Incannex Complete Successful Pre-IND Meeting with the FDA for CannQuit-O for treatment of opioid use disorder

May 7, 2024

MELBOURNE, Australia and NEW YORK, May 07, 2024 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (NASDAQ:IXHL), (Incannex or the Company), a leading cannabinoid and psychedelic medicine biotechnology company, is pleased to announce the successful completion of a pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) regarding the development of CannQuit-O for treatment of Opioid Use Disorder (OUD).

The pre-IND teleconference included representatives from various divisions of the FDA providing input on the CannQuit-O development program. The Agency had reviewed the CannQuit-O meeting package and provided recommendations on the proposed clinical development strategy, including patient populations, the selection and timing of efficacy endpoints and safety monitoring. These recommendations were discussed during the pre-IND teleconference where the company had the opportunity to seek further clarification on the agency's initial response.

The productive discussion with the FDA is an important milestone for the development of CannQuit-O and provides Incannex with clarity on the data required to open an IND with the FDA for this product and provides valuable guidance for successful clinical development in the OUD indication.

Incannex Chief Scientific Officer Dr Mark Bleackley said: "Opioid use disorder is a significant issue impacting millions of patients and their families. Developing new therapies, such as CannQuit-O, is critical for helping control the disease and improve quality of life for those who are suffering from the disease and those around them. Feedback from the FDA on the proposed development strategy for CannQuit-O will be taken on board so that the outcomes of research activities meet agency expectations and ensure that the appropriate steps are being taken towards drug registration."

About CannQuit-O

CannQuit-O is a chewable tablet with unique characteristics provided by novel combination of registered/FDA-approved polymers allowing for rapid and sustained release of its active ingredients, including an opioid agonist, antagonist and cannabidiol (CBD). The working hypothesis is that the bioavailability profile of the drugs can be significantly improved when formulated as water-soluble, chewable tablet. Incannex owns patents on chewable formulations cannabinoids and opioid agonists and/or antagonists and it is hypothesised that this combination of active pharmaceutical ingredients and delivery system will provide benefits for sufferers of OUD, of which there are estimated 26.8 million people worldwide[1]. In the USA the opioid epidemic has been declared a public health emergency, affecting millions with the misuse of prescription opioids and illicit substances. According to the National Institute of Health (NIH), by far the largest components of the overall economic burden, however, are the value of reduced quality of life from opioid use disorder ($390.0 billion) and life lost to opioid overdose ($480.7 billion). These two cost components account for over 85% of the total economic burden[2].

The Global OUD market size was valued at USD 2.8 Billion in 2022 and is estimated to grow at CAGR of 10.7% from 2022-2032, reaching USD 7.8 Billion in 2032. Asia Pacific is expected to grow the fastest during the forecasted period[3].

This announcement has been approved for release to NASDAQ by the Incannex Board of Directors.

About Incannex Healthcare Inc.

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for the treatment of obstructive sleep apnoea (OSA), traumatic brain injury (TBI) and concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis, inflammatory bowel disease, anxiety disorders, addiction disorders, and pain, among other indications.

U.S. FDA approval and registration, subject to ongoing clinical success, is being pursued for each drug and therapy under development. Each indication under investigation currently has no, or limited, existing registered pharmacotherapy (drug) treatments available to the public and represent major global economic opportunities to Incannex and its shareholders.

Incannex has a strong patent filing strategy in place as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners. The Company holds 19 granted patents and 30 pending patent applications. Incannex is listed on the NASDAQ as IXHL

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Forward-looking statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements are made as of the date they were first issued and were based on current expectations and estimates, as well as the beliefs and assumptions of management. The forward-looking statements included in this press release represent Incannex's views as of the date of this press release. Incannex anticipates that subsequent events and developments may cause its views to change. Incannex undertakes no intention or obligation to update or revise any forward-looking statements, whether as of a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Incannex's views as of any date after the date of this press release.

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[1] https://www.nature.com/articles/s41572-019-0137-5

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8091480

[3] https://www.sphericalinsights.com/reports/opioid-use-disorder-oud-market