



Novan Reports Top-Line Efficacy Results from Phase 3 Trials of SB206 for Molluscum Contagiosum

January 2, 2020

- **Company to hold conference call Friday, January 3, 2020 at 8:30 am Eastern Time**
- **Focus of call: top-line efficacy data and sensitivity analyses**

MORRISVILLE, N.C., Jan. 02, 2020 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced top-line efficacy results from its Phase 3 B-SIMPLE program with SB206 for the treatment of molluscum contagiosum ("molluscum"). Statistical significance was not achieved for the primary endpoint in either B-SIMPLE1 or B-SIMPLE2, however multiple sensitivity analyses are supportive and consistent across both studies and support a potential path forward for the asset. The two trials are ongoing, awaiting 24-week safety data, thus the top-line results are for efficacy data only.

Summary of Top-Line Efficacy Data and SB206 Program:

- SB206 did not achieve statistically significant results for the primary endpoint.
- B-SIMPLE2 was statistically significant for multiple pre-specified sensitivity analyses.
- Similar analyses with B-SIMPLE1 demonstrated results are reasonably consistent and supportive of B-SIMPLE2.
- Company intends to utilize B-SIMPLE2 as one of the confirmatory trials for New Drug Application ("NDA") submission, subject to discussions with the U.S. Food and Drug Administration ("FDA").
- Company intends to support and confirm B-SIMPLE2 with an additional confirmatory Phase 3 trial targeted to commence in April 2020, subject to additional funding and FDA feedback.
- Company's timeline for NDA submission remains consistent and targets potential NDA submission in the second quarter of 2021, depending on outcome of discussions with FDA and confirmatory results in the additional trial.
- Full efficacy and safety data from both trials, including the prospectively planned safety evaluation ongoing through Week 24, targeted to be available by March 2020.

The B-SIMPLE program consists of two multi-center, randomized, double-blind, vehicle-controlled pivotal trials of topical nitric oxide-releasing product candidate SB206 for the treatment of molluscum in 707 patients aged 6 months and older, with a 2:1 (active:vehicle) randomization.

Primary endpoint – proportion of patients with complete clearance of all treatable molluscum lesions at Week 12 (Intent-to-Treat or "ITT" population, where the analysis assumes that patients with Week 12 missing data are computed as treatment failures):

Pivotal Trial	SB206	Vehicle	p-Value
B-SIMPLE1	25.8% (n=236)	21.6% (n=116)	0.375
B-SIMPLE2	30.0% (n=237)	20.3% (n=118)	0.062

SB206 was near statistically significant for the primary endpoint in B-SIMPLE2, and was statistically significant in the secondary endpoint and several pre-specified sensitivity analysis, which were included within the statistical analysis plan:

Endpoint	Population	SB206	Vehicle	p-Value
Primary endpoint – complete clearance at Week 12	Per-Protocol ¹	36.1% (n=194)	23.3% (n=103)	0.028
	Intent-to-Treat ² with Last Observation Carried Forward ³ missing data method	30.8% (n=237)	20.3% (n=118)	0.044
Secondary endpoint – complete clearance at Week 8	Intent-to-Treat ²	13.9% (n=237)	5.9% (n=118)	0.028

1. Per-protocol ("PP") population: all patients in the ITT population who completed the 12-week treatment period and had no significant protocol deviations that impacted the analyses of efficacy endpoints.

2. Intent-to-Treat Population ("ITT"): consists of all subjects who are randomized.

3. Last Observation Carried Forward ("LOCF") method for handling missing data: all patients randomized (ITT population) and where a patient missed their Week 12 visit but had reported complete clearance at their last collected lesion assessment, their last visit lesion count is included in the analysis as complete clearance at Week 12.

Following an assessment of the primary analysis and pre-specified sensitivity analyses, Novan is able to demonstrate through multiple statistical tests

and trends that B-SIMPLE1, while not statistically significant, is consistent with and supportive of the B-SIMPLE2 trial and results.

Management, along with the Board of Directors, continues to explore both financial as well as strategic options in order to continue to progress SB206 for the molluscum indication. As disclosed in the latest 10-Q filing, as of September 30, 2019, the Company had \$22.5 million in total cash, cash equivalents and restricted cash, which is targeted to fund operations into the first quarter of 2020, excluding the effect of any potential sales of stock under the Company's stock purchase agreement with Aspire Capital Fund, LLC ("Aspire"), if available. The Company is working to further address current operations with the aim of achieving a reduction in near term cash expenditures. Substantial additional funding will be required in order to continue to sustain business operations.

The Company, along with the Board of Directors, will provide a further business update in a timely manner and when appropriate.

Select members of the management team will attend the 7th Annual Dermatology Summit, taking place on January 12, 2020, as well as participate in additional meetings around the 38th Annual J.P. Morgan Healthcare Conference, taking place January 13-16, 2020, both in San Francisco, California.

Conference Call & Webcast (with Slides)

Novan will host a webcast tomorrow, Friday, January 3, 2020 at 8:30 am Eastern Time to present top-line efficacy data and sensitivity analyses. There will not be any Q&A and the Company intends to provide a more extensive business update in the near term, upon receipt of the totality of efficacy and safety data from the B-SIMPLE program.

U.S. toll free: +1 (844) 707-0661

International: +1 (703) 318-2240

Conference ID: 8358294

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 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 and our intention to advance development of certain product candidates, including the timing of full results of our Phase 3 program to evaluate SB206 for the treatment of molluscum, the outcome of discussions with the FDA regarding our B-SIMPLE program, the timing for a third Phase 3 trial, the timing of potential regulatory submissions, and our needs for funding. 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, the risk that full results of the Phase 3 program will not be received timely or will not be consistent with our expectations; the risk that the FDA will not agree with our position that the B-SIMPLE2 results can be used to support an NDA alongside results of a third confirmatory trial; the risk that results from a third Phase 3 trial will not be received timely or will not achieve significance sufficient to support an NDA; our ability to obtain funding or enter into strategic relationships on a timely basis, or at all, to enable a third Phase 3 trial and to continue operations; our ability to reduce cash expenditures; our ability to utilize the stock purchase agreement with Aspire; 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; risks related to the manufacture of clinical trial materials; 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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Source: Novan, Inc.