ASX Announcement

CLEO Selects U.S. Clinical Trial Sites

Highlights

- **Initial U.S. clinical trial sites contracted following Institutional Review Board (IRB) approval**
- **7 sites selected across Texas, Arizona, Florida, Nevada, California, and New York**
- **First patients being recruited with trials to begin mid-August 2024**
- **Australian ethics approval also obtained with mirror trial to run at Monash Health.**

MELBOURNE, AUSTRALIA, 31 July 2024: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:**COV**) (**CLEO**, or the **Company**) is pleased to announce progress for its U.S. clinical trials in support of its FDA application for its ovarian cancer diagnostic blood test.

U.S. Clinical Trial Sites Selected

CLEO is pursuing regulatory approval in the U.S. as the largest diagnostics market in the world. Prior to submission with the Food and Drug Administration (**FDA**), the Company will complete a study that will benchmark CLEO's technology through a 500 patient clinical trial. CLEO's U.S.-based clinical trials manager, Lindus Health, has now obtained Institutional Review Board (**IRB**) approval for, and formally contracted 7 clinical trial sites across the U.S.

This follows CLEO obtaining IRB approval for its clinical trial design last month. A wide geographic range of sites ensures that a diverse representation of the U.S. population is met. Initial sites that have been selected and contracted are located in Texas, Arizona, Florida (x2), Nevada, California, and New York. First patients are being recruited with the trials to begin mid-August 2024.

Commenting on the selection of U.S. trial sites, CLEO Chief Executive, Richard Allman, said:

> *"This marks the first visible activity by CLEO in the U.S. and effectively a large step in the journey there to bring our ovarian cancer diagnostic blood test to the largest diagnostic market in the world.*
>
> *We believe that we have a sound strategy and plan that has been supported by the FDA and IRB, and we now move to progress our clinical trials that will ultimately drive our market entry.*
>
> *I look forward to announcing the start of trial activities in the coming weeks."*

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Australian Clinical Trials

CLEO is also pleased to announce that Human Research Ethics Committee Approval (HREC) has also been obtained for a similar trial design to be conducted in Australia. Whilst the U.S. arm will provide the full complement of samples for CLEO's FDA application, any supplementary samples obtained locally will be used to further refine CLEO's technology and test algorithms prior to commercial launch.

-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.