Innocan Pharma Provides its Annual "State of Research and Development" Update for 2024

HERZLIYA, Israel and CALGARY, Alberta, Dec. 12, 2024 /CNW/ -- Innocan Pharma Corporation (CSE: INNO) (FSE: IP4) (OTCQB: INNPF) (the "Company" or "Innocan") a pharmaceutical technology company focusing on developing innovative drug delivery platform technologies and an owner of a proprietary intellectual property portfolio, is pleased to share its annual "State of Research and Development" update for 2024. This year, the Company achieved significant milestones in advancing research and development for its drug delivery platforms as well as its intellectual property portfolio.

During 2024, Innocan achieved significant milestones in both scientific and regulatory domains. Preclinical studies of its liposome-cannabidiol technology (LPT-CBD(demonstrated high CBD bioavailability, along with long-lasting pain relief and improved well-being in various animal models. Building on this compelling data, the Company secured agreement from the United States Food and Drug Administration (FDA) on the preclinical and Phase 1 clinical development plan to advance LPT-CBD as a treatment for chronic pain in humans. Additionally, the FDA acknowledged LPT-CBD's development under the 505(b)(2) regulatory pathway, which provides Innocan with an accelerated route to patent utilization and commercialization.

On the veterinary front, LPT-CBD's innovation was recognized by the FDA's Center for Veterinary Medicine (CVM), which granted Innocan a fee waiver for 2024 and issued a number that identifies an Investigational New Animal Drug (INAD). This designation allows Innocan to facilitate correspondence and data exchange with the CVM to support the development of LPT-CBD as a new veterinary drug.

Iris Bincovich, CEO of Innocan Pharma, commented: "In 2024, we not only met but surpassed our FDA-related goals, achieving regulatory milestones ahead of schedule. With the FDA 505(b)(2) regulatory pathway meeting behind us, these advancements position us to accelerate our development in 2025, bringing us closer to delivering innovative pain management solutions for both human and veterinary applications."

The 505(b)(2) FDA regulatory pathway offers a streamlined approach for developing a long-acting injectable cannabinoid using a liposomal drug delivery platform to treat chronic pain. By leveraging existing pre-clinical data from approved products, this pathway is expected to significantly shorten both development time and cost. This pathway facilitates innovative formulations like liposomal delivery, by allowing for modifications to dosage forms, administration routes, or drug combinations, all while adhering to stringent safety and efficacy standards. This approach is expected to accelerate market entry and address unmet medical needs in chronic pain management.

Company's Update on its Activity in Research and Development and FDA interactions

On February 26, 2024, the Company announced the latest findings from the Company's pharmacokinetic study of its liposome CBD platform ("LPT-CBD") in rabbits. In agreement with studies conducted in other animals (mice, dogs, goats, and sheep) this study resulted in prolonged exposure of CBD obtained following a single subcutaneous LPT-CBD injection. This data along with data obtained from other organisms injected with the Company's liposomal CBD, consistently demonstrates that a detectable CBD level could be maintained for weeks following a single injection.

On March 5, 2024, the Company announced the results of a recent tissue distribution study of its liposome CBD platform (LPT-CBD), that indicated the potential of LPT-CBD to support a new therapeutic venue for neurological disorders. In this study, CBD was found to be in the brains of both mice and rabbits weeks after LPT-CBD was subcutaneously injected to them. LPT technology provides a long presence of CBD in the blood enabling CBD to pass the blood brain barrier (BBB) and deliver long brain exposure.

On April 22, 2024, the Company announced that it had submitted its letter of application for a Pre-IND meeting, the first phase in the FDA approval process in the United States for LPT-CBD. Innocan's Pre-IND meeting request letter to the FDA represents a key milestone and important first step in seeking approval of its LPT-CBD therapy for use in humans. The objective of the Pre-IND meeting is 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.

On May 9, 2024, the Company announced the successful pre-clinical treatment of amputee female donkey with a liposomal-CBD injection. Miri, a-7-year-old female donkey, had undergone amputation of her right front limb, leaving the weight burden primarily on her left front limb. This led to an inflammatory disease affecting the soft tissue that connects the foot bone to the hoof, seemingly causing extreme pain and limited mobility. In a compassionate act, Miri was administered a liposomal-CBD injection. The effect was immediate as Miri regained her ability to walk and move as she had before her inflammatory disease developed.

