DiaSorin The Diagnostic Specialist

PRESS RELEASE

DIASORIN RECEIVES FDA 510(K) CLEARANCE FOR ITS LIAISON® MEMED BV® TEST THE FIRST HIGH THROUGHPUT BLOOD TEST TO DIFFERENTIATE BETWEEN BACTERIAL AND VIRAL INFECTIONS

- LIAISON® MEMED BV® IS AN IMMUNE SYSTEM BASED PROTEIN SIGNATURE TEST ENABLING OBJECTIVE AND TIMELY DECISION SUPPORT FOR DISTINGUISHING BETWEEN BACTERIAL AND VIRAL INFECTIONS
- THE LIAISON® MEMED BV® TEST WAS DEVELOPED FOLLOWING THE LICENSING AGREEMENT SIGNED WITH MEMED AS ANNOUNCED IN SEPTEMBER 2020
- THE TEST WAS CE MARKED IN 2021 AND IS NOW CLEARED AND LAUNCHED ALSO IN THE USA

Saluggia, July 14, 2022 - DiaSorin (FTSE MIB: DIA) announced today the FDA 510(k) clearance and the commercial launch in the US of the host-protein signature-based assay LIAISON® MeMed BV®.

The launch follows a Licensing Agreement signed with MeMed that was announced in September 2020, under which DiaSorin obtained the rights to commercialize and make the MeMed BV® test available on the extensive installed base of LIAISON® platforms.

The LIAISON® MeMed BV® test is the first fully automated solution, which utilizes host response-based data to enable physicians to differentiate accurately between bacterial and viral infections, supporting fast and better-informed treatment and patient management decisions. The test also drives laboratory operational efficiency through time-labor reduction by using a fully automated and high-throughput approach when compared with traditional growth based microbiology methods.

The availability of this innovative test provides a valuable tool in the growing global threat posed by antimicrobial resistance (AMR). Infections with resistant organisms have higher morbidity and mortality, are costlier to treat, result in longer hospital stays and place a greater burden on health systems than infections caused by susceptible organisms[1]. According to the World Health Organization, AMR is, in fact, one of the top 10 global public health threats for humanity and a leading cause of death around the world. The CDC indicates that more than 2.8 million people in the United States become ill with antibiotic-resistant diseases every year, resulting in a minimum of 35,000 deaths and that the antibiotic resistance could add about $1,400 to the hospital bill for treating patients with any bacterial infections. The impact of these additional costs coming from AMR on overall healthcare expenditure, in the USA alone, could surpass $2 billion per year in the future.[2].

Distinguishing between bacterial and viral etiologies in acute infections has been a universal challenge for health care providers. Current practices such as medical history, physical findings and other medical tests provide incomplete answers, especially when the infection site is inaccessible. By relying on the immune response, rather than direct pathogen detection, the LIAISON® MeMed BV® test complements conventional technologies, providing actionable information and better-informed antibiotic and antiviral treatment decisions, allowing for rapid and accurate diagnosis.

The LIAISON® MeMed BV® test expands DiaSorin's market leading menu of fully-automated, chemiluminescent immunoassay (CLIA) panels for the diagnosis of infectious diseases and highlights the commitment to develop innovative, fully automated diagnostic solutions, with the aim of optimizing laboratory efficiency and clinical decision-making.

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[1] Frost I. et al.; Global geographic trends in antimicrobial resistance: the role of international travel. J Travel Med. 2019 Dec 23;26(8)

[2] Dadgostar P. Antimicrobial Resistance: Implications and Costs. Infect Drug Resist. 2019; 12:3903-3910

"The launch of the test developed in partnership with MeMed on our extensive U.S. installed base of LIAISON® XL platforms, extends the reach of this solution that is strategic for our future and provides laboratories and clinicians with an innovative diagnostic tool," said Mr. Carlo Rosa, CEO of DiaSorin. *"The test provides significant clinical value that supports accurate and informed decisions for patients, accelerating their recovery. The MeMed BV assay has the potential to support that critical decision of whether a patient may have a bacterial or viral infection when it is crucial to make a time sensitive treatment decision.*"

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 45 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".
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