Novan Expands External Business Partner Network

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- Expansion of the existing relationship with MedPharm around formulation science
- Manufacturing agreement established for production of proprietary drug substance
- Partner network now includes those located in the UK, Switzerland, Finland, Japan and the US

MORRISVILLE, N.C., June 19, 2019 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq: NOVN) today announced continued business advancements in both formulation science and manufacturing. These advancements are consistent with the Company's stated goal to extend the opportunities for nitric oxide-based therapeutics by leveraging global external expertise and capabilities that complement the Company's existing operations, significant internal proprietary knowledge and technology experience.

Novan has expanded its relationship with MedPharm Ltd ("MedPharm"). MedPharm is a leader in dermatological, nail, eye, airway, mucosal membrane and transdermal formulation science and drug delivery. Previously, Novan has worked with MedPharm across a number of specific projects, including non-clinical and in vitro permeation and penetration testing ("IVPT") studies, and a variety of targeted formulation projects. The newly expanded agreement will broaden the relationship from individually identified projects to a much broader scope of work, activity and initiatives. Examples would include some of the following:

- Creation of a product candidate, including formulation and drug delivery, for viral application of nitric oxide in women's health, with a goal of advancing to IND enabling studies,
- Formulation enhancement of current product candidates for potential application across a broader array of dermatology diseases,
- Development of a systematic and industrialized IVPT tool to assess product candidate performance characteristics,
- Integration of MedPharm's experience in drug delivery to complement the Company's work on current and future nitric oxide product candidates across various therapeutic applications.

"MedPharm is delighted to be able to support Novan in advancing and broadening its product pipeline," commented Eugene Ciolfi, MedPharm's President & Chief Executive Officer. "Our new agreement allows us to react quickly to changes in requirements and makes full use of MedPharm's comprehensive services for de-risking Novan's product development."

In addition, after a thorough global search, Novan has executed a master contract manufacturing agreement with a full-scale active pharmaceutical ingredient (API) manufacturer. The agreement establishes an operating and business relationship for this manufacturer to become the primary external supplier of Novan's proprietary berdazimer sodium drug substance. Also incorporated in the agreement is the process and analytical method transfer necessary to advance the production of the Company's berdazimer sodium drug substance for future clinical trials and importantly, upon approval of any of the Company's drug product candidates, for commercial purposes on a global basis. Adding an external API provider and business partner alongside the existing Orion Corporation relationship, announced in October 2018, completes a critically important operating model adjustment for the Company.

"These business advancements highlight our team's continued focus on leveraging our substantial internal expertise of nitric oxide science with external partners, all of whom are experts in their field," commented Carri Geer, PhD, Senior Vice President and Chief Technology Officer of Novan. Dr. Geer further added, "our experiences to date provide us with the foundation upon which to rapidly advance our progress from here across dermatology and other selected clinically meaningful therapeutic applications with the goal of bringing benefit to patients."

About Novan

Novan, Inc. is a clinical development-stage biotechnology company focused on leveraging nitric oxide's naturally occurring anti-microbial and immunomodulatory mechanisms of action to treat a range of diseases with significant unmet needs. We believe that our ability to deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to improve patient outcomes in a variety of dermatological, women’s health and gastrointestinal diseases.

About MedPharm

MedPharm is the world’s leading contract provider of topical and transdermal product design and formulation development services. MedPharm are experts at reducing risk and accelerating development times for generic and proprietary pharmaceutical customers through their unique, cost-effective and industry-leading performance testing models. Well established as the global leaders in dermatology, nail, mucosal membrane, and transdermal product development, MedPharm can also offer innovative solutions for ophthalmic and airway preparations recognized for their scientific rigor by regulators and investors. MedPharm has fully established R&D centers in the USA and UK and has its global HQ in Guildford, UK.

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, our intention to leverage the expertise and capabilities of third parties to advance our business and the future prospects of our business and our product candidates. 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, risks and uncertainties in the clinical development process, including, among others, length, expense, ability to enroll patients, reliance on third parties, potential for delays and that results of earlier research and preclinical or clinical trials may not be predictive of results, conclusions or interpretations of later research activities or additional trials; risks related to the
regulatory approval process, which is lengthy, time-consuming and inherently unpredictable, including the risk that our product candidates may not be approved or that additional studies may be required for approval or other delays may occur and that we may not obtain funding sufficient to complete the regulatory or development process; risks related to the manufacture of clinical trial materials and commercial supplies of any potentially approved product candidates, including the manufacture of our NVN1000 active pharmaceutical ingredient in our primary facility, our internal manufacturing capabilities and our ability to transfer technology and processes as contemplated by the manufacturing agreement; risks relating to the development process generally, including the ability to develop new or enhanced product candidates; our ability to obtain additional funding or enter into strategic relationships or other business development necessary for the further development or commercialization of our product candidates; and other risks and uncertainties described in our annual report filed with the SEC on Form 10-K for the twelve months ended December 31, 2018, and in our 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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