ASX Announcement

Peer-Review Further Supports CLEO's Ovarian Cancer Detection Technology

Highlights

- **CLEO's second peer-reviewed dataset has now been published in medical journal "Diagnostics"**
- **The study concluded that CLEO's test:**
  - **Correctly identified most cancer cases that were missed by the standard marker CA125;**
  - **Eliminated the majority of "false positive" results caused by CA125 use; and**
  - **Correctly identified the majority of patients with early-stage ovarian cancers.**
- **Peer review validates CLEO's technology and commercial strategy targeting the surgical triage market where accurate and early cancer identification is critical.**

MELBOURNE, AUSTRALIA, 25 March 2024: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:**COV**) (**CLEO**, or the **Company**) is pleased to announce the publication of further data on its triage test for ovarian cancer.

The article, entitled *'Reclassification of patients with ambiguous CA125 for optimised pre-surgical triage'* was published in the peer reviewed medical journal, Diagnostics.

A copy of the publication is available here: https://www.mdpi.com/2075-4418/14/7/671

The article concluded:

a) CLEO's test correctly identified most cancer cases missed by CA125, including a majority of patients with early stage cancers;

b) The test provided superior identification of benign disease to eliminate the majority of "false positive" results obtained using CA125; and

c) The test efficiently discriminated malignant from benign samples.

Commenting on the outcomes published, CLEO Chief Executive, Richard Allman, said:

"These results demonstrate that the CLEO ovarian cancer triage test is far superior to the current standard of care using the CA125 benchmark. Our test will improve the initial clinical investigation process, helping clinicians to triage patients far more effectively than current methods.

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The ability to identify early-stage cancers also supports our ultimate goal of an ovarian cancer screening program using CLEO technology.

Our cancer detection technology is supported by a foundation of gold-standard scientific evidence. These publications will underpin regulatory approvals with the Food and Drug Administration (FDA) and will form a crucial part of CLEO's market entry activities. They provide the required evidence for doctors to prescribe CLEO's blood test and for reimbursement by health insurers."

BACKGROUND

Further data for CLEO's ovarian cancer triage test has been published in the peer-reviewed international journal 'Diagnostics'.

The study assessed the use of CLEO's triage test to rescue those cases where CA125 provided an incorrect indication. Accurately identifying cancer patients early is critical to provide immediate referral to a gynaecological oncology specialist for surgery; whilst allowing better management of patients with non-malignant disease.

The study compared the potential clinical benefit to patients if CLEO's Test was used for initial diagnostic work-up instead of CA125, the current gold standard ovarian cancer biomarker.

CLEO's triage test accurately re-assigned the majority of "missed" cancers that were incorrectly identified as low risk using CA125, and was effective in both pre- and post-menopausal patients.

False negative detections (i.e. a "missed" cancer case) were reduced by ~71% for post-menopausal patients and ~54% for pre-menopausal patients, many of whom had early-stage disease. This is particularly important in the pre-surgical setting, where rapid identification and triage to a gynaecological oncology surgeon is critical to achieve greatest benefit for patients.

Similarly, false positive detections (i.e. where CA125 incorrectly classified benign disease as "high-risk") were reduced by ~57% and ~75% for post- and pre-menopausal patients respectively. This is essential to reduce unnecessary surgical interventions, which has significant relevance for pre-menopausal women where cancer diagnoses are typically rare and fertility preservation strategies are highly important.

IMPORVEMENT OVER EXISTING TECHNOLOGY

The current "gold-standard" tumour biomarker Cancer Antigen 125 (CA125) has poor accuracy, particularly for the detection of early-stage disease and discrimination between benign versus malignant status.

Around 20% of ovarian cancers do not express CA125, and it is often in the "normal" range in patients with early-stage disease. False negative CA125 results (where cancers are "missed") are common, and complicate the referral of cancer patients to a gynaecologic oncology specialist for primary surgery.

Conversely the abnormal elevation of CA125 in non-malignant conditions (e.g. endometriosis, fibroids, pelvic inflammatory disease and others) results in high false positive detection (where benign cases are incorrectly suspected to be cancer). Unsurprisingly, post-surgical diagnoses of benign disease out-number malignancy by ~9:1.

CLEO's latest data highlights the use of its triage test to rescue those cases where CA125 proves inaccurate, and demonstrates significant potential to improve the initial clinical management for patients with malignancy – particularly at an early stage.

-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

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.