Novan Announces Preclinical Data Demonstrating Immunomodulatory Effect In Vivo

Topical Application of SB414 Inhibited IL-17 in Psoriasis Mouse Model

Effect Relates to Multiple Inflammatory Skin Diseases

MORRISVILLE, N.C., Nov. 16, 2016 -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced preclinical data showing that the Company's nitric oxide-releasing product candidate SB414 significantly (p<0.05) reduced composite psoriasis scores, which consist of erythema and plaque scores, and pro-inflammatory cytokines, including interleukin-17, or IL-17, in a psoriasis mouse model.

"These data represent a significant advancement of Novan's platform, not only for the treatment of psoriasis, but also for the treatment of several other inflammatory skin diseases," said Nathan Stasko, PhD, President and Chief Executive Officer of Novan. "Biologics have shown dramatic effect against psoriasis in clinical trials but carry a risk-benefit profile that has reserved their use for patients with moderate-to-severe disease, or approximately 20% of the total psoriasis patient population.\(^1\) The newer biologics that target IL-17, such as secukinumab and ixekizumab, have dramatically elevated the field's understanding of the disease pathology and clinical outcomes for patients. We believe that a topical treatment utilizing Novan's nitric oxide-releasing technology may be able to disrupt the propagation of IL-17 locally in the skin and deliver clinical benefit without the systemic exposure and side effects of biologics. This is an exciting opportunity, and as a result we plan to accelerate clinical development of SB414."

According to a recent, peer-reviewed article in the British Journal of Dermatology, IL-17 is known to be or is likely to be related to the mechanism and severity of a number of inflammatory skin disorders, including psoriasis, acne, atopic dermatitis, vitiligo and alopecia areata.\(^2\)

"The evidence of clinical trials to date has shown a clear link between IL-17 inhibition and improved clinical outcomes for patients with psoriasis," said Dr. Bruce Strober, board-certified dermatologist, professor of dermatology, department chair and director of clinical trials at the University of Connecticut. "The broader connection of IL-17 to multiple inflammatory skin disorders would seem to suggest a novel approach for clinical developers and new hope for patients suffering from these diseases."

Based on the data generated in this preclinical \textit{in vivo} study, Novan expects to initiate clinical development with a Phase 2 proof-of-concept trial of SB414 as a topical treatment for psoriasis in the second quarter of 2017.
About Psoriasis

Psoriasis is a chronic inflammatory skin disease that affects approximately 7.5 million people in the United States.¹ The disease is characterized by an errant immune-system response that drives inflammation and hyperkeratosis, or thickening of the skin caused by rapid turnover of skin cells. This typically results in patches of plaques, or thick, red raised skin with silvery-white scales.¹³ Psoriasis can cause tremendous discomfort and can interfere with normal daily activities.³ It has also been associated with increased incidence of a number of other diseases¹ as well as significant psychological and emotional effect, including social isolation, depression and suicide.¹³ In fact, as many as 50% of psoriasis patients may experience depression.¹

There is no cure for psoriasis.⁴ The healthcare market has seen an increase in the introduction of systemic therapies, including biologics, to treat patients with higher disease burden, but all of the current systemic therapies are indicated only for patients with moderate-to-severe disease. For the approximately 80% of patients with mild-to-moderate psoriasis, prescription treatment options include topical corticosteroids, retinoids and vitamin D³.¹³ None of the currently approved therapies are without side effects, and none are well-suited for chronic use.³⁴

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-releasing 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, including, but not limited to, uncertainties and risks in the clinical development process, including, among others, length, expense, ability to enroll patients, reliance on third parties, and that results of earlier research and preclinical or clinical trials may not be predictive of results, conclusions or interpretations of later research or trials; whether we will be able to obtain additional funding when needed; and other risks and uncertainties described in our prospectus dated September 20, 2016 , filed with
the Securities and Exchange Commission (the "SEC") 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.

References


CONTACT:
(Investors)
Sean Andrews, Senior Director of Investor Relations
Novan, Inc.
919-627-6847
investors@novan.com

(Media)
Deb Holliday
Pascale Communications, LLC
412-877-4519
deb@pascalecommunications.com