ASX Announcement

Cleo Commences U.S. Clinical Trials

Highlights

- **U.S. clinical trials commenced with first patients enrolled over 8 recruitment centres**
- **Trial will validate the use of CLEO's ovarian cancer blood test for the U.S. market**
- **Pathway set toward FDA submission in CY2025.**

MELBOURNE, AUSTRALIA, 6 September 2024: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:COV) (CLEO, or the Company) is pleased to confirm the commencement of U.S. clinical trials for its ovarian cancer diagnostic blood test.

Commencement of U.S. Clinical Trials

CLEO's pivotal FDA-enabling clinical trial has commenced in the United States, with first patients recruited into the study. The trial is designed to benchmark CLEO's technology, with recruitment targeting a minimum of 500 patients with diversity representative of the U.S. population. The data collected will underpin a submission to the Food and Drug Administration (**FDA**) seeking approval for clinical use of CLEO's ovarian cancer detection blood test in the world's largest diagnostic market.

Eight participating medical institutions, located across 6 U.S. states, are currently recruiting patients. Eligible patients at these sites will be identified by their primary physician and given the opportunity to participate during their consultation. Additional sites may also be included as the trial progresses.

Commenting on the commencement of U.S. clinical trials, CLEO Chief Executive, Richard Allman, said:

> *"Commencement of our U.S. trials confirm a significant milestone for CLEO and sets a clear pathway now for our planned entry into the U.S. market.*
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> *We have already demonstrated that CLEO's ovarian cancer blood test is highly accurate, can detect early-stage cancer, and importantly is significantly better than clinical tools used today. This gives us confidence in moving through the trial activities to enable our FDA submission.*
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> *It is important to note that no diagnostic test exists today for ovarian cancer. Diagnosis can only be made after surgery. The opportunity in front of us is immense and CLEO is well positioned and funded to achieve access into our initial pre-surgery test market."*

-ENDS-

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.