ASX ANNOUNCEMENT

Lumos Diagnostics Reaches 50% Recruitment Milestone in FebriDx CLIA Waiver Clinical Study

Key Highlights

- **Successfully enrolled 61 of the required 120 bacterial positive patients in the CLIA waiver clinical study for FebriDx**
- **At the current accrual rate, the study is anticipated to be completed by Q4 CY2025, with an FDA CLIA waiver application expected to be submitted in October 2025**
- **439 Patients recruited, $298,457 payment from BARDA will be triggered when the 500th patient is enrolled**
- **A successful CLIA waiver would unlock access to a U.S. total addressable market exceeding US$1.0 billion, enabling broader deployment of FebriDx across healthcare settings**

MELBOURNE, Australia (2 June 2025) – Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") a leader in rapid, point-of-care diagnostic technologies, is pleased to announce a significant milestone in its ongoing FebriDx, CLIA waiver clinical study (ASX: 3 October 2024, 19 December 2024). The Company has now successfully achieved 61 bacterial positive patients representing 50% of the target of 120 bacterial positive patient results required for the study.

Total patients enrolled in the study to date are 439 and testing of the 500th patient will trigger a US$298,457 milestone payment from its partner, the Biomedical Advanced Research and Development Authority (BARDA). The bacterial prevalence rate in the study so far is currently at an average of 14% (61/439), however, since Lumos implemented its enrichment strategy in late March the bacterial prevalence rate in the trial has been around 35%.

FebriDx is a unique, rapid test that helps clinicians differentiate between bacterial and non-bacterial acute respiratory infections through a simple fingerstick blood sample, delivering results quickly at the point-of-care. This allows clinicians to make more informed treatment decisions at the initial point of care, supporting appropriate antibiotic stewardship and helping to combat the global challenge of antimicrobial resistance. By aiding clinicians in faster, better decisions at the point-of-care, FebriDx has the potential to improve patient outcomes, reduce unnecessary antibiotic prescriptions, and lower overall healthcare costs.

This clinical study is a critical step towards securing a CLIA Waiver from the U.S. Food and Drug Administration (FDA), enabling FebriDx to be used in a broader range of healthcare settings, including U.S. physician offices, urgent care clinics, or other outpatient clinics that do not operate under high-complexity laboratory certification.

At the current accrual rate the study is anticipated to conclude in Q4 CY2025. Subject to successful data outcomes, Lumos expects to submit its CLIA waiver application to the FDA in Q4 CY2025.

Lumos Diagnostics Managing Director, Doug Ward, commented: *"Reaching the halfway mark in bacterial positive patient recruitment for our CLIA waiver clinical study is an important achievement for Lumos. We are encouraged by the progress of the study with the support of BARDA and remain focused on delivering a successful outcome that expands the availability of FebriDx to clinicians and patients across the U.S."*

"A successful CLIA waiver would unlock access to a U.S. total addressable market exceeding US$1.0 billion and significantly expand the commercial potential for FebriDx in point-of-care settings by up to 15 times our current available market opportunity."

The Company continues to work closely with its clinical partners to complete enrolment and data collection in a timely manner. Lumos will provide further updates on the progress of the CLIA waiver study as key milestones are reached.

-Ends-

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.

Media Contact:
Haley Chartres – Australia
H^CK Director
haley@hck.digital
+61 (0) 423 139 163

Investor Contact:
George Kopsiaftis
IR Department
ir@lumosdiagnostics.com
+61 409 392 687

Company Registered Office:
Lumos Diagnostics Holdings Ltd
Level 4, 100 Albert Rd
South Melbourne, VIC 3205, Australia
+61 3 9087 1598