Innocan Pharma Initiates FDA Approval Process for Liposome Injection Therapy for Chronic Pain

With its submission of a Pre-IND Meeting Request Letter, Innocan initiates the regulatory process with the U.S. Food and Drug Administration (FDA) for the approval of its prolonged CBD release technology for human use

HERZLIYA, Israel and CALGARY, AB, April 22, 2024 /CNW/ -- Innocan Pharma Corporation (CSE: INNO) (FSE: IP4) (OTCQB: INNPF) ("Innocan" or the "Company"), is pleased to announce that is has reached a key milestone: the Company submitted its letter of application for a Pre-IND meeting, the first phase in the FDA approval process in the United States for Innocan's Liposome-Cannabidiol (LPT-CBD) injectable treatment of chronic pain.

With the global market for pain therapeutics widely expected to exceed US$100 billion by 2032[1], LPT therapy which requires only one single monthly subcutaneous injection, is positioned as a highly attractive alternative to opioid-based approaches. Opioids have and continue to take a significant human toll in recent years, with more than three-quarters of drug overdose deaths in the United States involving opioids, according to the United States Center for Disease Control and Prevention[2].

Innocan's therapy has shown consistent efficacy in multiple pre-clinical trials in recent years of it's LPT-CBD injectable treatment through prolonged and controlled release of CBD in animals with chronic pain conditions. Innocan's Pre-IND Meeting Request Letter to the FDA is a key milestone and important first step in seeking approval of its LPT-CBD therapy for use in humans. At the Pre-IND meeting, the objective will be to obtain guidance from the FDA on the preclinical and clinical development plan, enabling the initiation of an Investigational New Drug (IND) program in the United States.

Iris Bincovich, CEO of Innocan, commented: "We are extremely excited to embark on this next stage in the development of LPT-CBD injectables, this is a major Milestone for Innocan Pharma. We have invested significant effort and many thousands of person-hours in its research and development, accumulating a wealth of preclinical data that will serve as the foundation for our participation in the FDA process. This is a key milestone for Innocan and marks our first step towards the FDA's recognition of our technology. We see significant potential for our therapy, with an addressable market for pain management therapeutics expected to exceed US $100 billion by 2032, and we look forward to tapping that.**"**

Dr. Joseph Pergolizzi, Innocan's FDA Advisory Board Member, added:

"We have worked hard to catalogue the data collected as part of our animal LPT therapy testing program and prepare it for the FDA. We look forward to working under FDA guidance, with the goal of completing the review process as quickly and efficiently as possible. We believe that Innocan's unique treatment method, if and when it should become FDA-approved has the potential of being a highly valuable non-opioid addition in the medical arsenal of the management of chronic pain."

About Innocan

Innocan is a pharmaceutical tech company that operates under two main segments: Pharmaceuticals and Consumer Wellness. In the Pharmaceuticals segment, Innocan focuses on developing innovative drug delivery platform technologies based on advanced cannabinoids science, to treat various conditions to improve patients' quality of life. This segment involves two drug delivery technologies: (i) **LPT** CBD- loaded liposome platform facilitating exact dosing and the prolonged and controlled release of CBD into the blood stream. The LPT delivery platform research is in the preclinical trial phase for: Pain Management. In the Consumer Wellness segment, Innocan develops and markets a wide portfolio of innovative and high-performance self-care products to promote a healthier lifestyle. Under this segment, Innocan has established a joint venture by the name of BI Sky Global Ltd. that focuses on advanced targeted online sales. https://innocanpharma.com/

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Certain information set forth in this news release, including, without limitation, information regarding research and development, collaborations, the filing of potential applications with the FDA and other regulatory authorities, the potential achievement of future regulatory milestones, the potential for treatment of conditions and other therapeutic effects resulting from research activities and/or the Company's products, requisite regulatory approvals and the timing for market entry, is forward-looking information within the meaning of applicable securities laws. By its nature, forward-looking information is subject to numerous risks and uncertainties, some of which are beyond Innocan's control. The forward-looking information contained in this news release is based on certain key expectations and assumptions made by Innocan, including expectations and assumptions concerning the anticipated benefits of the products, satisfaction of regulatory requirements in various jurisdictions and satisfactory completion of requisite production and distribution arrangements.

Forward-looking information is subject to various risks and uncertainties which could cause actual results and experience to differ materially from the anticipated results or expectations expressed in this news release. The key risks and uncertainties include but are not limited to: general global and local (national) economic, market and business conditions; governmental and regulatory requirements and actions by governmental authorities; and relationships with suppliers, manufacturers, customers, business partners and competitors. There are also risks that are inherent in the nature of product distribution, including import / export matters and the failure to obtain any required regulatory and other approvals (or to do so in a timely manner) and availability in each market of product inputs and finished products. The anticipated timeline for entry to markets may change for a number of reasons, including the inability to secure necessary regulatory requirements, or the need for additional time to conclude and/or satisfy the manufacturing and distribution

arrangements. As a result of the foregoing, readers should not place undue reliance on the forward-looking information contained in this news release concerning the timing of launch of product distribution. A comprehensive discussion of other risks that impact Innocan can also be found in Innocan's public reports and filings which are available under Innocan's profile at www.sedar.com.

Readers are cautioned that undue reliance should not be placed on forward-looking information as actual results may vary materially from the forward-looking information. Innocan does not undertake to update, correct or revise any forward looking information as a result of any new information, future events or otherwise, except as may be required by applicable law.

[1] https://www.gminsights.com/industry-analysis/pain-management-drugs-market

[2] https://www.cdc.gov/opioids/data/index.html

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CNW 16:01e 22-APR-24