Novan Announces Both Phase 3 Pivotal Trials for SB204 Fully Enrolled

More than 2,600 Subjects Enrolled in US Ahead of Schedule

Top-Line Results Expected in First Quarter of 2017

DURHAM, N.C. – Sept. 28, 2016 – Novan, Inc. (the "Company" or "Novan") (NASDAQ:NOVN) today announced that the last patient has been randomized in the Company's two, identically designed Phase 3 pivotal clinical trials to evaluate the efficacy and safety of topical nitric oxide-releasing product candidate SB204 Gel in the treatment of acne vulgaris, or acne. Novan announced in February that the first patient had been dosed in these trials. Per the study protocol, the last patient randomized will be treated for 12 weeks. The Company is running the two Phase 3 pivotal trials in parallel and expects to report top-line results in the first quarter of 2017.

"We are extremely pleased with the rapid enrollment of these Phase 3 trials for our lead product candidate," said Nathan Stasko, PhD, President and Chief Executive Officer of Novan. "If approved, SB204 will be the first new chemical entity specifically developed for the treatment of acne in more than 20 years and, in our view, has the potential to redefine the standard of care for acne. We believe physicians and their patients deserve a new option for the treatment of this chronic inflammatory skin disease, and we are eager for the results of these trials."

Results from Novan's Phase 2b study evaluating the efficacy and safety of SB204 for the treatment of acne were presented in March by Lawrence Eichenfield, MD, during a Late-breaking Research in Dermatology Forum at the 74th Annual Meeting of the American Academy of Dermatology.[1]

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 have been randomized in a 1:1 ratio to two treatment arms, SB204 Gel 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 with approximately 1,300 subjects, ages 9 and older.

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. The Company enrolled the last of

more than 600 patients for this study in July, with a maximum duration of 40 weeks, and expects to report top-line results in the third quarter of 2017.

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 up to 50 million Americans annually. Approximately 85% of people between the ages of 12 and 24 experience at least minor acne.[2]

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-releasing 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 platform with the potential to generate differentiated, first-in-class product candidates. We are rapidly advancing programs in five dermatological conditions with significant unmet medical need. We believe that our ability to conveniently deploy nitric oxide on demand in topical formulations allows us the potential to significantly improve patient outcomes in a variety of skin diseases and positions us to be a commercially successful leader in the dermatology market.

For more information, visit the Company's website at www.Novan.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] http://www.Novan.com/files/1114/6040/2416/Novan_Phase_2b_AAD_2016.pdf.
[2] American Academy of Dermatology. "Acne." https://www.aad.org/media/stats/conditions (Sept. 23, 2016).

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