ASX ANNOUNCEMENT

Lumos Diagnostics Reaches 500th Patient Enrollment Milestone in FebriDx CLIA Waiver Clinical Study

Key Highlights

- **Successfully enrolled 500th patient in FebriDx CLIA waiver clinical study, triggering US$298,457 milestone payment from clinical study partner, BARDA**
- **Enrolled 78 of the required 120 bacterial positive patients to date**
- **Next BARDA milestone payment of US$746,143 subject to achievement of Last Patient Enrolled**
- **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**
- **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 (18 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). The Company has now successfully enrolled its 500th patient in the study, which has triggered a US$298,457 milestone payment from its partner, the Biomedical Advanced Research and Development Authority ("BARDA").

BARDA milestone payments to date now total US$1,223,674, from total committed milestone payments of US$2,984,571, for the achievement of a U.S. Food and Drug Administration ("FDA") CLIA waiver classification for FebriDx. The next BARDA milestone payment of US$746,143 will be triggered on the achievement of the Last Patient Enrolled in the study.

To date the study has recorded 78 bacterial positive patients representing 65% of the target of 120 bacterial positive patient results required for the study. This implies an average bacterial prevalence rate in the study so far of 15.6% (78/500). However, since Lumos implemented its enrichment strategy in late March 2025, 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. 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: *"We are very pleased to have reached this important enrollment milestone in the FebriDx CLIA waiver study. With the 500th patient now enrolled and bacterial prevalence tracking well due to our enrichment strategy, we are approaching the final stages of the study. This positions us well to complete enrollment in the coming months and target submission of our CLIA waiver application to the FDA around October 2025. We remain confident that FebriDx can play a meaningful role in improving point-of-care decision-making and antibiotic stewardship in the U.S. healthcare system."*

The Company continues to work closely with its clinical partners to complete enrollment 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.

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