Innocan Pharma Advances Liposomal CBD with Positive Response from FDA Following Successful Pre-IND Meeting

HERZLIYA, Israel and CALGARY, Alberta, Sept. 3, 2024 /CNW/ -- Innocan Pharma Corporation (CSE: INNO) (FSE: IP4) (OTCQB: INNPF) ("Innocan" or the "Company"), a pioneer in the pharmaceutical and biotechnology industries, is pleased to announce that it has received a positive response from the U.S. Food and Drug Administration (FDA) following Innocan's successful pre-Investigational New Drug (pre-IND) Type B meeting with the FDA held in July, for its lead drug product Liposomal Technology-CBD (LPT-CBD).

The FDA has agreed for LPT-CBD's submission under the 505(b)(2) New Drug Application (NDA) by establishing a scientific bridge to the reference listed drug. The 505(b)(2) abbreviated pathway, as it is often described, typically enables a faster route to patent utilization and commercial approval. This pathway is a significant milestone for Innocan, as it may pave the way for a streamlined and accelerated FDA approval process for LPT-CBD, while allowing Innocan to advance its patent protected innovation.

In addition, Innocan has reached an alignment with the FDA on both its non-clinical development plan and the clinical study design for LPT-CBD's proposed Investigational New Drug (IND) filing for a Phase I clinical study.

Professor Chezy Barenholz, Innocan's Chief Scientific Officer said, "We are very pleased with the conclusion of our meeting and interactions with the FDA. We now have a clear and straight forward pathway toward generating the data needed for the initiation of our clinical study with LPT-CBD to treat chronic pain."

"Innocan is fully committed to bringing new opportunities for chronic pain management," **added Dr. Eyal Kalo, Research and Development Director of Innocan**. "Chronic pain is a serious condition that affects around 20% of the population (1of 5 US Adults) (*) with significant unmet needs. The positive FDA feedback is a crucial milestone for us, enabling the advance of LPT-CBD to market and bring much-needed relief to millions suffering from chronic pain."

"Given the current standard of care for chronic pain, we believe clinicians' ability to address existing gaps will be significantly enhanced by LPT-CBD," emphasized **Dr. Joseph Pergolizzi, COO at NEMA Research Inc, Key Opinion Leader in chronic pain, and a member of Innocan's advisory board.**

Iris Bincovich, Chief Executive Officer of Innocan, highlighted that LPT-CBD has demonstrated long-lasting CBD release in nonclinical studies, and added, "Our work is a crucial element in the fight against chronic pain, bringing a novel technological approach to the forefront."

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https://www.cdc.gov/nchs/products/databriefs/db390.htm?utm_source=STAT+Newsletters&utm_campaign=94ea767867-MR_COPY_01&utm_medium=email&utm_

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 comprises with cannabinoids science, to treat various conditions to improve patients' quality of life. This segment involves innovative drug delivery technology: 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 Chronic 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 developing on advanced targeted online sales. https://innocanpharma.com/

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Caution Regarding Forward-Looking Information

Certain information set forth in this news release, including, without limitation, the Company's plans for human trials of its LPT-CBD platform, 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 production and distribution arrangements.

Forward-looking information is subject to various risks and uncertainties that 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: global and local (national) economic, political, market and business conditions; governmental and regulatory requirements and actions by governmental authorities; and potential disruption of 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). 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. A comprehensive discussion of other risks that impact Innocan can be found in Innocan's public reports and filings which are available under Innocan's profile at www.sedarplus.ca.

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.

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CNW 16:00e 03-SEP-24