

## 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.

#### Cleo Diagnostics Ltd ASX:COV

Level 2, 480 Collins Street, Melbourne, VIC, 3000  
ACN 655 717 169 T +61 3 9614 0600 E office@cleodx.com

#### Directors

Chair and Non-Executive Director: **Adrien Wing**  
Chief Executive Officer and Executive Director: **Dr Richard Allman**  
Chief Scientific Officer and Executive Director: **Dr Andrew Stephens**  
Non-Executive Director and Lead Medical Advisor: **Professor Tom Jobling**  
Non-Executive Director: **Lucinda Nolan**

## 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.

## -ENDS-

**This ASX announcement was authorised for release on behalf of the CLEO Diagnostics Ltd Board by:**

Richard Allman, Chief Executive Officer.

For more information, contact:

**Richard Allman**

Chief Executive Officer

+613 9614 0600

office@cleodx.com

**Elvis Jurcevic**

Investor Relations

+614 08 268 271

ej@cleodx.com

Forward Looking Statements: This release may contain certain forward-looking statements with respect to matters including but not limited to the financial condition, results of operations and business of Cleo and certain of the plans and objectives of Cleo with respect to these items. These forward-looking statements are not historical facts but rather are based on Cleo's current expectations, estimates and projections about the industry in which Cleo operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates", "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of Cleo, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. Cleo cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Cleo only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. Cleo will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

## 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.

