ASX ANNOUNCEMENT

Lumos Files Appeal To The FDA For FebriDx®

MELBOURNE, Australia (08 August 2022): Lumos Diagnostics (ASX: LDX) has filed an appeal to the US Food and Drug Administration (FDA) regarding its decision not to grant clearance to market FebriDx® in the US based on the Company's recent 510(k) application.

In July, Lumos announced that, following its review of Lumos' 510(k) application and the FDA's concerns regarding possible risks associated with false negative viral infection test results, the FDA determined that FebriDx did not demonstrate equivalence to the predicate device and consequently it was not granted clearance for marketing in the US. Lumos continues to believe that FebriDx has an important role as an aid to differentiate bacterial from viral infections and to assist with initiatives focused on improving antibiotic stewardship.

In view of this, the Company is continuing to pursue options to secure regulatory clearance to market FebriDx in the US, including the filing of this appeal to the decision that was handed down by the FDA in July. The outcome of this appeal application is expected in Q4 CY2022.

"FebriDx is a key asset in our Lumos-branded product portfolio," said Doug Ward, Chief Executive Officer of Lumo. "The US is a significant and important market for this product. At this time, there is no rapid, point-of-care test available in the US that clinicians can use to help distinguish a bacterial respiratory infection from a viral infection. We continue to believe that FebriDx has an important role in correctly identifying patients who will benefit from antibiotics and, as such, has a role in initiatives to improve antibiotic stewardship. We look forward to working with the FDA to establish a regulatory path to allow us to bring FebriDx to the US market."

This announcement has been approved by the Lumos Disclosure Committee

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About Lumos Diagnostics

Lumos Diagnostics specialises 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 customised assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercialises 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.

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