



Incannex Completes Successful Pre-IND Meeting with the FDA for CannQuit-N; a Novel Solution for Tobacco Smoking Cessation

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MELBOURNE, Australia and NEW YORK, Feb. 16, 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-N for tobacco smoking cessation and control of relapse.

The pre-IND teleconference included representatives from various divisions of the FDA covering all regulatory aspects of the CannQuit-N development program. The Agency had reviewed the CannQuit-N meeting package and provided recommendations on key design aspects of the proposed clinical trials, including the timing of efficacy endpoints and specific details on safety endpoints. The FDA also confirmed proposed strategies for manufacturing and quality control are appropriate.

The productive discussion with the FDA is an important milestone for the development of CannQuit-N and will guide the continued development of the drug product.

About CannQuit-N

CannQuit-N is a smoking cessation chewing gum that combines controlled-release of cannabidiol (CBD) with nicotine. Incannex holds granted patents on chewing gums that combine CBD and nicotine. The combination of CBD and nicotine is hypothesised to better assist addicted smokers to quit smoking than traditional nicotine containing chewing gum, an NRT (nicotine replacement therapy) per annum which totalled \$2.92 bln in 2021 and is expected to grow to \$7.93 by 2029 at CAGR of 13.31%. <https://www.databridgemarketresearch.com/reports/global-nicotine-replacement-therapy-market>

CBD has been found to inhibit the $\alpha 7$ nicotinic acetylcholine receptor which plays a role in the reinforcing effects of nicotine. Interactions of endocannabinoids with the CB1 receptor are essential in mediating behaviours associated with addiction and there are preliminary clinical observations suggesting that CBD may help to reduce the number of cigarettes smoked in a day.

Medicated chewing gums deliver their active ingredients directly into the circulation of the oral mucosa, ensuring that the effects of the ingredients are delivered rapidly, but also in a sustained manner to reduce cravings for longer than other delivery methods. Rapid onset and sustained effect are both qualities desirable for the treatment of addiction disorders. Furthermore, the act of chewing, known as mastication, has complex stimulating mechanisms including anxiolytic effects which have been demonstrated in other scientific assessments.

Cigarette smoking and nicotine addiction causes a wide variety of preventable diseases and remains a leading cause of preventable death in the United States, where it is responsible for more than 480,000 deaths per year, including nearly 42,000 deaths from second-hand smoke exposure. The total economic cost of smoking in the US is estimated at more than US\$300 billion per annum. This includes nearly US\$225 billion in direct medical care for adults and more than \$156 billion in lost productivity.

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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