ASX ANNOUNCEMENT

Lumos Diagnostics announces Commencement of FebriDx CLIA Waiver Study

Key Highlights

- Lumos has commenced the pivotal FebriDx CLIA Waiver study in the United States, with the first patient successfully tested
- FebriDx can aid clinicians with appropriate antibiotic use decisions and will hopefully improve antibiotic stewardship
- It is anticipated between 500 – 800 patients will need to be enrolled across six sites to achieve the required 120 positive bacterial cases for the study. Completion of the study is anticipated by the forthcoming US spring season of 2025
- The Biomedical Advanced Research and Development Authority (BARDA) is supporting the CLIA waiver study with previously announced non-dilutive funding of US$2,984,571
- Official study commencement and first patient tested triggers the first two milestone payments under the BARDA partnership, valued at a total of US$925,217
- In addition to funding, BARDA is providing study support, regulatory expertise, and support for the application to obtain a CLIA waiver from the US FDA

MELBOURNE, Australia (19 December 2024) – Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") a leader in rapid, point-of-care diagnostic technologies, is pleased to announce that the FebriDx CLIA Waiver study has officially commenced, with the first patient successfully tested.

Official study commencement and first patient in has triggered the invoicing by Lumos for the first two milestone payments, valued at US$925,217, under the previously announced non-dilutive BARDA partnership funding.

FebriDx is a unique, rapid point-of-care test that uses a fingerstick blood sample to aid in the differentiation between bacterial and non-bacterial infections. Knowing whether a patient has a bacterial infection has a direct impact on reducing unnecessary antibiotic prescriptions, limiting the spread of antibiotic-resistant bacteria, and helping providers know when to initiate antibiotic treatment.

This study will evaluate the use of the FebriDx device by untrained users in a CLIA waived setting compared to trained professionals. It will be conducted in multiple CLIA Waived clinical sites across the United States. Between 500 and 800 patients are expected to be enrolled to achieve the required 120 positive bacterial cases necessary for the study. It is anticipated to run through the forthcoming US spring season of 2025, after which a formal submission will be prepared for the FDA.

Doug Ward, Managing Director of Lumos Diagnostics, commented: *"We are very pleased to commence this pivotal clinical study, particularly with BARDA's invaluable support. Achieving CLIA-waived status would enable FebriDx to reach a broader market and empower healthcare providers with a reliable tool for delivering accurate and objective health insights to their patients."*

As previously announced (ASX: 3 October 2024), Lumos is proud to partner on the study with the Biomedical Advanced Research and Development Authority (BARDA). BARDA is providing US$2,984,571 in non-dilutive funding to support the FebriDx CLIA waiver study and US FDA application, as well as regulatory, technical and clinical expertise in support of this important initiative, reinforcing its commitment to advancing medical technologies.

The first two milestones under the funding initiative have now been achieved. The first, related to study preparation and launch, is valued at US$596,914, and the second, for enrolling the first patient, is US$328,303. Lumos has now submitted invoices to BARDA for these amounts and expects payment for these first two milestones by the end of January 2025.

At the conclusion of the study, Lumos hopes to achieve a successful reclassification of FebriDx from moderate complexity to a CLIA-waived device. This would significantly increase its market reach in the US, with the total addressable market expanding from 18,000 to around 270,000 potential customer sites—a 15-fold increase—unlocking a potential market opportunity, valued at approximately US$1.7 billion annually.

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This announcement has been approved by the Lumos Disclosure Committee.

About Lumos Diagnostics

Lumos Diagnostics specializes in rapid and complete point-of-care diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customized assay development and manufacturing services for point-of-care tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercializes novel Lumos-branded point-of-care tests that target infectious and inflammatory diseases.

For more information visit lumosdiagnostics.com.

Forward-Looking Statements

This announcement contains forward-looking statements, including references to forecasts. Forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions, and other important factors, many of which are beyond Lumos' control and speak only as of the date of this announcement. Readers are cautioned not to place undue reliance on forward-looking statements.

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