

Novan Announces First Patient Dosed in Phase 3 Program for SB204

Top-Line Results Expected in First Half of 2017

DURHAM, N.C. – Feb. 23, 2016 – Novan, Inc. today announced that the first patient has been dosed in its Phase 3 program to evaluate the efficacy and safety of its topical nitric oxide product candidate SB204 Gel in the treatment of acne vulgaris (“acne”). The Company is running two identically designed Phase 3 pivotal trials in parallel and expects to report top-line results in the first half of 2017.

“Dosing the first patient in our Phase 3 program for SB204 represents an important milestone for Novan in the development of our lead product candidate,” said Nathan Stasko, PhD, President and Chief Executive Officer of Novan. “It also represents a historic milestone for topical nitric oxide and for dermatology. Never before has a nitric oxide-releasing macromolecule made it this far in development, and, if approved, SB204 will be the first new chemical entity specifically developed for the treatment of acne in more than 20 years. We believe that this truly first-in-class investigational monotherapy has the potential to redefine the standard of care for acne, and we are eager for the results of these trials.”

Results from Novan’s maximal-use pharmacokinetic study showing no detectable systemic exposure to SB204 as well as the Company’s Phase 2b study evaluating the efficacy and safety of SB204 for the treatment of acne were announced in June and September 2015, respectively.

About the Phase 3 Program

Novan’s Phase 3 program includes three studies.

NI-AC301, “A Phase 3 Multi-Center, Randomized, Double-Blinded, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy, Tolerability and Safety of SB204 and Vehicle Gel Once Daily in the Treatment of Acne Vulgaris” is a 12-week, double-blind, placebo-controlled, parallel group study in subjects with moderate to severe acne across 55 sites in the United States. Approximately 1,300 subjects, ages 9 and older, who satisfy the entry criteria will be randomized in a 1:1 ratio to two treatment arms, SB204 4% topically once daily or Vehicle Gel topically once daily. Primary endpoints include absolute changes in inflammatory and non-inflammatory lesion counts and proportion of subjects with Investigator Global Assessment (IGA) success at week 12. Secondary endpoints include percent changes in inflammatory and non-inflammatory lesion counts, time to reduction in inflammatory lesion count and time to improvement in IGA.

NI-AC302, “A Phase 3 Multi-Center, Randomized, Double-Blinded, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy, Tolerability and Safety of Once Daily SB204 and Vehicle Gel in the Treatment of Acne Vulgaris” is an identically designed parallel study to NI-AC301.

NI-AC303, “A Phase 3 Multi-Center, Open-Label Study Evaluating the Long-Term Safety of SB204 Once Daily in the Treatment of Acne Vulgaris” is a long-term safety study in eligible patients who have completed 12 weeks of treatment in the NI-AC301 or NI-AC302 trials.

About Acne

According to the American Academy of Dermatology, acne is a chronic inflammatory skin condition, characterized by comedones (blackheads and whiteheads), pimples and deeper lumps (cysts or nodules)

that occur on the face, neck, chest, back, shoulders and upper arms. It is the most common skin condition in the U.S., affecting approximately 40 million to 50 million Americans annually. Approximately 85% of people between the ages of 12 and 24 experience at least minor acne.¹

About Novan

Novan, Inc. is a late-stage pharmaceutical company focused on redefining the standard of care in dermatology through the development and commercialization of innovative therapies using the Company's nitric oxide platform. Nitric oxide plays a vital role in the natural immune system response against microbial pathogens and is a critical regulator of inflammation. Our ability to harness nitric oxide and its multiple mechanisms of action has enabled us to create a pipeline of differentiated, first-in-class product candidates. We are rapidly advancing a pipeline in five dermatological indications with significant unmet medical need. We believe that our platform allows us the potential to significantly improve patient outcomes and positions us to be a commercially successful leader in the dermatology market.

For more information, visit the Company's website at www.NovanTherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements including, but not limited to, statements related to pharmaceutical development of nitric oxide-based product candidates and future prospects. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from our expectations. 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, except as expressly required by law.

References

¹ American Academy of Dermatology. "Acne." <https://www.aad.org/media/stats/conditions> (Feb. 19, 2016).

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