ASX Announcement

The Royal Women's Hospital Melbourne Joins CLEO Ovarian Cancer Trial

Highlights

- **Leading specialist hospital for women's health, the Royal Women's Hospital (the Women's) Melbourne to participate in CLEO's ovarian cancer trial**
- **The Women's inclusion is designed to broaden patient sampling that will ultimately be used to verify and optimise CLEO's ovarian cancer blood test**
- **Focus remains on U.S. clinical trial with patient recruitment progressing and program on track to support FDA submission in CY2025**

MELBOURNE, AUSTRALIA, 27 November 2024: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:**COV**) (**CLEO**, or the **Company**) is pleased to announce further progress across clinical trials for its simple and accurate blood test for the early detection of ovarian cancer.

Clinical Trials Advancing

The Royal Women's Hospital Melbourne Joins CLEO Trial

CLEO has expanded its ovarian cancer Australian trial with the inclusion of the Royal Women's Hospital as a participating site, with eminent gynaecological oncology specialist, Associate Professor Orla McNally, acting as Principal Investigator. The Women's is Australia's leading specialist hospital for women's health where the partnership aims to:

- complement CLEO's broader trial strategy by increasing the cohort of patient samples;
- expand market awareness for CLEO;
- verify and optimise CLEO's ovarian cancer blood test; and
- potentially bolster the U.S. trial.

Commenting on the partnership, Associate Professor Orla McNally, Director of Oncology and Dysplasia Service at the Women's, said:

> *"Early and accurate detection of ovarian cancer is a critical unmet need. CLEO's ovarian cancer blood test has the potential to better inform clinical workflows for clinicians to ultimately provide better health outcomes for women.*
>
> *We are pleased to be working with Cleo Diagnostics on this shared vision."*

U.S. Trials

Primary focus for the Company is the U.S. clinical trial in the world's largest diagnostic market. The trial will underpin a Food and Drug Administration (**FDA**) 510(k) submission which remains on track for

CY2025. Patient recruitment continues to progress as planned across eight medical trial locations. Patient samples are being collected in line with trial objectives targeting a minimum of 500 patients with diversity representative of the U.S. population.

The Company is also progressing multiple commercial initiatives in parallel with respect to its reimbursement strategy, international collaborations, grant applications, and market engagement of early adopters to ensure the CLEO ovarian cancer blood test is available quickly in initial targeted markets.

Commenting on the trial progress, CLEO Chief Executive, Richard Allman, said:

> *"The addition of the Royal Women's Hospital is important to our trials strategy in the context that CLEO is focused on working with leading organisations in the treatment of ovarian cancer.*
>
> *Our U.S. trials are progressing well which continues to support our plan for FDA submission in 2025. In parallel, we are working across a number of commercial initiatives that will ensure that CLEO's ovarian cancer blood test is positioned well to be available in our initial markets as soon as possible."*

-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
+613 9614 0600
office@cleodx.com

Elvis Jurcevic
Investor Relations
+614 08 268 271
ej@cleodx.com

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.