ASX Announcement

Completion of First Triage Test Clinical Validation Study

Highlights

- **Results from the first clinical validation study of the CleoDX Triage Test, performed in a 334 patient cohort, have been published in the peer-reviewed journal "Cancers"**
- **The article, entitled '*A novel predictive multi-marker test for the pre-surgical identification of ovarian cancer*' provides a detailed overview of the high performance of Cleo's ovarian cancer diagnostics test**
- **The article concluded that Cleo's ovarian cancer test:**
  - **Was highly accurate with 95% sensitivity[1] / 95% specificity[2];**
  - **Correctly discriminated malignant from benign samples; and**
  - **Out-performed and was superior to current clinical methods.**
- **Peer-review provides important validation of Cleo's technology and commercial strategy, targeting the surgical triage market where accurate and sensitive identification of malignant tumours is essential.**

MELBOURNE, AUSTRALIA, 6 November, 2023: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:COV) (CLEO, or the Company) is pleased to announce the publication of an article on its triage test for ovarian cancer.

PEER REVIEWED PUBLICATION

Cleo's first clinical validation study for its ovarian cancer triage test has been published in the peer-reviewed international journal 'Cancers'. The results confirm the high accuracy of the CleoDX Triage Test, which was independent of menopausal status, and showed that it out-performed the two most widely used clinical scoring systems (the "Risk of Malignancy Index" and "Risk of Malignancy Algorithm") for discriminating benign from malignant ovarian disease.

A copy of the publication is available here: https://www.mdpi.com/2072-6694/15/21/5267

Moreover, the CleoDX surgical triage test correctly identified 81% of early-stage cancer patients in the cohort.

---

[1] **Sensitivity** refers to the ability of a test to correctly identify patients with the tested for disease (true positive rate).

[2] **Specificity** refers to the ability of a test to correctly identify people without the tested for disease (true negative rate).

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 publication, Cleo Chief Scientific Officer, Dr Andrew Stephens, said:

> *"These results confirm that our core technology is robust and accurate, and most importantly can identify cancers at an early stage. These results strongly support our planned further development of this core technology aimed at ovarian cancer screening in the longer term".*

CLEO Chief Executive, Richard Allman, added:

> *"This is an important step forward as we work towards our goal of an FDA approved triage test. I look forward to providing further updates to the market as we progress through our development program."*

The next step in development will confirm functionality of the commercially available kits in an independent clinical trial, the results of which will be submitted to the FDA for regulatory approval. Cleo anticipates commencement of this trial before the end of CY 2023.

OPPORTUNITY FOR CLEO AND OVARIAN CANCER DIAGNOSTICS MARKET

At present there is no clinically routine pre-surgical method for reliable evaluation and differentiation of benign vs malignant ovarian cancer tumours. Radical surgery is the cornerstone of cancer management, with complete hysterectomy being the norm. Removal of the ovaries, however, predisposes women to multiple co-morbidities including increased risk of cardiovascular disease, dementia and certain cancers amongst others. There is a clear need to differentiate benign vs malignant cases pre-surgically to enhance patient outcomes.

Cleo has defined a staged execution strategy to deliver it's simple blood test which is focused on three key markets across pre-surgical triage testing, high-risk/recurrence detection, and broader screening programs. Achieving a positive outcome here from a peer-reviewed publication, has a material impact on the Company's pathway with respect to the initial triage market. The Company will now use the publication of its test performance to further define the scope of the triage market.

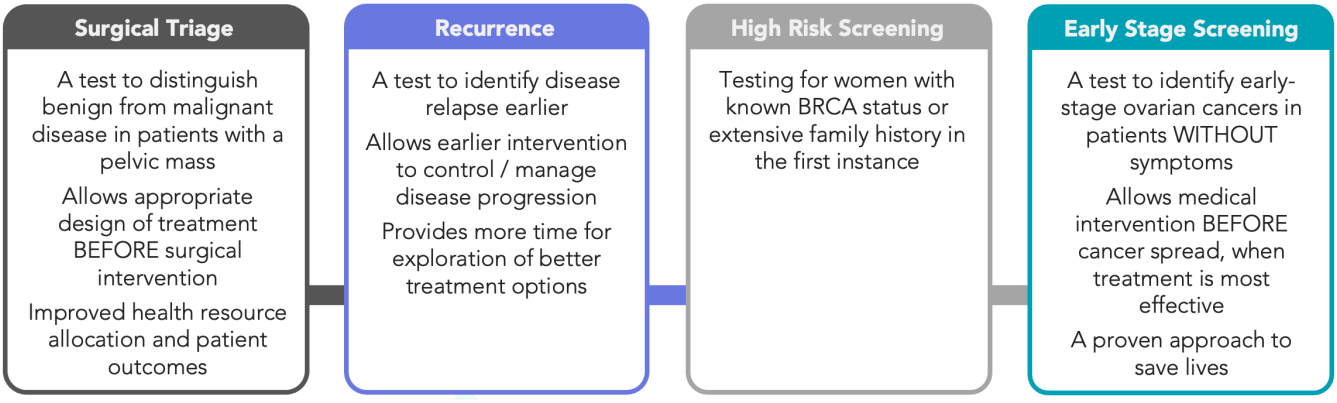


Figure 1: Ovarian cancer diagnostic markets targeted by Cleo

-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.