Novan Appoints Tomoko Maeda-Chubachi, MD, PhD, MBA as Chief Medical Officer

August 24, 2021

– Dr. Maeda-Chubachi, who served as Novan's Senior Vice President, Medical has played a key role in the design and execution of the Company's development programs –

– Dr. Maeda-Chubachi was instrumental in the execution of B-SIMPLE4, the Company's pivotal Phase 3 trial of SB206 in molluscum contagiosum, which recently reported positive topline efficacy and safety results –

– Additionally, the Company announces Dr. Maeda-Chubachi's publication in JID Innovations based on previously completed Phase 3 studies (B-SIMPLE1 and B-SIMPLE2) suggesting SB206 may trigger the beginning-of-the-end ("BOTE") inflammation and shorten the duration of molluscum infection –

DURHAM, N.C., Aug. 24, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq: NOVN), today announced the appointment of Tomoko Maeda-Chubachi, MD, PhD, MBA as Chief Medical Officer. Dr. Maeda-Chubachi has served as Novan's Senior Vice President, Medical since March of 2021 and Vice President, Medical Dermatology since joining the Company in September of 2017.

"The leadership and expertise that Dr. Maeda-Chubachi has brought to the Company have been invaluable. She has played an instrumental role in the advancement of our development programs, and of particular note, SB206, which recently demonstrated positive topline data in our pivotal Phase 3 study," commented Paula Brown Stafford, President and Chief Executive Officer of Novan. "With the leadership of Dr. Maeda-Chubachi as our Chief Medical Officer, I believe we are well-positioned to continue advancing our current development programs, unlock additional pipeline opportunities and build value for all stakeholders."

Prior to joining the Company, Dr. Maeda-Chubachi served as senior medical director at GlaxoSmithKline (GSK), leading clinical development projects for psoriasis, atopic dermatitis, pemphigus, and androgenic alopecia. Prior to GSK, she held clinical and medical affairs roles at Eli Lilly and Company and Pfizer, Inc. Dr. Maeda-Chubachi was an academic physician and dermatologist for ten years before entering the pharmaceutical industry. Dr. Maeda-Chubachi received her MD and PhD from Osaka University.

"Over the course of my career, I have been involved with and led numerous development programs but none have I been as excited about as I am for SB206. The recently observed data from the positive B-SIMPLE4 trial gives me great confidence as we work towards a potential NDA filing and potential approval for the treatment of molluscum contagiosum," stated Dr. Maeda-Chubachi, Chief Medical Officer of Novan. "Additionally, we are working to build on this successful study as we work to continue to leverage our clinically proven NITRICIL™ technology platform to advance additional pipeline candidates."

The Company also announced Dr. Maeda-Chubachi's manuscript entitled, *SB206, a Nitric Oxide–releasing Topical Medication Induces the BOTE (Beginning-of-the-End) Sign and Molluscum Clearance*[1], was recently published in the *JID Innovations* journal. The recently published data was an integrated analysis from two of Novan's previously completed Phase 3 studies (B-SIMPLE1 and B-SIMPLE2).

Dr. Maeda-Chubachi added, "The recently published integrated data from the previously completed B-SIMPLE1 and B-SIMPLE2 studies give us further confidence in the potential for SB206 as an important treatment for molluscum. With the average time to resolution of molluscum being 13 months, the analysis based on BOTE status of molluscum strongly suggests SB206 may shorten the duration of infection. The result not only suggests the mechanism of action of SB206, but also serves to elucidate the healing process of molluscum. We are committed to advancing the development of this important product candidate that we believe, if approved, has the potential to provide patients with a much-needed treatment benefit."

The BOTE sign is indicative of inflammation that predicts imminent resolution of molluscum. The integrated analysis of the two prospective, 12-week, randomized, double-blind clinical trials of topical nitric oxide–releasing SB206 gel evaluated an association between BOTE sign and molluscum contagiosum lesion reduction. Of the 707 randomized patients, ~80% exhibited BOTE sign during the treatment period regardless of treatment assignment. At week 12, molluscum lesions decreased from baseline by 50.7% for baseline BOTE+ versus 29.1% for BOTE– (P = 0.0015) vehicle-treated patients compared with a 63.3% decrease for baseline BOTE+ versus 51.7% for BOTE– (P = 0.0194) SB206-treated patients. Among vehicle-treated patients, 48 (22.3%) who were never BOTE+ had an 18.5% reduction from baseline versus a 34.0% reduction in 165 patients (76.7%) who experienced BOTE at any time, suggesting that the projected duration of lesion clearance for patients with 18–20 molluscum lesions is 15 months for BOTE– versus 6 months for BOTE+ patients. Patients who were both BOTE+ and treated with SB206 had the greatest reduction in lesions. This result strongly suggests SB206 may trigger BOTE signs and shorten the duration of molluscum contagiosum infection.

The article published in *JID Innovations* is now available online and can be accessed here: http://www.sciencedirect.com/journal/jid-innovations/vol/1/issue/3.

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, and the potential for an NDA submission for SB206. 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; risks and uncertainties in the Company’s ongoing or future product development activities and preclinical studies, which may not prove successful in demonstrating proof-of concept, or may show adverse toxicological findings, and even if successful may not necessarily predict that subsequent clinical trials will show the requisite safety and efficacy of the Company’s product candidates; 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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[1] JID Innovations (2021);1:100019 doi:10.1016/j.xjidi.2021.100019