ASX Announcement

Analysis of Insurance Data Significantly Expands Addressable Market for CLEO's Pre-Surgical Ovarian Cancer Test

Highlights

- **Updated U.S. insurance data identifies over ~2 million women per year[1] could benefit from CLEO's Pre-Surgical Ovarian Cancer Test**
- **Findings reinforce the unmet need and significant commercial potential for CLEO's patented technology**
- **Data will inform a broader health economic study to support CLEO's market entry, reimbursement and early revenue generation.**

MELBOURNE, AUSTRALIA, 6th November 2025: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce that it has established a significantly larger Total Addressable Market (**TAM**) for the United States (**U.S.**) with respect to its Pre-Surgical Ovarian Cancer Test.

Larger Initial Addressable Market Established

CLEO commissioned Norstella, a market-leading global pharma intelligence solution provider (*refer to ASX Announcement dated 18th August*), to reassess its initial pre-surgery patient market in the U.S. ahead of market entry next year.

Analysis of the U.S. patient market was based on open insurance claim data across commercial, Medicaid and Medicare channels, representing majority of the U.S. population and providing a near real-time snapshot of healthcare utilisation.

Using a comprehensive and detailed insurer dataset, ~3.4 million U.S. women each year were identified with a suspected ovarian or adnexal mass (including malignant, benign, and indeterminate disease states). Of these, an average ~2.0 million women per year proceeded to further diagnostic investigation through radiological imaging and/or biomarker testing (e.g. CA125 test). This ~2.0 million cohort aligns with current pre-surgical triage practice, and clearly defines the TAM and immediate commercial opportunity for CLEO's Pre-Surgical Ovarian Cancer Test.

Given the superior diagnostic performance of CLEO's test compared to existing methods (e.g. CA125), the broader population of ~3.4 million women may represent an extended market that could also benefit from CLEO's technology as clinical adoption expands. Over the longer term, increasing recognition by clinicians and payors of the accuracy, clinical utility, and cost-efficiency of CLEO's test could drive uptake beyond the initial addressable market.

[1] *Represents annual average from 1st January 2022 to 30th October 2025.*

Coupled with existing reimbursement levels for similar diagnostic technologies, the findings indicate a materially larger and more accessible commercial opportunity than previously estimated. Further refinement to quantify those women proceeding to surgery will provide an increasingly accurate view of the active pre-surgical triage market.

Importantly, the new data also highlights geographical areas of high patient volume allowing CLEO to strategically target and optimise its U.S. launch strategy. The Company acknowledges that the data does not capture the recurrence and/or asymptomatic population screening markets, which are substantially larger. CLEO's commercial strategy is built around a staged approach to ovarian cancer detection – beginning with pre-surgical triage and extending into recurrence monitoring, and ultimately early-stage screening. This deliberate pathway enables CLEO to progressively expand its addressable market and continue building value across all tiers of the ovarian cancer detection cycle, supporting long-term growth and leadership in women's health diagnostics.

The information underpins a broader health economic study being conducted in partnership with EntityRisk and Norstella that will quantify the clinical and economic value of CLEO's test in real-world healthcare settings. By linking robust TAM data with comprehensive health economic modelling, CLEO will generate evidence-based justification for reimbursement discussions with U.S. payors and healthcare networks – ultimately helping to maximise the availability and adoption of its test and future revenue generation.

Commenting on the outcome, CLEO's Chief Executive Officer, Dr Richard Allman, said:

> *"Establishing a much larger U.S. patient market is an amazing opportunity for CLEO's technology considering ovarian cancer has the highest mortality rate of all female gynaecological cancers.*
>
> *We also expand the evidence base we need to progress into detailed health economic modelling. This work will be central to our U.S. reimbursement strategy, ensuring we are positioned for successful market entry and adoption."*

-Ends-

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 15 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, and early-stage screening.