Novan Announces Statistically Significant Phase 2 Clinical Trial Results for SB206

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Number of Patients with Complete Clearance of Genital Warts Provides Clinical Evidence of Nitric Oxide Anti-Viral Activity Against HPV

Company Plans End-of-Phase 2 Meeting for First Half of 2017

MORRISVILLE, N.C. , Nov. 29, 2016 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced top-line results from the Company's Phase 2 clinical trial with SB206 for the treatment of genital warts caused by human papillomavirus, or HPV. The highest dose tested, SB206 12%, demonstrated a statistically significant improvement ($p<0.05$) in the incidence of complete clearance of all baseline warts compared to vehicle treatment after 12 weeks in both the intent-to-treat and per-protocol analyses.

"These data are impressive. The magnitude of effect with favorable tolerability provides us great enthusiasm for patients suffering from the most common sexually transmitted infection in the United States," said Nathan Stasko, PhD, President and Chief Executive Officer of Novan . "Importantly, SB206 represents another drug candidate from our platform that has now shown the repeatability of taking a fundamental nitric oxide mechanism of action, generating compelling preclinical evidence and then translating that success into statistically significant results in Phase 2 clinical trials. Genital warts was our first viral target, and as we develop SB206 further we intend to diligently investigate the numerous other viral skin infections in need of new treatment options."

In this randomized, double-blind, vehicle-controlled clinical trial, the safety and efficacy of SB206 was evaluated in 107 patients with external genital warts and perianal warts. The dose and dosing frequency of SB206 was tested in four independent cohorts in which patients were randomized in a 3:1 ratio to either SB206 or vehicle and treated for up to 12 weeks. SB206 doses included SB206 4% twice-daily, 4% once-daily, 8% once-daily and the highest dose evaluated, 12% once-daily. Patients eligible for this clinical trial were males or females, 18 to 50 years of age, with 2 to 20 warts on the genital or perianal area. The mean wart count burden per patient at baseline was 7.4 warts.

The primary endpoint for this clinical trial was the proportion of patients who were completely clear of warts that were present at baseline at or before week 12. In the intent-to-treat analysis, 33% of patients achieved complete clearance of all warts by week 12 when treated with SB206 12% once-daily, compared to only 4% of patients achieving complete clearance with vehicle once-daily ($p=0.0099$). In the per-protocol analysis containing patients who completed a full 12 weeks of dosing, 42% of patients achieved complete clearance of all warts when treated with SB206 12% once-daily, compared to only 7% of patients achieving complete clearance with vehicle once-daily ($p=0.0200$).

The cutaneous tolerability of SB206 was carefully monitored and recorded using scores on a four-point grading scale for erythema, edema, erosions or ulcers and burning or stinging. The once-daily treatment arms were generally well tolerated, including the most effective dose, 12% once-daily. The most frequently reported treatment-emergent adverse events were application site reactions, the percentage of which was highest in patients treated with SB206 4% twice-daily. Based on the local application site adverse-event profile and the Company's strict, pre-specified stopping criteria, SB206 4% twice-daily was discontinued, and all of the remaining cohorts were dosed once-daily.

"I am honored to be part of the SB206 investigative team, and it was exciting to observe the clinical benefits that a number of my patients experienced during the Phase 2 trial," said Dr. Valentin Almendarez, Jr., board-certified obstetrician and gynecologist at the Institute For Women's Health in San Antonio. "I believe that Novan's topical nitric oxide-releasing gel, SB206, could be a valuable treatment alternative to existing prescription therapies and locally destructive procedures, with a mechanism of action that would be truly groundbreaking for the treatment of viral infections if approved."

"Our SB206 development program now includes *in vitro* evidence against high-risk HPV-18 in a human raft cell culture model, *in vivo* data against papilloma virus in rabbits, and clinical evidence from our Phase 2 trial against genital warts commonly caused by HPV-6 and -11," said Dr. M. Joyce Rico, board-certified dermatologist and Chief Medical Officer of Novan . "The ability to directly inhibit viral replication suggests that our nitric oxide-releasing technology may demonstrate activity against a broad spectrum of HPV strains, including high-risk subtypes associated with cancers of the head, neck and cervix."

Based on the data generated in this Phase 2 dose-ranging trial, Novan expects to discuss the entirety of the SB206 development program with the U.S. Food and Drug Administration , or FDA , in the first half of 2017 and, assuming a successful end-of-Phase 2 meeting with the FDA , plans to initiate the Company's late-stage program with Phase 3 pivotal clinical trials of SB206 in the second half of 2017.

About Human Papillomavirus (HPV) and Genital Warts

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. There are over 100 subtypes of the virus, characterized as low-risk or high-risk based on their cancer-causing potential. The virus is typically transmitted via direct skin-to-skin contact through disruptions in the normal skin barrier. All warts are caused by HPV, including genital and perianal warts, common warts and plantar warts.

Genital warts are among the world's most common sexually transmitted diseases. Genital warts are usually flesh-colored growths that can be raised, flat or cauliflower-shaped and are typically found on the surface of the external genitalia or in and around the anus. In males, they can appear on the surface of the penis and scrotum, and in females inside the vagina or on the cervix. Genital warts carry a substantial psychosocial burden due to the shame and embarrassment related to having a sexually transmitted disease as well as the inconvenience and discomfort of current treatment modalities. Current treatment options for genital warts consist of ablative procedures that cut, burn or freeze the warts but do not address the underlying viral infection, and there are no currently approved oral or topical prescription products indicated for the treatment of genital warts with a direct anti-viral mechanism of action.

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 Sept. 20, 2016 , filed with the Securities and Exchange Commission (the "SEC"), in our quarterly report filed with the SEC on Form 10-Q for the three months ended Sept. 30, 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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