DiaSorin The Diagnostic Specialist

PRESS RELEASE

DIASORIN, IN PARTNERSHIP WITH QIAGEN, LAUNCHES THE NEW LIAISON® LYMEDETECT® ASSAY BASED ON QUANTIFERON TECHNOLOGY IN COUNTRIES ACCEPTING CE MARK FOR EARLY DIAGNOSIS OF LYME BORRELIOSIS

- THE LIAISON® LYMEDETECT® ASSAY IS A SOLUTION FOR THE EARLY DIAGNOSIS OF LYME BORRELIOSIS COMBINING DETECTION OF IGG AND IGM ANTIBODIES AND CELLULAR IMMUNITY
- THE TEST IS AVAILABLE IN COUNTRIES ACCEPTING THE CE MARK AND IS DESIGNED TO BE RUN ON THE LIAISON® XL AND LIAISON® XS PLATFORMS
- IN CLINICAL STUDIES, THE ASSAY SHOWED, WITHIN 21 DAYS FROM THE FIRST EVIDENCE OF INFECTION, A SENSITIVITY OF 74% VERSUS THAT OF EXISTING ESTABLISHED METHODS AT 49%, WHILE ALSO DEMONSTRATING A HIGH DIAGNOSTIC SPECIFICITY OF 100%

Saluggia (Italy) and Hilden (Germany), April 21, 2021 - DiaSorin (FTSE MIB: DIA) and QIAGEN N.V. (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced the launch of the LIAISON® LymeDetect® Assay for markets accepting the CE Mark, as an aid to detect early Lyme Borreliosis infection (Lyme) on LIAISON® analyzer systems.

Lyme is a tick-borne illness caused by the *Borrelia burgdorferi* bacterium species, with different types of manifestations in the early phase: early-localized rash (the typical Erythema Migrans) and early-disseminated forms, where people may develop a different kind of rash, remain asymptomatic or have quite non-specific symptoms such as fever, chills, headache, fatigue, muscle and joint aches.
If the early infection is left untreated, *Borrelia burgdorferi* might spread to joints, the heart and the nervous system becoming a chronic illness and evolving into severe complications.

A recent publication[1] estimates that the total number of yearly cases in Western Europe could be as high as 230,000.

The current diagnostic routine for early disseminated Lyme diagnosis uses serological testing for IgG and IgM antibodies detection (B cell response), followed by a confirmation using Western Blot in case of positivity or equivocal results.

In the early stages of the infection, however, results can be unsatisfactory because patients often get tested at the onset of the disease, when visible signs of the tick bite or the presence of the tick itself are detected, but before the appearance of antibodies (IgG or IgM) against the pathogen. An undetected Lyme disease presents an increased risk of developing into a severe chronic disease, and this represents a relevant untapped diagnostic need.

DiaSorin and QIAGEN have been collaborating to provide a solution to this diagnostic gap, developing a solution, which significantly improves the sensitivity in the early phase of Lyme borreliosis. The new LIAISON® LymeDetect® solution combines both humoral (detection of IgG and IgM antibodies) and cellular immunity through a specific interferon-gamma release assay, stimulated by specific Lyme peptides using QuantiFERON® LymeDetect® technology, providing significantly improved sensitivity and earlier detection of the infection.

In clinical studies, the LIAISON® LymeDetect® Assay showed, within 21 days from the first evidence of infection, a sensitivity of to 74% versus that of existing alternative methods (ca. 49%). Moreover, the LIAISON® LymeDetect® Assay also demonstrated a high diagnostic specificity of 100%.

[11] Source: "An estimate of Lyme borreliosis incidence in Western Europe" by Robert A. Sykes, Phoebe Makiello available at https://doi.org/10.1093/pubmed/fdw017

By providing a tool which significantly increases the sensitivity in the early stages of the disease, the LIAISON® LymeDetect® could help physicians identify and treat the disease earlier, minimizing the risk of late and chronic manifestation, with benefits for patients and a significant healthcare cost reduction, mainly due to shorter hospitalization and long-term care for late disease treatment.

