PRESS RELEASE

DIASORIN AND GILEAD SCIENCES COLLABORATE TO DEVELOP A FULLY AUTOMATED DIAGNOSTIC ASSAY FOR HEPATITIS DELTA VIRUS ON DIASORIN'S LIAISON XL® FOR THE U.S. MARKET

THE DEVELOPMENT OF THE HEPATITIS DELTA VIRUS ASSAY WILL:

- ENABLE THE COMMERCIALIZATION OF THE FIRST FULLY AUTOMATED LABORATORY TEST FOR HEPATITIS DELTA VIRUS (HDV) IN THE U.S., AIMED AT A FAST AND ACCURATE DIAGNOSIS OF THE MOST SEVERE FORM OF VIRAL HEPATITIS;
- AID IN ADDRESSING CURRENT NEEDS AND EXISTING DIAGNOSTIC LIMITATIONS TO IMPROVE BOTH SCREENING AND HDV DIAGNOSIS.

Saluggia (Italy) - November 6, 2023 - Diasorin (FTSE MIB: DIA) announced today it will develop the first fully automated diagnostic test for hepatitis delta virus (HDV) on the Diasorin LIAISON XL® immunoassay system in the United States. Designated as a Breakthrough Device by the U.S. Food and Drug Administration (FDA), the test will aid in the diagnosis of HDV in individuals living with acute and chronic hepatitis B virus (HBV). The development of the automated diagnostic assay will be supported by Gilead Sciences.

Hepatitis delta, also known as hepatitis D or HDV, is a viral liver infection caused by hepatitis delta virus that can result in one of the most severe forms of viral hepatitis. Occurring as a co-infection or a superinfection in individuals with HBV, HDV can progress to chronicity, cirrhosis, liver failure, and cancer. Mortality rates are up to 50% within 5 years in cirrhotic patients. It is estimated that the global hepatitis delta virus epidemic affects more than 15 million individuals worldwide, with many cases going undiagnosed in both endemic and non-endemic geographies.

HDV is a satellite virus of HBV that requires the presence of HBV for viral replication and dissemination in liver cells. It is important that people living with chronic HBV get tested for HDV, as they are most at risk. Getting tested for HDV can help improve patient outcomes by ensuring infected individuals receive appropriate medical care and treatment promptly.

The Diasorin LIAISON HDV Immunoassay aims to deliver the first fully automated FDA-approved immunoassay for HDV detection in the U.S., addressing current availability and testing limitations to improve patient identification.

"Hepatitis D is a fatal and highly progressive form of liver disease" said Dr. Robert Gish, Medical Director of the Hepatitis B Foundation and Asian Pacific Health Foundation. *"With incomplete testing access for anti-HDV, in the U.S. and throughout the world, Hepatitis D is underdiagnosed. Expanding testing will help accelerate diagnosis and linkage to care of this very important form of liver disease."*

The fully automated HDV immunoassay test on the Diasorin LIAISON XL® is expected to be available in the United States in 2024, pending regulatory approval.

"We are proud to announce this new development in HDV, that confirms our ability to grow Diasorin's offering of innovative specialty tests" commented Carlo Rosa, CEO of Diasorin. *"We believe that this new innovative diagnostic solution will support future critical clinical decisions, aiding in the prevention of Hepatitis Delta severe complications".*

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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 39 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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