



Press Release

Novan Acquires IP Rights to Treat Viral Malignancies with Nitric Oxide

Expanded Indications in Field of Virology Build on SB206 Clinical Success Against Human Papillomavirus

Company Doses First Patient in Inflammatory Skin Disease Program in Phase 1b Psoriasis Trial with SB414

MORRISVILLE, N.C., Oct. 18, 2017 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced that it has completed a transaction with KNOW Bio, LLC granting Novan exclusive worldwide rights for certain oncovirus applications of nitric oxide-based products. An *oncovirus* is a virus that causes cancer. The agreement allows Novan to expand its viral platform by exploring nitric oxide's antiviral activity against neoplasias and carcinomas caused by high-risk human papillomavirus (HPV). Novan intends to focus HPV-related development on localized therapies to treat HPV-associated sexually transmitted infections, including pre-cancerous lesions of the cervix and anus.

The intellectual property rights also allow for potential future translations of nitric oxide as a treatment for rare and orphan diseases caused by other double stranded DNA viruses including Kaposi's sarcoma-associated herpesvirus (HHV-8) and Merkel cell polyomavirus (MCV).

Strength of Data Against Papillomavirus Enables Path Forward

Novan has demonstrated Phase 2, statistically significant complete clearance rates of external genital warts caused by HPV with product candidate SB206. Collaborators at the University of Alabama at Birmingham previously presented preclinical data at the 31st International Papillomavirus Conference demonstrating the antiviral effects of Novan's nitric oxide-releasing drug candidates against the high-risk HPV-18 genotype and an inhibition of the E6 viral protein. The E6 protein impedes the immune system's ability to recognize HPV-infected cells and disrupts the cells' ability to repair DNA damage and

prevent abnormal cellular replication. As a result, E6 is believed to be a primary driver of HPV-related cancers and other abnormal growths.

“Nitric oxide inhibits replication of the human papillomavirus through a mechanism that potentially translates to numerous HPV subtypes,” stated Dr. Nathan Stasko, President and Chief Scientific Officer. “The cascade of preclinical and clinical data generated with our nitric oxide-based product candidates give us confidence to expand our focus beyond dermatology, and towards nitric oxide-based treatments for cancer.”

SB414 as a Potential Non-Steroidal Topical Treatment for Inflammatory Skin Diseases

Novan also announced today that it has initiated clinical development of the Company’s nitric oxide platform in the field of immunology. The first patient has been dosed in a Phase 1b clinical trial to evaluate topical product candidate SB414 cream for the treatment of psoriasis. The purpose of the Phase 1b trial is to evaluate safety and to assess target engagement through a reduction of key pro-inflammatory biomarkers like interleukin-17, or IL-17, before progressing to Phase 2 clinical trials. 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, rosacea and alopecia areata.¹ Earlier this year, Novan presented mechanistic evidence for SB414, demonstrating a statistically significant reduction in composite psoriasis scores and an inhibition of IL-17a and IL-17f.

Top line results for the Phase 1b trial are expected in the second quarter of 2018. Additionally, Novan is targeting to begin a Phase 1b trial with SB414 in adults with atopic dermatitis before year end with top line results expected in the third quarter of 2018.

“The news announced today reflects our deepened strategic focus in the areas of virology and immunology,” stated Kelly Martin, Novan’s Interim Chief Executive Officer. “These milestones illustrate the immense potential of our nitric oxide platform and provide Novan broader opportunities to demonstrate the healing power of nitric oxide. Perhaps more importantly, these developments may lead to desirable, new treatment paradigms for patients suffering from viral malignancies and inflammatory skin diseases.”

Corporate Update Conference Call and Webcast

The Company will host a conference call today at 8:30 a.m. Eastern Time. The phone number to join the conference call is +1 (844) 707-0661 (toll-free in the United States and Canada) or +1 (703) 318-2240 (international). The conference ID for the live call is 1458576. A live webcast will be accessible from the Events page of the Company's website at <http://Events.Novan.com>.

About Human Papillomavirus

An oncovirus is a virus that causes cancer. Approximately 20% of all human cancers, worldwide, are caused by oncoviruses.² As an example, HPV refers to a large family of double-stranded DNA viruses that induce abnormal growths on the skin or mucosal surfaces. HPV affects nearly 80 million Americans, and an estimated 14 million new cases of the virus are reported each year, according to the Centers for Disease Control and Prevention, or CDC.³ The virus is typically transmitted via direct skin-to-skin contact through disruptions in the normal skin barrier. There are over 100 subtypes of the virus, characterized as low-risk or high-risk based on their cancer-causing potential. While low-risk variants of HPV typically are associated with two types of papillomas – common warts and genital warts – high-risk strains of the virus are associated with cervical intraepithelial neoplasia (CIN) and cervical cancers; high-grade anal intraepithelial neoplasia (HGAIN) and anal cancer; and, other cancers of the vagina, vulva, rectum and penis. High risk strains 16 and 18 cause approximately 60% of all oropharyngeal cancers and 70% of cervical cancers.⁴

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 diseases⁵ 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} None of the currently approved therapies are without side effects, and none are well-suited for chronic use.^{6,7}

About Novan

Novan, Inc. is a clinical-stage biotechnology company aiming to leverage 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.

References

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- ⁶ National Institutes of Health. "Questions and Answers about Psoriasis."
- ⁷ Vaidya T, Feldman SR, Kirk J. Patient-centered approach to biologics in the treatment of psoriasis. *Journal of Nature and Science*. 2015 Mar;1 (3):e53.

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