Novan Adds Clinical Exposure and Safety Data to SB204 Acne Program
Results Presented at the 23rd World Congress of Dermatology;
Company Anticipates Phase 2b Clinical Trial Results Third Quarter of 2015

DURHAM, N.C. (June 10, 2015) - Novan Therapeutics, a clinical-stage biotechnology company focused on advancing innovation in dermatology via nitric oxide therapies, today announced that following topical application of SB204 there was no measurable systemic exposure in patients with acne vulgaris. SB204 was generally well-tolerated and not associated with any significant safety issues under maximal use conditions in a Phase 1 clinical study in adults with moderate-to-severe acne. The results will be reported this afternoon in a featured poster presentation, titled “Pharmacokinetics of SB204 in Subjects with Acne Vulgaris,” at the 23rd World Congress of Dermatology (WCD), which is currently taking place in Vancouver, Canada. This global event is held once every five years and is organized by the International League of Dermatological Societies (ILDS).

The Phase 1 study assessed the pharmacokinetics and safety of SB204 Gel applied topically to the chest, back, and face of adults with moderate to severe acne vulgaris. Subjects meeting entry criteria were administered SB204 8% or Vehicle Gel twice daily during the 5-day treatment period. Serial blood samples were collected on Days 1 and 5 and analyzed for systemic exposure. After a washout period, subjects were administered the alternate treatment over five days, with the same blood sampling schedule. SB204 was generally well-tolerated and was not associated with significant safety or tolerability issues. There was no evidence of systemic exposure to the drug under maximal topical use conditions. Markers for nitric oxide exposure in subjects treated either with SB204 or Vehicle Gel were bioequivalent.

“We are honored that our work with SB204 will be highlighted in a featured poster during the World Congress of Dermatology,” commented Dr. M. Joyce Rico, Novan’s Chief Medical Officer. “SB204 has resulted in a series of encouraging clinical findings to date, including a significant reduction in non-inflammatory and inflammatory lesions in Phase 2 acne testing. Our drug contains one of the few new chemical entities specifically developed for acne in decades, with activity to stop inflammation, and kill bacteria associated with acne using a non-antibiotic approach.”

Novan anticipates top-line results of the fully enrolled US Phase 2b trial with SB204 in 200 subjects with acne by the third quarter of this year. The Phase 3 pivotal clinical trials with SB204 are expected to begin in the first quarter of 2016.

Abstract ID 3002037: Pharmacokinetics of SB204 in Subjects with Acne Vulgaris, J. Rico, E. de Leon, C. Geer, R. Guttendorf, and N. Stasko

Presenter: M. Joyce Rico, MD, Chief Medical Officer, Novan Therapeutics

Session Information: Wednesday, June 10, 2015: 1:00 pm – 6:00 pm PDT: Session (1) Acne, Rosacea and Related Disorders (2) Connective Tissue Diseases (3) Hair, Nails, and Sweat Disorders (4) Inflammatory Disorders

About Novan, Inc.
Novan is a privately-held, clinical stage biotechnology company advancing therapies for skin diseases using drugable nitric oxide. Nitric oxide, one of the most studied molecules in human physiology, has been shown to exhibit broad anti-microbial activity and to promote vasodilation, regulate inflammation, stimulate tissue repair, and eradicate cancer cells. Novan’s patented Nitricil™ technology overcomes the previous delivery issues with nitric oxide by stably storing the gaseous species as a solid that can
be transformed into targeted therapeutics. The design of Novan’s products is driven by the patient experience, as the Company aims to create medicines that are safe, easily accessible, and can improve outcomes by using nitric oxide to target multiple aspects of disease pathology. The Company’s advanced-stage product candidates are SB204 for the treatment of acne vulgaris and SB206 for the treatment of genital warts, both currently in Phase 2 clinical trials.

This press release contains forward-looking statements involving risks and uncertainties, both known and unknown, that may cause actual results to differ materially from those indicated. Actual results may differ materially due to a number of factors, including, but not limited to, risks associated with pharmaceutical development, clinical trials that may not proceed as intended or produce the results expected, clinical trials that cost more, are less effective and take longer to complete than expected, raw materials and drug supply, changes in regulatory requirements, competition, and financing.

To learn more about Novan Therapeutics, please visit www.novantherapeutics.com.

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