On May 21, 2024, the Company announced significant advancements in the regulatory process for its LPT-CBD, which provides an innovative solution in non-opioid pain management. The FDA granted Innocan an INAD number and approved an initial meeting with the Company to discuss the strategic path forward. The meeting with the FDA was on July 31, 2024, where Innocan presented its preclinical results and proposed clinical development plan. The meeting is key to launching human clinical trials for the LPT-CBD injectable drug, developed to provide a novel treatment option for chronic pain.

On June 11, 2024, the Company announced the success and conclusion of a preliminary safety evaluation of Innocan's single injection and sustained-release LPT-CBD conducted on minipigs. Recognized by the FDA as an excellent model for toxicology, minipigs are small breeds of miniature domestic pigs which share strong similarities with humans in crucial aspects such as drug metabolism, skin structure, genetics, and physiological mechanisms. In this preliminary safety study, minipigs received a single subcutaneous injection of LPT-CBD and were closely monitored for pharmacokinetics and basic safety parameters over one month. The animals all exhibited good drug tolerance and did not manifest any drug-related adverse reactions.

On July 2, 2024, the Company announced that it engaged the Past President of the Eastern Pain Association, Dr. William K. Schmidt, to support its LPT-CBD submission process to the FDA for chronic pain. His extensive expertise in pain-related clinical development and regulatory affairs will

strongly contribute to Innocan's team during the LPT-CBD submission process with the FDA. Dr. Schmidt brings over 25 years of pharmaceutical industry clinical trial experience, specializing in analgesic and narcotic antagonist drug development.

On July 26, 2024, the Company announced that the CVM) granted the Company a sponsor fee waiver and assigned an INAD number for its LPT-CBD product. This represented a significant step for the Company, as an INAD designation facilitates correspondence and data exchange with CVM to support LPT-CBD development as a new veterinary drug. The Company further announced that following the assessment of LPT-CBD's scientific package, the CVM recognized Innocan's contribution to pursuing innovative animal drug products and technology and granted the Company a sponsor fee waiver for fiscal year 2024. Over the past year, repeated administration of LPT-CBD in dogs and other animals demonstrated both efficacy and tolerability, providing sufficient evidence for the INAD application.

On September 3, 2024, the Company announced that it received a positive response from the FDA following Innocan's successful pre-IND Type B meeting with the FDA held in July, for its lead drug product LPT-CBD. The FDA has agreed to 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 IND filing for a Phase I clinical study.

On October 9, 2024, The Company announced that Dr. Joseph V. Pergolizzi, Jr., M.D., a member of the Company's Scientific Advisory Board, was recognized among the top 2% most cited scientists in the world in a new list published by Stanford University. This achievement underscores Dr. Pergolizzi's long-term contribution to medical science and his influential role in shaping global healthcare practices.

Dr. Pergolizzi was appointed to be part of Innocan's Scientific Advisory Board in September 2023. His role focuses on promoting pharmaceutical human product R&D and supporting the Company's planned FDA filing for new medications. His expertise in pain management, critical care medicine, and regulatory processes are key in advancing the issuer's pharmaceutical developments.

On October 11, 2024, the Company announced promising results from a multi-year compassionate therapy using repeated LPT-CBD injections for pain relief in dogs with naturally occurring osteoarthritis. The therapy consistently demonstrated pain reduction and improved mobility, with effects lasting for several weeks after each injection as expected. These results further demonstrate that LPT-CBD can be a viable treatment option for managing chronic pain and enhancing the quality of life in animals.

In two ongoing cases, dogs suffering from osteoarthritis who were treated with LPT-CBD after failing to respond to non-steroidal anti-inflammatory drugs (NSAIDs) and oral CBD, showed noticeable pain relief, substantially improved mobility and increased well-being which was clearly noticeable. Both dogs remained on LPT-CBD treatment for 2 and 2.5 years, respectively after their owners reported significant improvement in quality of life, receiving the treatment in addition to other conventional treatments.

About Innocan

Innocan is an innovator in the pharmaceuticals and wellness sectors. In the pharmaceuticals sector, Innocan developed a CBD-loaded liposome drug delivery platform with exact dosing, prolonged and controlled release of synthetic CBD for non-opioid pain management. In the wellness sector, Innocan develops and markets a wide portfolio of high-performance self-care and beauty products to promote a healthier lifestyle. Under this segment Innocan carries on business through its 60% owned subsidiary, BI Sky Global Ltd. which focuses on advanced, targeted online sales.

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Cautionary note regarding forward-looking information

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 and potential for patent utilization and commercialization 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.

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