ASX Announcement

CLEO Continues on Pathway for U.S. Regulatory Approval with Positive FDA Feedback

Highlights

- **CLEO receives positive feedback from the U.S. FDA at a second pre-submission meeting for its Ovarian Cancer Pre-Surgical Triage Test**
- **FDA guidance supports CLEO's clinical trial design and regulatory positioning**
- **Feedback reinforces alignment with FDA expectations, reduces regulatory risk and positions CLEO strongly ahead of its upcoming 510(k) submission.**

MELBOURNE, AUSTRALIA, 15th September 2025: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce that it has received positive feedback from the U.S. Food and Drug Administration (**FDA**) at its second pre-submission meeting for the Company's first commercial product, being its Ovarian Cancer Pre-Surgical Triage Test.

CLEO's Ovarian Cancer Test Progresses Towards U.S. Commercial Launch

Following its initial meeting with the FDA last year, CLEO has completed its second pre-submission meeting with the Company's Quality and Regulatory Manager, Emma Lester, attending in person at the FDA Headquarters in Silver Spring, Maryland. The focus of the meeting was on technical details surrounding the following:

- Clinical trial design;
- Sample stability;
- Use of biobank samples to support critical studies;
- Clinical specificity (the ability of its test to correctly identify ovarian cancer without mistake identifying other conditions); and
- Intended use and clinical workflow.

The meeting was highly constructive, with the FDA offering positive and detailed feedback. The guidance reinforces confidence that CLEO's clinical trial and broader strategic direction remain aligned with regulatory expectations.

Importantly, this feedback enables CLEO to further enhance the robustness its pivotal clinical trial design by strengthening data collection processes to support a high-quality submission. In addition, it helps reduce regulatory risk ahead of the Company's 510(k) submission - an expedited approval process for technologies that demonstrate substantial equivalence to an existing predicate device. CLEO will remain actively engaged with U.S. regulatory bodies leading up to its submission next year.

Commenting on the meeting, CLEO Chief Executive Officer, Dr Richard Allman, said:

"This second round of positive feedback from the FDA marks another important milestone in our regulatory journey. The FDA's guidance enables us to strengthen our trial design and move forward with greater confidence in our 510(k) strategy. It supports our approach and underscores the opportunity CLEO has to deliver a clinically meaningful and accessible solution to support more appropriate surgical triage for ovarian cancer."

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This ASX announcement was authorised for release on behalf of the CLEO Diagnostics Ltd Board.

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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.