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.”
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.

IMPROVEMENT 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:
Richard Allman, Chief Executive Officer.

For more information, contact:
Richard Allman
Chief Executive Officer
+61 3 9614 0600
office@cleodx.com

Elvis Jurcevic
Investor Relations
+61 4 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

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.