ASX Announcement

CLEO Delivers Commercial Development Milestone

Highlights

- **CLEO has commenced technology transfer marking the completion of a critical milestone towards the commercial production of its first Ovarian Cancer diagnostic tests**
- **Development will be carried out by global leader in immunoassay technology, R&D Systems, Inc. a subsidiary of Bio-Techne Corporation based in Minneapolis, USA**
- **Final negotiations are underway with selected FDA-registered CMO's ahead of transition to large-scale manufacturing**
- **Milestone achievement represents significant progression along CLEO's strategic pathway towards FDA submission.**

MELBOURNE, AUSTRALIA, 18 March 2025: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO**, or the **Company**) is pleased to announce the commencement of technology transfer activities supporting the development of its simple blood test for the early and accurate detection of Ovarian Cancer. This marks the completion of a critical milestone in the manufacturing pathway for CLEO to deliver its commercially available, FDA-compliant diagnostic test kit.

TECHNOLOGY TRANSFER

After successfully completing design transfer, CLEO has commenced the next phase of its strategic development with the commencement of technology transfer. This process involves the transfer of its in-house development activities, including hybridoma cell line development, antibody production and testing, and selection and finalisation of reagents, to a manufacturer to facilitate commercial production.

To assist with this, CLEO has engaged U.S.-based R&D Systems, Inc., a global leader in immunoassay technology and a subsidiary of the Bio-Techne Group, to scale-up and assemble CLEO's proprietary antibodies for use in CLEO's initial Ovarian Cancer test targeted at the surgical triage market. With state-of-the-art production facilities and globally recognised expertise, the partnership with R&D Systems, Inc. ensures the successful progression of commercial prototype development and supports CLEO's transition to large-scale manufacturing. R&D Systems, Inc. will undertake the remaining steps towards pre-production kit assembly and testing.

Following successful testing, CLEO's selected CMO will assist in scaling production capability, in addition to verification and validation activities, ensuring the production of GMP and ISO13485 compliant in-vitro diagnostic (**IVD**) kits for clinical deployment. These test kits will support the

completion of CLEO's ongoing clinical trials in the U.S. and Australia, which will enable CLEO to submit its 510(k) application to the FDA.

Negotiations with key FDA-approved CMOs are in their final stages, with the ultimate decision to be based upon manufacturing capability, regulatory compliance and ability to scale to production to meet demand upon product launch.

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

> *"The commencement of technology transfer marks a pivotal milestone in CLEO's strategic pathway toward commercialisation. During this phase, we refine and scale our assay technology, to ensure the Company is well positioned to progress its Ovarian Cancer test from prototype production to a commercially available, FDA-compliant diagnostic kit.*
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> *More broadly, this step is also integral to our strategy of delivering a highly accurate, accessible cancer diagnostic solution that addresses a critical and global unmet need in population screening for Ovarian Cancer detection."*

-ENDS-

This ASX announcement was authorised for release by the Board of Cleo Diagnostics Limited.

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About Cleo Diagnostics Ltd ASX:COV

CLEO is bringing 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.