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ASX Announcement

Cleo Completes Design Transfer

Highlights

- **Design transfer establishes Cleo's capability to deliver reproducible and reliable results for its ovarian cancer detection test**
- **Tender process for the selection of an antibody manufacturer in final stage**
- **Technology transfer to commence by end of the calendar quarter**

MELBOURNE, AUSTRALIA, 12 February 2024: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:COV) (CLEO, or the Company) is pleased to confirm that it has concluded design transfer activities relating to the core technology for its ovarian cancer detection test.

DESIGN TRANSFER

Cleo has completed the design transfer of the CXCL10 active ratio test into a more rigorous laboratory environment, ensuring the capability to deliver reproducible and reliable results. This advancement enhances the performance of the test, transitioning it from academic methodologies to a compliant and robust laboratory setting. The test will continue to progress through the development pathway, culminating in an FDA 510K application for regulatory approval.

As outlined in the clinical validation study publication (see ASX Announcement 6 November 2023), the CXCL10 active ratio measures changes in a key immune process to give an indication of the presence of a tumour, and is an important component of Cleo's biomarker panel to be incorporated within its commercially available test kits.

Cleo's first product to market will be a pre-surgical triage test, designed to determine the likelihood that a pre-surgical ovarian mass is either benign or malignant prior to referral for surgical intervention. The test will be used in conjunction with clinical and radiological evaluation of a patient by physicians, to improve the referral process and better inform clinical decision making workflows. Ovarian masses (typically benign cysts) are very common and non-life threatening; around 10% of women will have surgery during their lifetime for investigation of an ovarian mass, representing a significant market opportunity for Cleo's first product.

The completion of design transfer forms the basis for Cleo to progress technology transfer to a manufacturer as the next step. The Company is currently finalising a tender process for the selection of an antibody manufacturer and expects it will be in a position to announce a partner by the end of the quarter, with completion of technology transfer to follow shortly thereafter.

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Non-Executive Director and Lead Medical Advisor Professor Tom Jobling
Non-Executive Director Lucinda Nolan

Commenting on the completion of design transfer, Cleo Chief Scientific Officer, Dr Andrew Stephens, said:

"The confirmation of design transfer demonstrates that the Cleo core antibody reagents and methodologies are robust and suitably reliable for transfer to a third party manufacturer for commercial test-kit development."

-ENDS-

This ASX announcement was authorised for release on behalf of the CLEO Diagnostics Ltd Board by:
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About Cleo Diagnostics Ltd ASX:COV

CleoDX aims to bring to market a simple blood test for the accurate and early diagnosis of ovarian cancer based on the novel patented CXCL10 biomarker, which is produced early and at high levels by ovarian cancers but is largely absent in non-malignant disease. The test aims to distinguish benign from malignant growths in a standard format that will be readily compatible with existing equipment used by diagnostic laboratories worldwide.

The platform is backed by over 10 years of scientific Research & Development at the Hudson Institute of Medical Research, with two clinical studies conducted with over 500 patients. Pursuant to a licence agreement with the Hudson Institute of Medical Research, Cleo has a worldwide exclusive licence to commercialise the intellectual property which underpins its operations and the ovarian cancer tests.

The clinical unmet worldwide need is urgent. An accurate and early detection blood test could shift survivability for ovarian cancer significantly as seen with other cancers. Cleo is advancing the availability of its simple blood test, under a modular execution strategy which is designed to eventually address all ovarian cancer detection markets with specific tests including surgical triage, recurrence, high risk, and early-stage screening.

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