ASX Announcement

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.

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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%[1]. 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-

[1] CA125 Test Market – Industry Size, Share, Trends 2032. www.marketresearchfuture.com

This ASX announcement was authorised for release on behalf of the CLEO Diagnostics Ltd Board by:
Richard Allman, Chief Executive Officer.

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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.