ASX ANNOUNCEMENT

Lumos Receives US FDA Clearance for FebriDx®

MELBOURNE, Australia (3 July 2023) – Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") a leader in rapid, point-of-care (POC) diagnostic technologies, is pleased to announce that it has received clearance from the US Food and Drug Administration (FDA) to market its FebriDx® rapid, point-of-care test in the United States.

The clearance allows FebriDx to be marketed in the US for use by healthcare professionals as an aid in the diagnosis of bacterial acute respiratory infection and differentiation from non-bacterial etiology in patients presenting in urgent care or emergency care settings. FebriDx is intended to be used in conjunction with clinical signs and symptoms, including other clinical and laboratory findings, to evaluate patients for acute respiratory infection.

Following a presubmission meeting in January 2023, Lumos submitted a new 510(k) application for FebriDx to the FDA earlier this year. The FDA has completed its review of this new application and determined that FebriDx has demonstrated substantial equivalence to the predicate device cited in this application, and has consequently cleared it for marketing in the US. FebriDx is already registered in the UK, Europe, Canada, UAE, Brazil, Turkey, Pakistan, Singapore, Malaysia and Australia.

The inappropriate and unnecessary prescribing of antibiotics is recognised as a significant contributing factor to the growing global emergence of antimicrobial resistant (AMR) strains of bacterial pathogens. In 2021, US healthcare professionals in outpatient settings issued 211 million prescriptions for antibiotics—equivalent to 636 prescriptions per 1,000 persons[1]. Despite acute respiratory infections being predominantly viral in origin, they are the most common diagnosis for which antibiotics are prescribed and up to 40% of these prescriptions are considered unnecessary[2]. As a consequence, one of the core elements of the Centers for Disease Control and Prevention (CDC) Outpatient Antibiotic Stewardship program is to improve antibiotic prescribing by clinicians and their use in patients so that antibiotics are only prescribed and used when needed.

[1] https://www.cdc.gov/antibiotic-use/data/report-2021.html
[2] Antibiotics 2022, 11, 1058. https://doi.org/10.3390/antibiotics11081058

“We are delighted to finally secure clearance to market our FebriDx rapid, point-of-care test in the US as we continue to believe it has an important role to play in antibiotic stewardship,” said Doug Ward, CEO of Lumos Diagnostics. “It is a credit to the Regulatory team at Lumos that we have been able to deliver this outcome from our new 510(k) application significantly ahead of our initial expectations. With this clearance in hand, we anticipate securing our first commercial orders in the US before the end of calendar year 2023. In the meantime, we are continuing to work with distribution partners and potential licensees, as well as establish our own focused sales effort, as we prepare to launch FebriDx in the US.”

-Ends-

This announcement has been approved by the Lumos Disclosure Committee.

About Lumos Diagnostics

Lumos Diagnostics specializes in rapid, cost-effective, and complete point-of-care (POC) diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customized assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercializes novel Lumos-branded POC 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 Contacts:
Matthew Wright – Australia
Director, NWR Communications
matt@nwrcommunications.com.au
+61 (0) 451 896 420

Investor Contact:
Matthijs Smith – Lumos Diagnostics

ir@lumosdiagnostics.com
+61 3 9087 1598

Company Registered Office:

Lumos Diagnostics Holdings Ltd
Level 4, 100 Albert Rd
South Melbourne, VIC 3205
+61 3 9087 1598