ASX ANNOUNCEMENT

US FDA Grants Emergency Use Authorisation For ViraDx™

MELBOURNE, Australia (11 Sep 2023) – Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") a leader in rapid, point-of-care (POC) diagnostic technologies, is pleased to announce that the US Food and Drug Administration (FDA) has granted Emergency Use Authorisation (EUA) and a CLIA Waiver (Clinical Laboratory Improvement Amendments) for the ViraDx test which is a combined COVID-19/Flu A/Flu B rapid POC test.

ViraDx is a rapid POC test that simultaneously tests for acute respiratory infections caused by the COVID-19, influenza A, and influenza B viruses. The test uses nasal or nasopharyngeal swab samples and provides a result within 15 minutes. The qualitative results are visually read, easy to interpret, and require no additional instruments. ViraDx has been authorised for use by healthcare professionals in the US including for use at any healthcare site operating under a CLIA Certificate of Waiver, which means it is of insignificant risk for an incorrect result. As part of the EUA, the FDA has requested some post-marketing studies that may require additional investment in the future. ViraDx was granted Interim Order Authorisation by Health Canada in June 2022.

Lumos intends to offer ViraDx to healthcare providers in the US through its recently established sales channel for POC products for women's health, STI's and infectious diseases. ViraDx will expand the product menu available through this channel which will include molecular POC tests for chlamydia and gonorrhea and, later this year, Lumos' FebriDx® product. With a number of COVID-19/influenza tests having entered the market in the last 12 months and a declining use of rapid antigen tests (RATs) for COVID-19, Lumos will monitor its sales and marketing investment for ViraDx to ensure that it is supported by robust end-user demand.

"We are delighted to be granted Emergency Use Authorisation to market the three-in-one ViraDx test for acute viral respiratory infections in the US" **said Doug Ward, CEO and Managing Director of Lumos.** *"This is an important addition to the suite of products that we will offer healthcare professionals through our recently established US sales channel. It is also a credit to the expertise and capabilities of Lumos' clinical and regulatory teams that they have managed to secure two US regulatory registrations for Lumos' point-of-care products within the last three months."*

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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.

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