ASX ANNOUNCEMENT

Lumos Completes ViraDx™ Development and Provides FebriDx® Regulatory Update

- *All development activities for ViraDx™ SARS-CoV-2 COVID-19/Flu A/Flu B combined rapid antigen test are complete.*
- *Regulatory submissions for ViraDx are underway in the U.S. and Canada.*
- *FebriDx® receives clearance in United Arab Emirates, and following the filing of response to feedback from FDA, remains on track for an outcome from 510(k) application in the U.S. in FY 2022.*

Melbourne, VIC. (22 December 2021) - Lumos Diagnostics (ASX:LDX), a leader in rapid point-of-care (POC) diagnostic technologies, today announced that it has completed all the development, verification and validation activities to support regulatory submissions for ViraDx™, a three-in-one COVID-19/Flu A/Flu B rapid antigen test. Regulatory submissions are underway in the U.S. and Canada where ViraDx falls into a category that is prioritized for regulatory reviews.

ViraDx is a 15-minute, three-in-one COVID-19/Flu A/Flu B rapid antigen test for use by qualified healthcare professionals to assess patients with acute respiratory symptoms. Following necessary regulatory authorizations, ViraDx may complement Lumos' FebriDx® test.

"We have already commenced preparations for our commercial launch of ViraDx in the North American market," said Rob Sambursky, MD, President and CEO of Lumos Diagnostics. "With the evolution of the COVID-19 pandemic, and new U.S. reports indicating that influenza is on the rise and this year's flu vaccines may not be matched to the predominant strain, we see a significant commercial opportunity for ViraDx.

"In addition, FebriDx is already approved in Europe, Canada and Australia, and has now received market clearance for the United Arab Emirates (UAE)," said Dr. Sambursky. "An application for regulatory clearance of FebriDx in the U.S. is currently under review by the FDA. Based on recent progress in the FDA's 510(k) review process, we remain on track to have a decision during FY 2022."

About FebriDx

FebriDx is an all-in-one, 10-minute test that measures a patient's immune response to acute respiratory infections (ARIs) using a patented dual biomarker technology – without any additional instruments or equipment. When used as part of a clinical exam, FebriDx helps healthcare professionals manage patients with a wide range of acute respiratory symptoms such as sore throat, acute cough and sinus congestion.

For bacterial infections, FebriDx provides a 99% negative predictive value (NPV), allowing healthcare professionals to confidently rule out bacterial infections for their patients. The ability to rule out bacterial infection is especially important during the respiratory (cold and flu) season because it can help reduce the use of medically unnecessary antibiotics.

FebriDx is manufactured in the U.S. in ISO 13485 and MDSA-certified facilities. FebriDx is under review with the U.S. FDA and not cleared for use in the U.S.

This announcement was approved by the Lumos Diagnostics Board of Directors 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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