PRESS RELEASE

DIASORIN SUBMITS LIAISON NES GROUP A STREP MOLECULAR TEST TO THE U.S. FDA FOR 510(K) CLEARANCE AND CLIA WAIVER

- GROUP A STREPTOCOCCUS IS A LEADING BACTERIAL CAUSE OF ACUTE PHARYNGITIS AND ONE OF THE MOST COMMON REASONS FOR OUTPATIENT VISITS IN PEDIATRIC, PRIMARY CARE, AND URGENT CARE SETTINGS
- THE LIAISON NES GROUP A STREP TEST IS DESIGNED TO DELIVER DEFINITIVE MOLECULAR RESULTS AT THE POINT OF CARE IN APPROXIMATELY 15 MINUTES
- LIAISON NES GROUP A STREP IS THE SECOND ASSAY AVAILABLE ON THE GROUP'S NEW MOLECULAR DIAGNOSTIC POINT-OF-CARE PLATFORM, FOLLOWING THE CLEARANCE OF THE LIAISON NES FLU A/B, RSV & COVID-19 ASSAY

Saluggia, Italy – February 3, 2026 – Diasorin (FTSE MIB: DIA) today announced the submission of a 510(k) premarket notification and CLIA waiver application to the U.S. Food and Drug Administration (FDA) for a Group A Streptococcus (GAS) molecular assay for use on the LIAISON NES Point-of-Care (POC) molecular diagnostics system.

Strep throat is a bacterial infection caused by Group A Streptococcus. It is a leading bacterial cause of acute pharyngitis, particularly in children and adolescents, and one of the most common reasons for outpatient visits in pediatric, primary care, and urgent care settings. Because symptoms of streptococcal and viral pharyngitis frequently overlap, accurate and timely identification of GAS is critical to support appropriate patient management during the clinical encounter. The estimated U.S. market for Group A Strep testing is approximately 150$ million.

The LIAISON NES Group A Strep test is designed to deliver definitive molecular results at the point of care in approximately 15 minutes, enabling prompt diagnosis and timely treatment decisions. By providing a reliable answer in a single visit, the assay helps clinicians avoid diagnostic uncertainty and supports more appropriate antibiotic use without the delays associated with confirmatory laboratory testing.

Compared to rapid antigen tests, which may require send-out molecular confirmation following negative results, the LIAISON NES Group A Strep assay is intended to provide clear, actionable results directly at the near-patient setting, improving efficiency and patient experience.

A key feature of the assay is its early call capability, which allows the system to identify and report positive results as soon as the presence of the pathogen is detected. This feature supports faster clinical decision-making and improved patient flow in busy outpatient environments.

"This submission reflects our continued execution and long-term commitment to the LIAISON NES platform," said Angelo Rago, President of Luminex. *"Following the recent FDA clearance of our first LIAISON NES FLU A/B, RSV & COVID-19 assay, we are already advancing the next test to expand clinical utility and reinforce the role of LIAISON NES as a credible, scalable molecular solution for decentralized care."*

The LIAISON NES Group A Strep test builds on the recent U.S. FDA clearance of the LIAISON NES FLU A/B, RSV & COVID-19 panel, announced on December 28, further strengthening Diasorin's near-patient molecular menu. Together, these assays address some of the most frequent and clinically relevant infectious diseases encountered in non-acute care settings.

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 30 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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