Incannex Engages Eurofins to Manufacture ReneCann Therapeutic Topical Application for Immune Disordered Skin Diseases

Melbourne, Australia, November 29, 2022 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), (‘Incannex’ or the ‘Company’) a clinical-stage pharmaceutical company developing medicinal cannabinoid and psychedelic therapies for unmet medical needs, is delighted to announce that it has engaged multinational contract development and manufacturing organisation (CDMO) Eurofins Scientific (‘Eurofins’) to manufacture ReneCann therapeutic for topical applications.

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 ReneCann formulation is commercially protected by granted and pending patents acquired by Incannex as part of the APIRx acquisition that was finalised in August of 2022.

The unique formulation combines Cannabigerol (‘CBG’) and Cannabidiol (‘CBD’). CBG is a non-psychoactive cannabinoid with potent anti-inflammatory properties. A previous version of ReneCann 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. Vitiligo is observed when pigment-producing cells (melanocytes) stop producing melanin, causing the loss of skin colour in patches and the discoloured areas generally become larger over time. ReneCann was associated with diffuse re-pigmentation (usually perifollicular or from the borders of the lesion) and efficacy lasted for weeks eventually before depigmentation recurred.

The ReneCann Drug product that is produced by Eurofins CDMO will be used in clinical trials confirming the safety and therapeutic effect of ReneCann in vitiligo, psoriasis, and atopic dermatitis. Data on the quality and stability of ReneCann generated as part of this project at Eurofins will be used in the chemistry and manufacturing control modules of future regulatory packages with the US Food and Drug Administration (FDA). ReneCann also has the potential to be assessed for efficacy in other diseases where topical application may provide a benefit over conventional oral dosed cannabinoid formulations.
Dr Mark Bleackley, chief scientific officer of Incannex, said: “The production of ReneCann adds a new route of cannabinoid delivery to the Incannex portfolio, opening the possibility for direct application of cannabinoid medicines to affected areas in dermatological conditions. ReneCann is also Incannex’s first product to incorporate CBG, a minor cannabinoid. Expansion into minor cannabinoids provides us the opportunity to explore different activity profiles of this diverse family of molecules across a range of new therapeutic areas”.

About Eurofins Scientific

Eurofins Scientific through its subsidiaries is the world leader in food, environment, pharmaceutical and cosmetic product testing, discovery pharmacology, forensics, advanced material sciences, and in agroscience Contract Research services. It is also one of the global independent market leaders in genomics and in the support of clinical studies, as well as in BioPharma Contract Development and Manufacturing. In addition, Eurofins is one of the key emerging players in specialty esoteric and molecular clinical diagnostic testing in Europe and the USA. With over 61,000 staff across a network of more than 1,000 independent companies in 59 countries and operating 940 laboratories, Eurofins offers a portfolio of over 200,000 analytical methods for evaluating the safety, identity, composition, authenticity, origin and purity of biological substances and products, as well as for innovative clinical diagnostics. The objective of Eurofins companies is to provide their customers with high-quality services, accurate results on time and expert advice by their highly qualified staff.

Eurofins is listed on the Paris Euronext exchange with a market valuation of approximately 13B Eurodollars. Incannex is investigating the use of Eurofins to develop and manufacture additional drug candidates acquired via the acquisition of APIRx Pharmaceuticals.

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 patents. Incannex is listed on the Australian Stock Exchange (ASX) with stock code “IHL” and has American Depository Shares listed on NASDAQ under code “IXHL”.

Investors: [investors@incannex.com.au](mailto:investors@incannex.com.au)

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.

Contact Information:

**Incannex Healthcare Limited**
Mr Joel Latham
Managing Director and Chief Executive Officer
+61 409 840 786
joel@incannex.com.au

**Investor Relations Contact – United States**
Alyssa Factor
Edison Group
+1 (860) 573 9637
afactor@edisongroup.com