Novan Announces First Patient Dosed in Phase 1b Atopic Dermatitis Trial with SB414

MORRISVILLE, N.C., Dec. 05, 2017 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced that the first patient has been dosed in the Company's Phase 1b clinical trial to evaluate topical nitric oxide product candidate SB414 cream for the treatment of mild-to-moderate atopic dermatitis. Novan is developing SB414 as a nitric oxide-releasing topical cream product candidate for the treatment of inflammatory skin diseases.

The Phase 1b clinical trial is being conducted in 48 adults with mild-to-moderate atopic dermatitis with up to 30% body surface area at baseline. Two concentrations of SB414 and vehicle cream, applied twice-daily for two weeks, are being evaluated for safety, for systemic exposure and to assess target engagement through a reduction of key pro-inflammatory biomarkers such as interleukin-4, or IL-4, before progressing to Phase 2 clinical trials. Eczema area severity index (EASI) scores are also being recorded at baseline and at the end of treatment. Top line results are targeted for the third quarter of 2018.

“Atopic dermatitis is a common and upsetting skin disease that is in need of more effective and safe treatments,” stated Lisa A. Beck, M.D., professor, Department of Dermatology, University of Rochester School of Medicine. “The topical products currently available target only one aspect of the disease pathology, the inflammation. We recognize that skin colonization with *Staphylococcus aureus* and a leaky skin barrier are strongly associated with disease severity. We need new treatments that address these critical features of atopic dermatitis. A therapy that utilizes the anti-inflammatory and antimicrobial actions of nitric oxide in a single, nonsteroidal, dual-action topical therapy would be a welcomed innovation for our patients with atopic dermatitis.”

Earlier this year, Novan presented mechanistic evidence for SB414 in two *in vivo* models that assess critical components of atopic dermatitis disease pathology at the 76th Annual Meeting of the Society for Investigative Dermatology in Portland, Oregon. SB414 displayed potent anti-staphylococcal activity in partial-thickness skin wounds infected with a methicillin-resistant *Staphylococcus aureus* strain isolated from an atopic dermatitis

patient. Additionally, Novan reported dose-dependent inhibition of inflammation in a preclinical mouse model comparable to that of betamethasone, a mid-potency corticosteroid used to treat eczema patients.

Novan previously announced, in October, the initiation of a Phase 1b clinical trial with SB414 for the treatment of psoriasis. Similar to the Phase 1b trial with SB414 for the treatment of atopic dermatitis, this trial is designed to evaluate safety and systemic exposure, and to assess target engagement through a reduction of key pro-inflammatory biomarkers such as interleukin-17, or IL-17, before progressing to Phase 2 clinical trials. Top line results are targeted for the second quarter of 2018.

About Atopic Dermatitis

Atopic dermatitis, also known as atopic eczema, is the most common chronic relapsing inflammatory skin disease, affecting nearly 18 million people in the United States with no FDA-approved cure.[1] Stabilizing the disease and reducing the number and severity of flares are the primary goals of current treatment. The diseases is characterized by intense itching, dry skin with red papules and plaques, “weeping” clear fluid, crust and scaling. Immune cells in the deep layers of skin release inflammatory signals, causing an itchy rash. Scratching leads to defects in the skin barrier function, allowing environmental triggers, such as the bacteria *Staphylococcus aureus,* to penetrate the skin barrier and further exacerbate the immune cells, triggering the “itch-scratch” cycle. *S. aureus* has a documented association with atopic dermatitis. More than 90% of atopic dermatitis patients have skin that is colonized with *S. aureus*.[2,3] The density of *S. aureus* colonization has been correlated with both the severity of atopic dermatitis lesions and the degree of cutaneous inflammation. A recent study showed that the entry of *S. aureus* into the dermis triggers immune abnormalities seen in atopic dermatitis skin.[4]

Nearly eighty percent of the atopic dermatitis population suffers from mild-to-moderate disease and are treated with first-line monotherapies, however, corticosteroids and calcineruin inhibitors have side effects and are not well-suited for chronic use.[1] Recently, the first biologic treatment for atopic dermatitis targeting IL-4 and IL-13 was approved, but it is reserved for patients with moderate-to-severe disease. Topical PDE4 inhibitor was also recently approved after more than a decade of absence of new mechanism of action.

About Psoriasis

Psoriasis is a chronic inflammatory skin disease that affects approximately 7.5 million people in the United States.[5] The disease is characterized by an errant immune-system response that drives inflammation and 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.[6,7] Psoriasis can cause tremendous discomfort and can interfere with normal daily activities.[5] It has also been associated with increased incidence of a number of other diseases[5] as well as significant psychological and emotional effect, including social isolation, depression and suicide.[5,6] In fact, as many as 50% of psoriasis patients may experience depression.[5]

There is no cure for psoriasis.[7] 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.[5,6] Vitamin D3 is not efficacious enough as monotherapy and topical corticosteroids and retinoids have well-known side effects and restrict the chronic use.

References

[1] IMS Health Disease Insights. “Atopic Dermatitis – US.” June 2015.

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[5] American Academy of Dermatology . "Psoriasis." https://www.aad.org/media/stats/conditions/psoriasis (Nov. 15, 2016)

[6] National Institutes of Health. "Questions and Answers about Psoriasis."

[7] Vaidya T., et al. Journal of Nature and Science. 2015 Mar;1 (3):e53.

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, including our interpretation of preclinical studies and the expected success and timing of our product development activities and clinical trials, and the future prospects of our business. 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 outcomes of our current clinical trials and future preclinical studies and clinical trials, including the timing of initiation of such trials and availability of data from such trials, 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; the lengthy and unpredictable nature of the U.S. Food and Drug Administration's drug approval process; whether we will be able to enter into strategic arrangements or obtain adequate funding to support our operations and initiatives on acceptable terms, or at all; 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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