LumiraDx Receives CE Mark for Two Multiplex Tests: LumiraDx Dual-Target SARS-CoV-2 STAR Complete and LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete

June 8, 2022

LONDON, June 8, 2022 /PRNewswire/ -- LumiraDx Limited (Nasdaq: LMDX) today announced that it has achieved CE Mark for two new Fast Lab Solutions molecular tests, including Dual-Target SARS-CoV-2 STAR Complete and SARS-CoV-2 & Flu A/B RNA STAR Complete. These high-sensitivity and high-throughput tests help to expand testing capabilities across the globe.

LumiraDx's continued innovation of its qSTAR technology, which utilizes a single-step direct method for nucleic acid extraction and amplification on validated open RT-PCR instruments, has led to the development of multiplexing capabilities.

The LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete assay allows for the simultaneous detection and differentiation of influenza A, influenza B, and SARS-CoV-2. SARS-CoV-2 & Flu A/B RNA STAR Complete compares to high sensitivity RT-PCR with a positive percent agreement (PPA) of 94.1% for SARS-CoV-2, and 92.3% for influenza A, and 95.7% for influenza B and a negative percent agreement (NPA) of >99.5% in symptomatic individuals.

The Dual-Target SARS-CoV-2 STAR Complete multiplex assay simultaneously detects two gene markers to identify the presence of SARS-CoV-2, which will meet certain regulatory requirements in numerous regions that need two or more targets for a COVID-19 diagnostic. Compared to a high sensitivity RT-PCR, Dual-Target SARS-CoV-2 STAR Complete proved to have a PPA of 97.7% for SARS-CoV-2 and a NPA of 100% in symptomatic individuals.

"As the pandemic persists, we remain focused on bringing to market high-quality molecular diagnostics that further remove testing barriers and enhance laboratory operations," explained Sanjay Malkani, President of LumiraDx Fast Lab Solutions. He continued, "We are pleased to demonstrate unrivaled innovation with direct method, high-throughput, highly sensitive assays for open molecular platforms - with results available in 20 minutes - and the added benefit of accurately detecting influenza and COVID-19 from a single sample."

About LumiraDx Fast Lab Solutions

LumiraDx Fast Lab Solutions supports high-complexity laboratory testing by utilizing its innovative qSTAR nucleic acid amplification technology in an accessible high-throughput format to leverage current molecular laboratory operations. Utilizing Fast Lab Solutions enables laboratories to improve efficiency and reduce time to result.

About LumiraDx

LumiraDx (Nasdaq: LMDX) is a next-generation point of care diagnostics company that is transforming community-based healthcare. Founded in 2014, LumiraDx manufactures and commercializes an innovative diagnostic Platform that supports a broad menu of tests with lab comparable performance at the point of care. LumiraDx diagnostic testing solutions are being deployed by governments and leading healthcare institutions across laboratories, urgent care, physician offices, pharmacies, schools, and workplaces to screen, diagnose, and monitor wellness as well as disease. LumiraDx has on the market and in development, 30+ tests covering infectious diseases, cardiovascular diseases, diabetes, and coagulation disorders, all on the LumiraDx Platform. In addition, LumiraDx has a comprehensive portfolio of fast, accurate, and cost-efficient COVID-19 testing solutions from the lab to point of need.

LumiraDx is based in the UK with more than 1600 employees worldwide.

Further information on LumiraDx and the LumiraDx Platform is available at www.lumiradx.com

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding the performance and benefits of the Fast Lab Solutions molecular tests, including Dual-Target SARS-CoV-2 STAR Complete and SARS-CoV-2 & Flu A/B RNA STAR Complete. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements, including, among others, general economic, political and business conditions; regulatory changes; the ability of LumiraDx to maintain CE marking for its Fast Lab Solutions molecular tests; and those factors discussed under the header "Risk Factors" in the Annual Report on Form 20-F for the year ended December 31, 2021, which was filed by LumiraDx with the Securities and Exchange Commission ("SEC") on April 13, 2022, and in other filings made by LumiraDx with the SEC. Although LumiraDx believes that it has a reasonable basis for each forward-looking statement contained in this press release, LumiraDx cautions you that these statements are based on a combination of facts and factors currently known by it and its projections of the future, about which it cannot be certain. LumiraDx undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise, except as required by applicable law.

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