

## Cleo's Ovarian Cancer Blood Test Outperforms Current Clinical Benchmark

### Highlights

- A benchmarking study comparing CLEO's ovarian cancer blood test against ultrasound has been published in scientific journal "Cancers"
- The study confirmed that CLEO's initial test for the surgical triage market:
  - Significantly outperforms current clinical workflows that use CA125 and ultrasound to predict malignancy;
  - Correctly detected 90% of early-stage cancers compared to only 50% using standard workflows; and
  - Can be easily adopted for use into clinical practice.
- The superior performance of CLEO's test now compared to all current routine clinical tools shows the significant global potential for the test in clinical decision making prior to surgical intervention.

MELBOURNE, AUSTRALIA, 29 May 2024: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:COV) (CLEO, or the Company) is pleased to announce the publication of a milestone article on its blood test for the accurate and early detection of ovarian cancer.

The article, entitled 'Utility of a Multi-Marker Panel with Ultrasound for Enhanced Classification of Adnexal Mass' was published in peer reviewed medical journal, "Cancers".

A copy of the publication is available here: <https://www.mdpi.com/2072-6694/16/11/2048>

### CLEO's Blood Test Far Superior to Current Standard of Care

The benchmarking study compared CLEO's ovarian cancer blood test against the current standard clinical workflows that use CA125 and ultrasound to predict malignancy. The outcomes of the study build on previous results (see ASX Announcements 6 November 2023, and 25 March 2024) which clearly demonstrate that CLEO's ovarian cancer blood test is far superior to all routine clinical tools used by doctors to 'predict' the diagnosis of an adnexal mass prior to surgery.

Importantly, CLEO's test correctly detected 90% of early-stage cancers compared to only 50% using current standard of care workflows of CA125 and ultrasound.

#### 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](mailto: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 latest study data, CLEO Chief Executive, Richard Allman, said:**

*“Our peer-reviewed publication strategy is delivering gold-standard clinical evidence which is vitally important as we begin to engage with potential early adopters of our technology.*

*Having demonstrated now that the CLEO ovarian cancer blood test is far superior to CA125 and ultrasound in our initial pre-surgical triage market, we open up new dialogue with physicians to consider the potential material benefits that CLEO brings for their patients.*

*More broadly, these encouraging results on early-stage cancer detection provide impetus for us to progress the development of CLEO’s screening test for ovarian cancer.”*

### **Clinical Evidence Supports Commercial Pathway**

As a part of CLEO’s commercialisation program, the Company is focusing on a number of initiatives in parallel that will deliver appropriate routes to adoption of its tests following regulatory approval and market launch. CLEO’s publication strategy continues to deliver gold-standard clinical evidence which provides a strategic foundation for clinical implementation and uptake, and critically supports the Company’s case for reimbursement of the blood test to enable early revenue.

Over the past 6 months CLEO has generated significant performance data for its initial test aimed for the pre-surgical triage market. The test has now been benchmarked against all of the routinely available clinical tools which aid in the assessment of an adnexal mass. The Company is pleased to report that our prototype test is superior to all of those existing tools.

### **Current Standard of Care Inadequate**

When a physician identifies a suspected adnexal mass, the patient will typically be referred for ultrasound imaging and a CA125 test to ‘predict’ the risk of malignancy. Ovarian cancers are only diagnosed after extensive and radical surgical intervention, and currently up to 90% of suspected malignancies are post-surgically diagnosed as benign. Conversely, less than half of cancer patients receive primary referral to an oncology surgeon, delaying (and sometimes compromising) their treatment. This is a major failing in the pre-surgical clinical evaluation process that impacts both patient treatment outcomes and the allocation of healthcare resources.

Despite its poor performance CA125 is exclusively recommended in medical guidelines, and represents over \$1 billion market with an estimated CAGR ~4%<sup>1</sup>. Its ubiquitous use has remained largely unchallenged since its introduction in the 1980s.

For this reason, CLEO has focused on generating strong evidence to show doctors how the CLEO test can provide an important and material improvement to their current clinical practice. The test has been developed in a format familiar to clinicians prescribing standard panel blood tests, and will integrate seamlessly into current workflows. It is minimally invasive, economical and will utilise existing pathology lab infrastructure.

**-ENDS-**

---

<sup>1</sup> CA125 Test Market – Industry Size, Share, Trends 2032. [www.marketresearchfuture.com](http://www.marketresearchfuture.com)



**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

CLEO 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.

