

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.

Cleo Diagnostics Ltd ASX:COV

Level 2, 480 Collins Street, Melbourne, VIC, 3000
ACN 655 717 169 T +61 3 9614 0600 E office@cleodx.com

Directors

Chair and Non-Executive Director: **Adrien Wing**
Chief Executive Officer and Executive Director: **Dr Richard Allman**
Chief Scientific Officer and Executive Director: **Dr Andrew Stephens**
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:

Richard Allman, Chief Executive Officer.

For more information, contact:

Richard Allman
Chief Executive Officer
+613 9614 0600
office@cleodx.com

Elvis Jurcevic
Investor Relations
+614 08 268 271
ej@cleodx.com

Forward Looking Statements: This release may contain certain forward-looking statements with respect to matters including but not limited to the financial condition, results of operations and business of Cleo and certain of the plans and objectives of Cleo with respect to these items. These forward-looking statements are not historical facts but rather are based on Cleo's current expectations, estimates and projections about the industry in which Cleo operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates", "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of Cleo, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. Cleo cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Cleo only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. Cleo will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

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.

