ASX ANNOUNCEMENT

Outcome of Appeal Application to the FDA for FebriDx®

MELBOURNE, Australia (3 October 2022) – Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") has been advised that, following completion of a supervisory review requested by Lumos, the FDA has upheld its decision that FebriDx® has not demonstrated substantial equivalence to the predicate device identified in its 510(k) application. Consequently, FebriDx has not been granted clearance for marketing in the US. In view of this outcome, Lumos intends to direct its efforts for commercialising FebriDx in markets where it has been already been granted clearance, while primarily focusing on growing its development services and contract manufacturing business.

In response to the FDA's decision in July 2022 not to grant clearance for marketing FebriDx, Lumos initiated an appeal process. The review under this appeal process was not able to consider any information that had not been included in the original application. This review has now been completed and the reviewer has decided to uphold the FDA's original decision that substantial equivalence to the predicate device has not been demonstrated. Consequently FebriDx is not eligible to receive clearance for marketing in the US under the FDA's 510(k) pathway.

Lumos is able to file a new application to the FDA for FebriDx. However, based on the feedback received from the FDA, this is likely to require further investment and time to generate additional data before a new application could be submitted. At this time, Lumos is actively focused on building its pipeline of commercial, revenue-generating projects for its development services and contract manufacturing businesses with a view to accelerating the growth of sustainable revenue streams from these business units. In view of this, Lumos will direct its efforts to commercialise FebriDx in markets where it already has clearance. For the time being, Lumos does not intend to further invest in activities directed towards securing US clearance for FebriDx.

"Clearly this is a disappointing outcome for Lumos as we believe there is a significant need and opportunity for FebriDx in the US," said Doug Ward, Chief Executive Officer of Lumos Diagnostics. "However, we are committed to ensuring that investment and expenditure is closely aligned to achieving commercial outcomes for Lumos. At this time, this means focusing our efforts on building our services and manufacturing businesses and selling our own POC diagnostic products in markets where they are cleared."

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 or febridx.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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