ASX Announcement

CLEO Advances Commercial Product Development with Completion of Alpha Testing

Highlights

- **Completion of alpha testing using commercial prototypes of CLEO's Ovarian Cancer pre-surgical triage assay kits**
- **Testing was conducted at CLEO's laboratory and confirmed:**
  - **Robust and reproducible performance of all assay kit components;**
  - **Ability to differentiate Ovarian Cancer from benign disease;**
  - **Performance consistent with CLEO's previously published in-house testing.**
- **CLEO now moves to next phase of development comprising assay optimisation, beta testing, and manufacturing scale-up in parallel to ongoing clinical trials to support FDA submission.**

MELBOURNE, AUSTRALIA, 12 May 2025: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited (ASX:COV) (CLEO** or **the Company)** is pleased to announce the successful completion of alpha testing for its Ovarian Cancer pre-surgical triage test kit, marking a critical step along its manufacturing pathway towards commercial production.

Alpha Testing Completed

Alpha testing involved in-house testing of 120 blood samples using fully functional commercial prototypes provided by R&D Systems, a Food and Drug Administration (**FDA**) approved Contract Manufacturing Organisation **(CMO)**. Testing confirmed a number of important outcomes that allow CLEO to progress its manufacturing activities, including:

- All components of the assay kits met design input specifications;
- Assays demonstrated robust and reproducible performance in multiple validation metrics across analytical precision, reproducibility, and measurement range;
- Most importantly, it confirmed differentiation of benign versus malignant ovarian disease, consistent with CLEO's previously published studies[1].

[1] 3.Stephens AN, Hobbs SJ, Kang S-W, Bilandzic M, Rainczuk A, Oehler MK, Jobling TW, Plebanski M, Allman R (2023). A Novel Predictive Multi-Marker Test for the Pre-Surgical Identification of Ovarian Cancer. *Cancers* doi: 10.3390/cancers 15215267

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Commenting on the achievement, CLEO's Chief Executive Officer, Dr Richard Allman, said:

> *"Completing alpha-testing is a pivotal achievement for CLEO. This validation of technical performance now clears the path to proceed towards scaled-up manufacturing. With strong partners and a clear roadmap, we are confident in our progress toward regulatory clearance and commercial launch."*

Next Steps and Strategic Outlook

This successful completion of this milestone triggers the next phase of development comprising assay feasibility testing, optimisation, verification and manufacturing scale-up for commercial production. These activities will be carried out in partnership with CLEO's U.S. based development and manufacturing collaborator, R&D Systems, a subsidiary of Bio-Techne Corporation based in Minneapolis, USA.

CLEO's structured development strategy ensures that the assay kits used in the Company's ongoing U.S. clinical trials are materially identical to those intended for market release following FDA submission and approval, thereby improving the Company's time to market.

Ovarian Cancer remains a significant unmet need, with over 300,000 new cases diagnosed each year and a 5-year survival rate of only 49%, making it the deadliest cancer to impact women globally. CLEO's pre-surgical test aims to improve diagnostic accuracy and clinical decision-making at the earliest possible point in patient care.

-ENDS-

This ASX announcement was authorised for release by the Board of Cleo Diagnostics Limited.

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About Cleo Diagnostics Ltd ASX:COV

CLEO is bringing 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.