

Incannex Engages Catalent for Development and cGMP Manufacture of Psilocybin Drug Product for Clinical Trials and Potential Commercial Use

Highlights:

- Incannex has engaged Catalent for the development and cGMP manufacture of Incannex's own psilocybin drug product.
- The psilocybin is designed for use in Incannex's ongoing psilocybin-assisted psychotherapy "PsiGAD" clinical development program for generalised anxiety disorder and for potential future commercial use or supply as a cGMP pharmaceutical grade product.
- Development of the drug product includes generation of the necessary quality and stability data to support future regulatory filings including IND applications.

Melbourne, Australia, March 03, 2023 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a pharmaceutical company developing proprietary medicinal cannabinoid products and psychedelic medicine therapies for unmet medical needs, is pleased to announce that it has engaged Catalent ('Catalent') to develop and manufacture a cGMP-grade psilocybin drug product for: (1) use in Incannex's proprietary psilocybin-assisted psychotherapy drug development program and (2), potential wider commercial use.

Commencing development and manufacture of a psilocybin drug product follows an internal analysis of the interim data from the PsiGAD phase 2 clinical trial, giving Incannex confidence to proceed with formulation development and cGMP manufacture of its own psilocybin. Interim results from the PsiGAD trial remain internally confidential to maintain blinding and integrity of the trial, however, a report from the independent data safety monitoring board (DSMB) on the interim results will be released soon, when available.

Incannex CEO and Managing Director Mr Joel Latham said; "Having our own source of pharmaceutical grade psilocybin not only allows our company to freely undertake clinical trials, it also creates and assists with number of commercial opportunities which are currently at an advanced stage of investigation by the company, and will be announced in the coming weeks, following board appraisal and approval."

Catalent has been engaged to develop the formulation, generate required quality and stability data for regulatory filings, and establish cGMP manufacture of a drug product to be used in future clinical trials. The proposed manufacturing process will be designed so that it will be scalable to commercial supply levels when appropriate.

Incannex Chief Scientific Officer Dr Mark Bleackley said; "Engaging Catalent for development and cGMP manufacture of Incannex's psilocybin drug project is an important milestone for the PsiGAD program.



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The resulting drug product, and supporting data, will form an important component of future regulatory filings and will facilitate Incannex's development of psilocybin-assisted psychotherapy for Generalised Anxiety Disorder. This therapy has the potential to help millions of people whose lives are seriously impacted by severe anxiety and for whom current treatment options have not been effective. We look forward to working with Catalent on the continued development of this exciting drug product."

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.

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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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