ASX Announcement

Cleo Commences U.S. Regulatory Process with FDA

Highlights

- **Initial pre-submission meeting held with the U.S. Food & Drug Administration (FDA) where CLEO outlined its submission framework and clinical plan**
- **Positive feedback from FDA provides confidence in CLEO's U.S. regulatory strategy**
- **Clinical trial design receives Institutional Review Board (IRB) approval in both U.S. and Australia**

MELBOURNE, AUSTRALIA, 26 June 2024: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:**COV**) (**CLEO**, or the **Company**) is pleased to announce progress in its regulatory strategy for its first commercial product, the pre-surgical triage test.

Commencement of U.S. Regulatory Process

CLEO has completed an initial pre-submission meeting with the U.S. Food and Drug Administration (**FDA**) where the Company outlined its submission framework and clinical plan for its ovarian cancer detection blood test. The pre-submission meeting is designed to permit CLEO to receive early guidance from FDA review teams prior to an eventual application submission.

The meeting was interactive with the FDA providing constructive and positive feedback on CLEO's approach to obtaining regulatory approval in the U.S. for its ovarian cancer detection blood test. This outcome provides confidence that CLEO's clinical trial designs and strategic direction are appropriately aligned with FDA requirements.

Early interaction with the FDA is important as a part of CLEO's U.S. market access strategy for a number of reasons, as the guidance outcomes allow CLEO to:

- Refine its clinical trial design to maximise resourcing and quality of data;
- Reduce the possibility of rework;
- Shorten the potential timeframe to application submission; and
- Operate with an open and transparent approach.

CLEO is pursuing expedited FDA approval for its first ovarian cancer detection product - the pre-surgical Triage test - via the 510(k) application pathway. This approach provides the quickest pathway to achieve regulatory approval for devices that achieve "substantial equivalence" to an existing predicate.

Clinical Trial Activity

CLEO's clinical trial design has now been reviewed and approved in both the U.S. and Australia. Institutional Review Board (**IRB**) approval is a legal requirement for any clinical trial, to ensure trial activities are ethically sound and compliant with federal regulations.

Trial sites are being formally contracted, and patient recruitment is to commence shortly. CLEO is working with U.S.-based Contract Research Organization (**CRO**), Lindus Health to manage the international arm of the trial.

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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.