ASX Announcement

CLEO Appoints Partner to Commence U.S. Market Access Program

Highlights

- **CLEO has appointed New York-based healthcare industry consultancy, HcFocus, to support the commencement of its U.S. market access program**
- **HcFocus will provide specialised and strategic expertise to assist CLEO to navigate the complexities of U.S. health systems and the regulatory environment**
- **The U.S. program will focus on a roadmap to achieve FDA approval, reimbursement, a clinical trial, as well as industry and doctor engagement**
- **Ultimately, the partnership will ensure CLEO achieves regulatory approval in the U.S. and can deliver early revenue from its ovarian cancer blood test in the world's largest diagnostic market.**

MELBOURNE, AUSTRALIA, 2 April 2024: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:**COV**) (**CLEO**, or the **Company**) is pleased to announce the appointment of New York-based HcFocus as a key partner for its U.S. market access program.

U.S. Market Access Program

The U.S. represents CLEO's largest market opportunity for its ovarian cancer blood test and is the focus for initial regulatory approval through the Food and Drug Administration (**FDA**). In order to successfully execute on its U.S. market entry plan, CLEO will partner with New York-based strategic healthcare consultancy, HcFocus, appointing the company now to assist it with commencing commercial activities.

HcFocus specialises in helping med-tech companies access the U.S. healthcare market by leveraging their deep healthcare industry experience and networks to deliver market access results.

CLEO will leverage HcFocus' expertise to navigate the complexities of U.S. health systems and regulatory environment, with the companies to focus on a roadmap to achieve:

- FDA approval for CLEO's ovarian cancer blood test;
- Reimbursement, including with private insurers;
- Clinical trials;
- Support KOL appointments; and
- Industry and doctor engagement.

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The move to advance the U.S. market access program is well timed following two initial peer-reviewed publications recently released assessing the performance and benchmarking of CLEO's ovarian cancer blood test. These publications detail the performance characteristics of the prototype triage test, which significantly exceeded comparable tests on market and the existing gold-standard biomarker, CA125 – the current guideline mandated test (See ASX Announcements 6 November 2023 and 25 March 2024).

CLEO's publication strategy will underpin market access activities and is designed to publicise the test performance parameters and develop the clinical utility message, essentially building the clinical evidence bank required for doctors and insurers to support and adopt the prescribing of CLEO's ovarian cancer blood test. HcFocus will be able to quickly assess the results from the initial peer-reviewed publications and provide guidance to ensure that Cleo's evidence package will meet the needs of U.S. reimbursement bodies, including the private insurers. Further clinical evidence will be delivered in the coming months as the Company progresses towards the initial FDA 510(k) application for the pre-surgical triage test.

Commenting on the partnership with HcFocus, CLEO Chief Executive, Richard Allman, said:

> *"Dr Gross and the team at HcFocus are extremely well-credentialed with a wealth of practical experience navigating the U.S. healthcare system, private insurers and the FDA in the field of women's health.*
>
> *The commencement of CLEO's U.S. market access program now sets us on a clear path to ensure that once we achieve regulatory approval, the Company can be in a strong position to deliver early revenue from its ovarian cancer blood test in the world's largest diagnostic market."*

HcFocus President, Dr Susan Gross, added:

> *"HcFocus is delighted to aid CLEO's efforts in expanding this important technology for women's health into the U.S. market. As an Ob/GYN, I know that finding ways to identify this disease early will be a game changer".*

-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 HcFocus LLC

HcFocus is a boutique firm with deep connections to payors, including decades of experience obtaining reimbursement and helping high-impact companies achieve success in the U.S. market. HcFocus offers innovative, comprehensive consultancy services to companies including medical device, biotech and pharma, seamlessly integrating reimbursement, regulatory and medical affairs teams to achieve clients' financial goals.

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.