Novan Announces Plan to Complete Development of SB204 Acne Candidate via Third Party Funding and Execution

Proposed Structure Creates Optionality for Novan

MORRISVILLE, N.C., Nov. 07, 2017 (GLOBE NEWSWIRE) -- Novan, Inc. (“the Company” or “Novan”) (NASDAQ:NOVN) today announced that it has agreed in principle to a business structure that would enable further development and advancement of SB204 for the treatment of acne vulgaris via third party financing and third party execution of one additional Phase 3 pivotal trial that is required before the filing of a New Drug Application (NDA).

The proposed Phase 3 trial would be executed by the third party’s dermatology drug development team which plans to utilize a clinical research organization with extensive dermatology clinical trial experience.

Under the proposed transaction, a new entity established by the third party would provide both the necessary capital to fund and the clinical expertise to execute an additional Phase 3 pivotal trial for SB204. The financial return to the new entity would be a pre-determined multiple of the costs incurred to execute the trial, assuming successful completion of the trial and Novan’s election to retain all rights to the asset. The new entity would also be entitled to a milestone payment upon NDA approval, as well as potential future sales-based milestone payments tied to the commercial success of SB204 and potential future payments related to certain agreed variations of SB204 that may be subsequently developed. If Novan does not make the election to retain the asset (SB204), the new entity would be granted an exclusive license to SB204 in all geographies apart from Japan, with proceeds from any monetization of the licensed technology being split between the new entity and Novan after returning a multiple of the execution costs to the new entity. In connection with the proposed transaction, the new entity would be granted an option to acquire shares of Novan’s common stock (currently anticipated to be approximately 500,000 shares) at an exercise price determined by the trailing 30 day average just prior to the execution of definitive agreements.
Having achieved an agreement in principle around the business terms of the transaction, the parties have entered into an exclusive negotiation period and anticipate finalizing binding definitive agreements for the proposed transaction and clinical trial execution following the parties’ joint discussion of the Phase 3 pivotal trial protocol with the FDA in the first quarter of 2018.

“The advancement of SB204 for the treatment of acne vulgaris is of critical importance to Novan and its shareholders,” said G. Kelly Martin, Novan’s Chief Executive Officer. “Reaching an agreement in principle to progress SB204 is a ‘win/win’ for Novan and our third party partner. The deal structure enables Novan to be the beneficiary of the potential successful completion of SB204’s development without any direct (to Novan) financial or execution risk relating to the trial.”

Mr. Martin continued, “Additionally, we believe this creative structure will enable Novan to retain, with the completion of a successful trial and accepted NDA, a significant share of the net present value of SB204, when the value is calculated over the life of the molecule in the marketplace.

“Lastly, the combination of the optionality on SB204 with the expansion of the nitric oxide technology into the areas of inflammatory skin diseases and virology allows Novan and its shareholders to have exposure to multiple therapeutic opportunities while distributing inherent drug development risk across a broader platform.”

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 and the negotiation, execution and expected terms of definitive agreements related to continued development of SB204 for acne vulgaris. 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 the parties may not reach agreement and enter into binding agreements as contemplated by the non-binding term sheet, uncertainties and risks in the clinical development process and related to the proposed transaction, including, among others, that the parties may not be able to obtain commitments for adequate funding for the collaboration, the accounting treatment of the potential transaction is not yet determined, the contemplated Phase 3 trial may fail, and other risks and uncertainties described in our annual report filed with the Securities and Exchange Commission, or SEC, on Form 10-K for the twelve months ended Dec. 31, 2016, and in any 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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