Date: August 02, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex Engages Curia to Scale-up Manufacture of cGMP IHL-216A

Highlights:

- Incannex have engaged Curia to scale up cGMP fill-finish manufacture of IHL-216A
- Engagement of Curia follows achievement of "proof-of-concept" formulation development
- A patent has been filed on the composition of IHL-216A
- The first cGMP batch of IHL-216A manufactured at Curia will be used in a phase 1 clinical trial
- Incannex is targeting a pre-IND meeting with FDA in Q3 2022 to discuss the most efficient clinical trial development plan to achieve commercialisation for IHL-216A.

Melbourne, Australia, August 02, 2022 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing unique medicinal cannabinoid pharmaceutical products and psychedelic medicine therapies for unmet medical needs, is pleased to announce that it has engaged Curia Global, Inc. ('Curia') to further develop and manufacture GMP-grade IHL-216A, Incannex's proprietary inhaled drug product for the treatment of concussion and traumatic brain injury ('TBI').

Engagement of Curia represents substantial progress in the development of IHL-216A and follows the achievement of pleasing results from extensive proof-of-concept studies that were initiated in June 2021 (announced on June 21, 2021). This foundational work established the optimal inhaled formulation of IHL-216A at an experimental scale. Curia is engaged to scale-up the fill-finish manufacture of IHL-216A in compliance with Current Good Manufacturing Practice ('cGMP').

Curia will also generate data on the quality and stability of IHL-216A to support future regulatory filings, including a US Food and Drug Administration ('FDA') pre-investigation new drug ('IND') package and subsequent IND application. The first cGMP batch manufactured at Curia will be used in a phase 1 clinical trial, which will commence once feedback on the proposed IHL-216A development plan is received from FDA in a pre-IND meeting that Incannex is aiming to set with FDA in Q3 2022.

Incannex Chief Scientific Officer Dr Mark Bleackley said; "Scaling up cGMP manufacture of IHL-216A is an exciting step in the development of our product and represents a critical milestone for delivering an inhaled drug, such as IHL-216A. Its manufacture will facilitate investigation of the product in the well-controlled clinical trials we are designing, with feedback from FDA, to assess the safety and therapeutic benefit in patients with traumatic brain injuries".

"IHL-216A has been observed to have a greater neuroprotective effect in a rodent model of sports concussion than CBD, and results indicate restoration of the spatial memory deficit post-concussion with IHL-216A administration. Given that there is no registered treatment for the secondary effects of

concussion, or traumatic brain injury, we look forward to working with Curia during this exciting phase of development for IHL-216A".

"Curia is honoured to be partnering with Incannex as it addresses an area of unmet patient need," said Chris Conway, president, R&D, Curia. "We look forward to our scientific collaboration to help advance this potential treatment from idea to impact."

About Curia Global

Curia, formerly AMRI, is a leading contract research, development and manufacturing organization providing products and services from R&D through commercial manufacturing to pharmaceutical and biopharmaceutical customers. Curia's 3,700 employees at 29 locations across the U.S., Europe and Asia help its customers advance from curiosity to cure. Learn more at CuriaGlobal.com.

About IHL-216A

IHL-216A is a combination drug that combines CBD with any volatile anaesthetic agent, including isoflurane. IHL-216A has been designed to be administered soon after head trauma to reduce secondary brain injuries that lead to neurological deficits.

CBD and isoflurane, as combined in IHL-216A, have previously been found by Incannex to act synergistically to reduce neuronal damage, neuroinflammation and behavioural deficits that are consequences of TBI. In experiments using a rodent controlled cortical impact model of TBI, IHL-216A outperformed CBD in reducing neuronal damage in post-mortem Nissl staining analysis of brain tissue by 53% for CA1 and 60% for CA2 in the hippocampal region of the brain. IHL-216A reduced the Iba1 neuroinflammation marker by 35% more than CBD alone and 123% more than isoflurane administered alone. IHL-216A also restored the spatial learning and memory deficit associated with TBI to a greater extent than either CBD or isoflurane alone in a rodent model of sports concussion (announced May 10, 2022).

An International Patent Application entitled "Compositions and methods for the treatment or prevention of traumatic brain injury" has been filed as part of the IHL-216A development program. This patent application has entered the national phase in multiple jurisdictions. A second patent on the specific composition of the formulation used in IHL-216A has also been filed.

About Traumatic Brain Injury and Concussion

Sixty-nine (69) million people are estimated to incur a TBI annually(1). There are currently no registered pharmaceutical agents approved for the treatment of TBI. Current treatment strategies for TBI range from rest in minor TBI and concussion to surgical interventions to deal with hematomas in severe TBI(2).

1. Dewan MC, Rattani A, Gupta S, Baticulon RE, Hung Y-C, Punchak M, Agrawal A, Adeleye AO, Shrime MG, Rubiano AM. 2018. Estimating the global incidence of traumatic brain injury. J Neurosurg 130:1080–1097.

2. Galgano M, Toshkezi G, Qiu X, Russell T, Chin L, Zhao L-R. 2017. Traumatic Brain Injury: Current Treatment Strategies and Future Endeavors. Cell Transplant 26:1118–1130.

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 anxiety disorders, obstructive sleep apnoea (OSA), traumatic brain injury (TBI)/concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis and inflammatory bowel disease. U.S. FDA approval and registration, subject to ongoing clinical success, is being pursued for each drug and therapy under development. Each indication represents major global markets and currently have no, or limited, existing registered pharmacotherapy (drug) treatments available to the public.

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. Incannex is listed on the Australian Stock Exchange (ASX) with stock code “IHL” and also 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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