Date: April 14, 2023
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

# Incannex Appoints QPS to Advance CannQuit-N™ (Nicotine), CannQuit-O™ (Opioid) and Renecann™ Products in the USA and EU

**Melbourne, Australia, April 14, 2023** – Incannex Healthcare Ltd (Nasdaq: IXHL). (ASX: IHL) ('Incannex' or 'the Company') a pharmaceutical company developing proprietary medicinal cannabinoid products and psychedelic assisted psychotherapies for unmet medical needs is pleased to announce that is has appointed Quest Pharmaceutical Services ('QPS') to provide regulatory advice and manage clinical trials for the development of CannQuit™ and ReneCann™ products for addiction and immune-disordered skin diseases.

QPS was founded in 1995 to provide high-quality bioanalytical LC-MS/MS contract services. Since then, QPS has grown from a small molecule bioanalysis shop of three people to more than 1,250+ employees in the United States, Europe, India, and Asia. Over the years, QPS has adopted additional services, including Neuropharmacology, DMPK, Toxicology, Translational Medicine, Early Phase Clinical Research and Phase II – IV Clinical Research.

QPS is currently drafting pre-investigational new drug (pre-IND) submissions for both the European Union's European Medicines Agency ('EMA') and the US Food and Drug Administration ('FDA') for the CannQuit™ and ReneCann™ Products. Once advice is received from the regulators over the proposed research and development programs, QPS will retain a leading role in the management of clinical trials, which will be undertaken to provide relevant evidence of safety and efficacy.

CEO and Managing Director, Mr Joel Latham said; "QPS is a perfect fit for us to develop these products across the globe. Not only will QPS assist us with conducting clinical research, it has been engaged to advise upon the quickest route to commercialising the products in different regulatory jurisdictions."

The CannQuit™ and ReneCann™ products are patent protected and were acquired as part of the acquisition of APIRx Pharmaceuticals ('APIRx'), completed in 2022. These products are being developed and manufactured by Eurofin's Scientific (Eurofins). Data collected by Eurofins on the quality and stability of the products will be key components of future regulatory packages.

**CannQuit-Nicotine (N)™**

A functional, controlled-release, pharmaceutical-grade (cGMP) medicated chewing gum formulation comprising cannabidiol (CBD) and nicotine. Drug product development and testing is underway at Eurofins.

Nicotine chewing gum is already an effective and accepted treatment and maintenance product throughout the globe with annual sales amounting to $US5.2B in 2020, however, the progression to complete smoking cessation is limited. By adding CBD in a patented combination, CannQuit-N™ is hypothesised by Incannex to improve upon the therapeutic outcomes of nicotine only gum. The patented technology of controlled and sustained release of the active ingredients also is believed to improve the therapeutic value of this novel drug candidate.

**CannQuit-Opiod (O)™**

A functional, controlled-release, pharmaceutical-grade medicated chewing gum formulation that combines CBD and an opioid antagonist/agonist in a proprietary water-soluble chewable tablet for the treatment of opioid addiction. The water-soluble chewable tablet, known as CheWell, is uniquely loaded with a high CBD dose and in addition the unique polymer composition that ensures faster onset and higher bioavailability as shown in preliminary PK/PD studies. At present, stability evaluation is being done for the pharmaceutical ingredients within CannQuit-O™.

The opioid epidemic has reached critical levels in the United States and the industrialized world. Fatal opioid overdoses and opioid use disorder cost the United States $1.02 trillion in 2017, as measured by the Centre for Disease Control (CDC) in the journal Drug and Alcohol Dependence, which is the most complete accounting of America's opioid crisis to date. Treatments for opioid use disorder total US$64B per annum and there have been no major new treatment solutions in recent decades.

**Renecann™**

ReneCann™ is Incannex's proprietary topical cannabinoid formulation for treatment of dermatological conditions caused by disorders of the immune system, including vitiligo, psoriasis, and atopic dermatitis, otherwise known as eczema. The unique formulation combines Cannabigerol ('CBG') and CBD. CBG is a non-psychoactive cannabinoid with potent anti-inflammatory properties. Analytical characterization of the APIs, including validation of the assay methods have been completed and formulation development of the Renecann drug product, including placebo, have commenced.

A previous version of ReneCann™, formulated by APIRx, was used in an in-human proof of concept study with dosing over a 6-week period. The study was conducted at the Maurits Clinic, The Netherlands, and led by a world-renowned dermatologist Dr. Marcus Meinardi, MD, PhD. In the study, ReneCann™ reduced disease scores in patients with each of the target skin diseases. Patients with vitiligo, psoriasis and atopic dermatitis were observed to experience improvements in symptoms of 10%, 33% and 22% respectively. In particular, the results for study participants with vitiligo are highly encouraging, partly because the incidence of the disease is high at 0.5-1.0% of the global population and treatments for it are limited.

According to Allied Market Research:

- The global vitiligo treatment market size was valued at $410.5 million in 2021, and is projected to reach $625.8 million by 2031, according to the Allied Market Research.
- The global atopic dermatitis market size was valued at $5.3 billion in 2021, and is projected to reach $22.6 billion by 2031.
- The global psoriasis treatment market size was valued at USD 25.3 billion in 2021 and is estimated to reach around USD 51.24 billion by 2030.

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

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**About Incannex Healthcare Limited**

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 Australian Stock Exchange (ASX) with stock code "IHL" and has American Depository Shares listed on NASDAQ under code "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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