



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular Receives Additional BARDA Funding in Support of Submitting the Simplexa™ COVID-19 Direct and the Simplexa™ COVID-19 & Flu A/B Direct kits for FDA 510(k) Clearance

Cypress, California (USA) – January 13, 2021 - DiaSorin Molecular LLC, a subsidiary of DiaSorin S.p.A. (FTSE MIB:DIA), announced today that it has received additional federal funding from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, for the validation and submission of the Simplexa COVID-19 Direct kit and the Simplexa COVID-19 & Flu A/B Direct kit for FDA 510(k) clearance. The company initially received BARDA funding in March 2020 to test, validate, and submit the Simplexa COVID-19 Direct kit for FDA Emergency Use Authorization (EUA).

The Simplexa COVID-19 Direct kit detects the presence of the RNA of SARS-CoV-2, including the variants VUI 202012/01 strain (lineage B.1.1.7) and the variant 20C/501Y.V2 (B.1.351 lineage), recently isolated in the United Kingdom and in South Africa respectively. The test has been available in countries accepting CE Mark and in the U.S. through FDA EUA since the end of March 2020 and it is designed for use on more than 1,200 LIAISON® MDX instruments installed worldwide, the majority of which are installed in laboratories around the United States. DiaSorin Molecular has shipped over 1 million tests in the month of December 2020 alone.

The solution provides accurate results in around 1 hour, with a demonstrated clinical agreement of close to 100 percent against an established comparator. The rapid turnaround time allows for prompt decision making in patient management, which is critical to help hospitals contain the pandemic and guide treatments.



The Simplexa COVID-19 & Flu A/B Direct kit, for the simultaneous detection and differentiation of Influenza A, B, and SARS-CoV-2, is expected to be finalized and available for the 2021 influenza season.

“The funding we received from BARDA will enable us to submit our Simplexa COVID-19 Direct and Simplexa COVID-19 & Flu A/B Direct kit molecular tests for FDA 510(k) clearance more rapidly,” said John Gerace, President of DiaSorin Molecular. “These products will allow for fast diagnosis of COVID-19 and Flu, which can be difficult to differentiate based on symptoms alone, and will be a critical component for guiding treatment decisions and managing patients in healthcare settings.”

About DiaSorin Molecular

DiaSorin Molecular LLC manufactures and distributes innovative molecular diagnostic products for hospital and reference laboratories. The company’s products help laboratories consolidate their testing, streamline processes and increase efficiency. DiaSorin Molecular’s Simplexa molecular diagnostic kits are designed for use on the company’s versatile LIAISON MDX platform. The company provides service and support solutions for its kits and instruments through a global network of offices and distributors. DiaSorin Molecular also markets a range of ASRs (analyte-specific reagents) for use in lab-developed tests.

The Simplexa COVID-19 Direct test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens. The Simplexa COVID-19 Direct is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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