ASX Announcement

CLEO Reaches Key Milestone with Completion of Sample Collection for Pivotal U.S. Clinical Trial

Highlights

- **514 blood samples collected for CLEO's clinical trial, representing a key step toward the Company's FDA submission for its Pre-Surgical Ovarian Cancer Test**
- **624 women enrolled across 19 U.S. sites, demonstrating strong trial execution supporting a robust final study dataset**
- **Binding manufacturing agreement for test kit production remains in the final stages following recent biomarker panel optimisation**
- **Achieving sample target moves CLEO into final execution phase comprising pre-verification, analytical validation, sample testing, clinical data analysis & validation.**

31st March 2026: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce that it has now achieved its recruitment target with 514 blood samples collected for its pivotal U.S. clinical trial, marking completion of a key milestone in the Company's clinical, regulatory and commercialisation pathway.

CLEO's pivotal clinical trial was designed to demonstrate the performance of the Company's Pre-Surgical Ovarian Cancer Test and benchmark against existing tools used to assess the risk of ovarian malignancy. The intended use population comprises women with an adnexal mass for whom surgery is planned.

The trial was designed to recruit a minimum of 500 women, representing a diverse U.S. population. Blood samples were collected prior to surgery and stored under controlled conditions, whilst pathology information was subsequently captured following surgery and diagnosis.

The Company has now successfully recruited 624 women across 19 clinical trial sites, with 514 samples from eligible patients in storage. The natural lag between enrolment and collected samples reflects the standard clinical workflow, where women may be enrolled but still awaiting surgery and / or post-surgical finalisation of their diagnosis.

Consistent with standard clinical trial practice, recruitment continued beyond the 500-women target to ensure a sufficient number of usable samples for final analysis. This strategy recognises that not all recruited patients will ultimately yield complete blood samples and confirmed pathology suitable for inclusion in the final dataset.

CLEO is also in final discussions with a manufacturing partner to enter into a binding agreement for test kit production, following the recent completion of its biomarker panel optimisation (*refer to ASX Announcement dated 23rd March 2026*). Execution of this agreement triggers the next step in the pathway to formal clinical testing.

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Next Steps Toward FDA 510(k) Submission

Next steps to generate the clinical dataset required for FDA submission include:

- **Pre-verification:** internal readiness activities to confirm that CLEO's assay, kit components and testing workflow perform as expected prior to formal validation and subsequent clinical sample testing
- **Analytical validation:** formal demonstration that CLEO's assay, kit components and testing workflow perform consistently and reproducibly on the Ella™ platform, providing the technical foundation required to commence clinical sample testing
- **Clinical sample testing:** testing of collected blood samples from the clinical trial in accordance with approved protocols to generate assay result data using the final CLEO test kit
- **Clinical data analysis and validation:** statistical analysis of assay results against confirmed pathology outcomes to evaluate test performance (e.g. sensitivity, specificity, NPV, PPV) and generate the clinical evidence package required for FDA 510(k) submission.

The timeline of these activities is dependent upon manufacturing scheduling, which will be released to the market following execution of a binding agreement with CLEO's manufacturing partner.

-ENDS-

This ASX announcement was authorised for release on behalf of the CLEO Diagnostics Ltd Board.

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About Cleo Diagnostics Ltd ASX:COV

CleoDX aims to bring to market a simple blood test for the accurate and early diagnosis of ovarian cancer based on the novel patented biomarker, CXCL10, 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 15 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.