once-daily achieved the highest rate of complete clearance out of all active treatment groups at Week 12 ( $p < 0.05$ )**
- **Statistically significant reductions in molluscum lesions as early as Week 2 with 12% once-daily**
- **No quantifiable levels of systemic exposure detected for SB206 12% twice-daily or once-daily following 12 weeks of treatment**
- **A once-daily, at-home, caregiver-applied topical therapy with a clear treatment benefit, if approved, would satisfy an important patient-care need for the treatment of molluscum**
- **During the end-of-Phase 2 meeting with the FDA, Novan will propose 12% once-daily as the active treatment group for the Phase 3 program**

MORRISVILLE, N.C., Dec. 10, 2018 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced full top line results from the Company's Phase 2 clinical trial to evaluate topical nitric oxide product candidate SB206 for the treatment of molluscum contagiosum, including results from the fourth cohort, SB206 12% once-daily. Results demonstrated a clear treatment effect on the complete clearance of all molluscum lesions at Week 12 for 12% once-daily SB206 gel, with signs of efficacy evident as early as Week 2. The safety and tolerability profiles for all treatment groups were favorable, with no serious adverse events reported. Preliminary top line results from the first three cohorts, 4%, 8% and 12% twice-daily, were announced in November.

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

- Number of patients: 256 total; 190 with SB206 and 66 with vehicle.
- 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: 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 Intent-to-Treat (ITT) population.

Results from 12% once-daily are consistent with and support previously announced results from 4%, 8% and 12% twice-daily:

- For the primary endpoint, 12% once-daily was the most effective dose with 42% (mITT,  $p < 0.05$ ) and 38% (ITT,  $p < 0.05$ ) complete clearance rates compared to 20% and 18% for vehicle, respectively.
- For the secondary endpoint of mean percent change from baseline molluscum lesion count at each visit, patients treated with 12% once-daily experienced 29% ( $p < 0.05$ ), 37% ( $p < 0.01$ ), 56% ( $p < 0.001$ ) and 55% reductions in molluscum lesions at Week 2, 4, 8 and 12, respectively (mITT).
- The 12% once-daily treatment group had the lowest dropout rate out of all treatment groups, 9%, with 0 patients discontinuing treatment due to adverse event.

“The consistency in the trial results with 8% and 12% twice-daily and now 12% once-daily is very encouraging,” stated Paula Brown Stafford, Novan’s Chief Development Officer. “The 12% once-daily dose has several key characteristics that would make it the optimal choice going forward from both a clinical and commercial perspective, including high complete clearance rates and a treatment benefit as soon as Week 2. SB206, as a once-daily, at-home, caregiver-applied, safe and well tolerated topical therapy, if approved, would benefit a significant number of patients currently facing an inadequate treatment paradigm.”

With the full results from this Phase 2 trial now available, the Company intends to request, by the end of December, an end-of-Phase 2 meeting with the FDA. This meeting would enable Novan and the FDA to agree on a Phase 3 development plan for molluscum with SB206 12% once-daily as the active treatment arm. 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.



## **About Molluscum Contagiosum**

Molluscum contagiosum is a common, contagious skin infection caused by the *molluscipoxvirus*, affecting approximately six 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 around 100 lesions. Due to the largely pediatric nature of the disease, parents are the caregivers for these children, in most cases, and tend to seek treatment. There are no FDA approved therapies for molluscum, and, upon seeking treatment, caregivers are faced with potentially painful in-office, dermatologist-administered physical procedures or cantharidin, or recommended off-label prescriptions and over-the-counter products. More than half of the patients diagnosed with molluscum are untreated and over 30% of those treated receive an off-label prescription with no molluscum indication or proven clinical efficacy. The average time to resolution is 13 months, however, some children experience lesions that may not resolve in 24 months. Further dissemination of this highly-contagious disease is common, and transmission to other children living in the household is reported to be 41%. There is a significant unmet need in the molluscum treatment landscape.

## **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 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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