ASX Announcement

CLEO Further Expands Ovarian Cancer Trial with Siles Health

Highlights

- **Prominent women's ultrasound specialist Siles Health joins CLEO's ovarian cancer trial**
- **Inclusion of Siles will provide important insights to support clinical implementation strategies for market adoption of CLEO's ovarian cancer blood test**

MELBOURNE, AUSTRALIA, 10 December 2024: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:**COV**) (**CLEO**, or the **Company**) is pleased to announce further expansion of clinical trial sites for its simple and accurate blood test for the early detection of ovarian cancer.

Further Expansion of Clinical Trials

CLEO has expanded its ovarian cancer Australian trial to include Siles Health network of 13 clinics across Melbourne and regional Victoria. Siles Health is a prominent women's health and ultrasound specialist, with Associate Professor Charles Siles, acting as Principal Investigator. The collaborative partnership aims to:

- provide important insights into clinical workflows that will ultimately support clinical implementation strategies for successful market adoption of CLEO's ovarian cancer blood test;
- supplement CLEO's broader trial strategy by accessing a larger cohort of patient samples that may bolster the FDA-enabling U.S. trial;
- continue to expand broader market awareness for CLEO; and
- verify and optimise CLEO's ovarian cancer blood test.

Commenting on the partnership, Associate Professor Charles Siles, Founder of Siles Health, said:

"The opportunity to collaborate with Cleo Diagnostics on their ovarian cancer diagnostics technology reflects our shared commitment to advancing women's health. We see the unmet clinical need every day therefore we are genuinely excited that CLEO's ovarian cancer blood test has the potential to positively impact women's lives through accurate and early diagnosis."

CLEO Chief Executive, Richard Allman, added:

"As we progress though our clinical trials initiatives, our focus continues on how this ultimately supports successful market adoption of CLEO's ovarian cancer blood test, specifically in the U.S. as our first market in the next year.

In this context, the partners that CLEO is engaging play an important role in how the Company is executing on its ambition to transform ovarian cancer diagnostics."

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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.