CLEO Granted U.S. Patent for Key Novel Ovarian Cancer Biomarker

Highlights

- **U.S. Patent secures IP protection in one of the world's largest diagnostics markets**
- **Supports CLEO's commercialisation pathway into its primary U.S. target market**
- **Further patents are pending in additional countries**

MELBOURNE, AUSTRALIA, 22 August, 2023: Ovarian cancer diagnostics company Cleo Diagnostics Limited (ASX: COV) (CLEO, or the Company) is pleased to announce the grant of U.S. Patent No: US 11,725,048, "CXCL10 Binding Proteins and Compositions Thereof" (Patent), by the U.S. Patents and Trademarks Office (USPTO).

U.S. PATENT

The granted Patent covers CLEO proprietary biomarkers and antibody formulations, which comprise the core technology of the Company's ovarian cancer diagnostic blood test. This Patent family is directed towards C-X-C motif chemokine ligand 10 (CXCL10) binding proteins and methods of diagnosing a condition, such as a malignancy, comprising determining a level of CXCL10 in a subject. Determination of the level of CXCL10 may also be utilised to monitor tumour burden, malignancy progression or likelihood of tumour recurrence in a subject.

The U.S. Patent expands the Company's Intellectual Property (IP) portfolio, adding to the patent granted in Australia earlier this year (patent number 2020404453). Additional patent applications are currently pending in Europe, China, India, Japan, Korea, Israel, New Zealand and Singapore.

U.S. MARKET OPPORTUNITY

The U.S. is the largest diagnostic market in the world, and represents the Company's primary target market for its potentially lifesaving simple diagnostic blood test. Ovarian cancer survival rates are much lower than other cancers that affect women, largely due to the fact that existing testing is insufficient to identify early stage cancers or differentiate from benign disease. Diagnosis is only made following radical surgery to remove the ovaries. The 5 year survival rate for ovarian cancer is 49%, compared to 92% for breast cancer1 where early detection screening exists.

A significant unmet clinical need exists and CLEO plans to bring to market a suite of ovarian cancer diagnostic blood tests based on the novel patented CXCL10 biomarker, which is expressed early and at high levels by ovarian cancers, but not in non-malignant disease. The tests aim to distinguish benign from malignant growths in a standard format that will be readily compatible with existing equipment used by pathology laboratories worldwide.

The U.S. Patent complements CLEO's regulatory approval strategy designed to access target markets and secure a path to reimbursement approvals in the future. The Company is also currently preparing for the submission of a 510(k) U.S. Food and Drug Administration (FDA) application.

CLEO is initially targeting the delivery of its blood test for the surgical triage market, however has a staged execution strategy that de-risks a pathway to all ovarian cancer diagnostic markets:

- Surgical Triage — Distinguishes benign from malignant disease to allow appropriate design of treatment before surgical intervention is considered;
- Recurrence — Identifies relapse for earlier intervention to control/manage disease progression;

- High Risk Screening — Testing women with known BRCA status or extensive family history; and
- Early Stage Screening — Systematic national screening to identify early stage ovarian cancers in patients without symptoms, to allow medical intervention before cancer spreads.

Early detection is vital. When ovarian cancers are diagnosed at stage 1, patients have over a 90% 5 year survival rate. However, this rate reduces rapidly to <40% if diagnosed once the cancer has spread beyond the ovaries.

Commenting on the U.S. Patent grant, CLEO CEO, Richard Allman, said:

> *"Securing a U.S. Patent not only expands the Company's IP portfolio, but it also marks an important milestone which effectively activates our commercialisation plans to pursue market entry in the largest diagnostics market in the world.*
>
> *CLEO's simple blood test for accurate and early detection of ovarian cancer has the potential to transform the standard of care for women globally."*

-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

CleoDX 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 not 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.