DiaSorin and QIAGEN worked together to co-develop the new LIAISON® LymeDetect®, an innovative solution for diagnosing Lyme disease, designed to be run on the LIAISON® XL and LIAISON® XS platforms. Under the development agreement, DiaSorin is responsible for commercialization of the new LIAISON® LymeDetect, while QIAGEN and DiaSorin are jointly responsible for development and production of the solution.

"We are very proud of this new goal reached in partnership with QIAGEN, because we think it is going to be a game-changer in the Lyme disease diagnosis space and a milestone in our Value Based Care strategy", commented Carlo Rosa, Chief Executive Officer of DiaSorin Group. "*The collaboration between our companies leverages on their QuantiFERON technology and our extensive installed base of LIAISON family analyzers and is positioning us both as leaders in the T-cell response market with a unique franchise for laboratories looking for an efficient way to detect asymptomatic infections and risks that cannot be detected in all situations with standard diagnostic technologies. This new solution, together with our already validated Lyme disease tests, will strengthen our role as a company committed to find solutions for diagnosing a disease so prevalent in specific regions and so difficult to detect at an early stage that causes painful and long-lasting consequences in the lives of affected patients".*

"*QIAGEN believes in expanding and maximizing the value of our QuantiFERON portfolio, led by the gold-standard QuantiFERON TB Gold-Plus Assay that forms the foundation of our collaboration with DiaSorin and the joint global marketing of our solution for use on the LIAISON family of analyzers,*" said Thierry Bernard, Chief Executive Officer of QIAGEN. "*The fight against Lyme disease is increasingly critical given the risks and symptoms and estimates that the number of ticks carrying the disease is on the rise worldwide. For this collaboration, we are taking a new approach with DiaSorin that builds on our unique strengths, in particular our capabilities to develop and gain approval for novel QuantiFERON-based tests and DiaSorin's expertise with its current portfolio of solutions for this disease. We are eager to see the benefits of this partnership in improving outcomes for patients suffering from a disease with often debilitating consequences*."

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, with 26 companies, 4 branches, 5 manufacturing facilities and 5 research and development centers.
For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.
The extensive diagnostic testing 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.diasoringroup.com

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare) and Life Sciences (academia, pharma R&D and industrial applications, primarily forensics). As of December 31, 2020, QIAGEN employed approximately 5,600 people in over 35 locations worldwide. Further information can be found at http://www.qiagen.com

QIAGEN forward-Looking Statement

Certain statements contained in this press release may be considered forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. To the extent that any of the statements contained herein relating to QIAGEN's products, including those products used in the response to the COVID-19 pandemic, timing for launch and development, marketing and/or regulatory approvals, financial and operational outlook, growth and expansion, collaborations markets, strategy or operating results, including without limitation its expected adjusted net sales and adjusted diluted earnings results, are forward-looking, such statements are based on current expectations and assumptions that involve a number of uncertainties and risks. Such uncertainties and risks include, but are not limited to, risks associated with management of growth and international operations (including the effects of currency fluctuations, regulatory processes and dependence on logistics), variability of operating results and allocations between customer classes, the commercial development of markets for our products to customers in academia, pharma, applied testing and molecular diagnostics; changing relationships with customers, suppliers and strategic partners; competition; rapid or unexpected changes in technologies; fluctuations in demand for QIAGEN's products (including fluctuations due to general economic conditions, the level and timing of customers' funding, budgets and other factors); our ability to obtain regulatory approval of our products; difficulties in successfully adapting QIAGEN's products to integrated solutions and producing such products; the ability of QIAGEN to identify and develop new products and to differentiate and protect our products from competitors' products; market acceptance of QIAGEN's new products and the integration of acquired technologies and businesses; actions of governments, global or regional economic developments, weather or transportation delays, natural disasters, political or public health crises, including the breadth and duration of the COVID-19 pandemic and its impact on the demand for our products and other aspects of our business, or other force majeure events; as well as the possibility that expected benefits related to recent or pending acquisitions may not materialize as expected; and the other factors discussed under the heading "Risk Factors" contained in Item 3 of our most recent Annual Report on Form 20-F. For further information, please refer to the discussions in reports that QIAGEN has filed with, or furnished to, the U.S. Securities and Exchange Commission.

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