Novan Engages Syneos Health as Commercial Solutions Provider for SB206

September 8, 2021

– Company targeting New Drug Application (NDA) for SB206 in Q3 2022, following recent clinically and statistically significant topline efficacy results from a pivotal Phase 3 B-SIMPLE4 trial in patients with molluscum contagiosum –

– Syneos Health provides immediate access to commercial infrastructure with deep dermatology expertise and a track record of success –

DURHAM, N.C., Sept. 08, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. (“the Company” or “Novan”) (Nasdaq: NOVN), today announced its selection of Syneos Health (Nasdaq: SYNH), a fully integrated biopharmaceutical solutions organization, as its commercial solutions provider for SB206 for the treatment of molluscum. The strategic relationship with Syneos Health will focus on implementing the SB206 prelaunch strategy and commercial preparation, followed by sales of SB206, if approved by the U.S. Food and Drug Administration. SB206, Novan’s lead product candidate, utilizes its innovative and proprietary NITRICIL™ technology platform.

Syneos Health is an industry leader for helping biopharma companies commercialize products and is the longest-tenured U.S. provider of outsourced field teams. Novan and Syneos Health began working together in 2019 to assess molluscum market data. The companies have since expanded their relationship to assemble a leadership team and incorporate full-service commercialization solutions to support Novan’s SB206 program.

“This strategic relationship brings together our robust clinical and scientific data from SB206 for the treatment of molluscum and Syneos Health’s deep dermatology expertise, experience, and network,” commented Paula Brown Stafford, Novan’s President and Chief Executive Officer. “As we prepare for commercialization of SB206, subject to FDA approval, Syneos Health’s proven track record will be invaluable to Novan as we plan to maximize the market opportunity of SB206, which has the potential to be the first in class in-home topical treatment for molluscum.”

Michelle Keefe, President, Commercial Solutions at Syneos Health, added, “We are proud to expand our relationship with Novan, and be part of filling a high unmet medical need in the dermatology and pediatric spaces with SB206. We believe our comprehensive, best-in-class capabilities will provide the strategic insights needed to execute a successful launch of Novan’s first potential commercial product.”

In June 2021, the Company reported positive topline results from its pivotal Phase 3 B-SIMPLE4 clinical study for the primary endpoint (p-value ≤ 0.0001), with complete clearance of all treatable lesions in more than 32% of patients at week 12. The Company targets submitting a new drug application for SB206 for the treatment of molluscum with the FDA during the third quarter of 2022.

About Syneos Health

Syneos Health® (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. The Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Syneos Health brings together approximately 27,000 clinical and commercial minds with the ability to support customers in more than 110 countries. Together Syneos Health shares insights, uses the latest technologies and applies advanced business practices to speed Syneos Health’s customers’ delivery of important therapies to patients. To learn more about how Syneos Health is **Shortening the distance from lab to life®**, visit syneoshealth.com or subscribe to its podcast.

About Novan

Novan, Inc. is a late clinical-stage biotechnology company focused on leveraging its proprietary nitric oxide (NO) based technology platform, NITRICIL™, to generate macromolecular New Chemical Entities (NCEs) to treat multiple indications in dermatology, men’s and women’s health, infectious diseases, and various other medical conditions with significant unmet needs. The Company’s lead product candidate is SB206, a topical gel with antiviral properties, for the treatment of molluscum. The Company believes that SB206, as a topical, at-home, caregiver-applied therapy with a rapid treatment benefit, if approved, would address an important unmet medical need for the treatment of molluscum.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe,” “expect,” “target,” “anticipate,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on the Company’s current beliefs and expectations. These forward-looking statements include, but are not limited to, statements related to the potential therapeutic value of the Company’s NITRICIL™ platform technology, the Company’s pharmaceutical development of nitric oxide-releasing product candidates, including SB206, the potential timing of an NDA submission for SB206, the potential market opportunity and plans for launch and commercialization of SB206, if approved, and the Company’s intention to partner with third parties. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from the Company’s expectations, including, but not limited to, risks related to the regulatory approval process, which is lengthy, time-consuming and inherently unpredictable, including the risk that the FDA will not agree with the Company’s approach to a potential NDA submission, that the Company’s product candidates may not be approved or that additional studies may be required for approval or other delays may occur, that the Company may not have sufficient quantities of drug substance and/or drug product to support regulatory submissions and that the Company may not obtain funding sufficient to complete the regulatory or development process; the Company’s limited experience as a company in obtaining regulatory approvals and commercializing pharmaceutical products; changes in the size and nature of the market for our product candidates, including potential competition; any operational or other disruptions as a result of the COVID-19 pandemic; the Company’s ability to obtain additional funding or enter into strategic or other business relationships necessary or useful for the further development or commercialization of the Company’s product candidates; risks related to the manufacture of raw materials, including the Company’s active pharmaceutical ingredient and drug product components utilized in

clinical trial materials, including supply chain disruptions or delays, failure to transfer technology and processes to third parties effectively or failure of those third parties (or the Company in connection with the upfit of the Company's new facility) to obtain approval of and maintain compliance with the FDA or comparable regulatory authorities; the Company's reliance on arrangements with third parties to support its operations and development efforts and the risk that such parties will not successfully carry out their contractual duties or meet expected deadlines; and other risks and uncertainties described in the Company's annual report filed with the Securities and Exchange Commission on Form 10-K for the twelve months ended December 31, 2020, and in the Company's subsequent filings with the Securities and Exchange Commission. Such 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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