



DIASORIN ANNOUNCES THAT IT SUBMITTED THE LIAISON[®] LYMEDETECT[®] TEST TO THE U.S. FOOD AND DRUG ADMINISTRATION IN DECEMBER 2023

Saluggia, Italy - January 25, 2024 - Diasorin (FTSE MIB: DIA) announces that it submitted the LIAISON[®] LymeDetect[®] test to the U.S. Food and Drug Administration (FDA) in December 2023, as communicated during the Investor Day on December 15, 2023.

LIAISON[®] LymeDetect[®] is a novel test with breakthrough potential that uses 3 chemiluminescent immunoassays for the early diagnosis of Lyme disease. It detects, in conjunction with clinical signs and symptoms, early *Borrelia burgdorferi* infections in human subjects.

The test, developed in partnership with QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA), allows the detection of IgG, IgM and T-cell mediated response, which can be measured through the QIAGEN's proprietary QuantiFERON[®] technology, an interferon-gamma release assay (IGRA).

The development of LIAISON[®] LymeDetect[®] is part of the global partnership with QIAGEN, which also includes the LIAISON[®] QuantiFERON[®]-TB Gold Plus Test, for fast and accurate detection of latent tuberculosis infections.

Lyme disease (LD), also called borreliosis, is an infection caused by the *Borrelia burgdorferi bacterium (Bb)*, which is transmitted to humans through the bite of infected blacklegged ticks. It is the most common vector-borne disease in the United States with an estimated 476,000 patients treated per year, according to the U.S. Center for Disease Control (CDC).

Typical early symptoms include fever, headache, fatigue and an expanding skin rash called *erythema migrans*. If left untreated, the Lyme infection can evolve into a late and disseminated stage of the disease that is characterized by arthritis with severe joint pain, neurological symptoms, cardiac inflammation and irregular heart beat.

LD exhibits a highly seasonal incidence pattern and April through October is considered the tick season.

“As communicated in our 2023 Investor Day, we have submitted the LymeDetect[®] test and we are waiting for the FDA approval” commented Chen Even, Chief Commercial Officer of Diasorin. *“This novel solution will enhance our LIAISON immunodiagnostic offering in the U.S. market, and will represent a further milestone reached in partnership with QIAGEN”*.

“The submission of the LymeDetect[®] test for FDA approval marks another milestone as we expand this important partnership that has proven its value in expanding access to TB testing”, said Fernando Beils, Senior Vice President and Head of the Molecular Diagnostics Business Area at QIAGEN. *“We look forward to deepening this partnership in the coming years as we consider additional opportunities to apply QuantiFERON to improve diagnosis and enable better treatments for a range of diseases.”*

About Diasorin

Headquartered in Italy and listed at the Italian Stock Exchange in the FTSE MIB Index, Diasorin is a global leader in the In Vitro Diagnostic (IVD) field and is active since 2021 in the Life Science business. For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.

The Group operates in 5 continents through 35 companies, 4 branches, 10 manufacturing facilities and 9 research and development centers. The extensive diagnostic testing and Life Science offer, made available through continuous investments in research, positions Diasorin as the player with the broadest range of specialty tests available within the diagnostic market, and identifies the Group as the “Diagnostic Specialist”.

More info at www.diasorin.com



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