DiaSorin The Diagnostic Specialist

Press Release

DIASORIN LAUNCHES THE THIRD MOLECULAR DIAGNOSTICS TEST ON ITS LIAISON IAM PLATFORM: PARVOVIRUS B19

June 20, 2013 - Saluggia (VC) - **DiaSorin** (FTSE MIB:DIA) is pleased to announce the launch of a **new molecular diagnostic test** for the detection of **Parvovirus B19** on plasma and serum samples, available on the market outside of the United States and Canada.

The new **IAM PARVO** is the **third test** used on the **LIAISON® IAM** after the first two assays already launched in late 2012 (IAM BKV and IAM VZV), which further strengthens DiaSorin's position as **leader in the market** of serology tests for **Parvovirus** and, more generally, as the **Diagnostics Specialist leader**.

The new molecular diagnostic test is of primary importance because, while the serological tests in immunodiagnostic are normally used for the initial diagnosis in immunocompetent individuals (i.e. with healthy immune systems), the **molecular methods** are **needed** for **immunocompromised patients** and are **recommended** to **confirm IgM anti-Parvovirus positive results**.

Parvovirus B19 (B19V) is a common childhood infection that causes particular concern in the case of suspicion of infection in a pregnant woman; from as early as 6 weeks gestation, B19V can be transferred from mother to foetus across the placenta, causing hydrops fetalis, miscarriage, severe neurological disease or poor survival of the foetus.

Diagnosis of maternal infection relies on the detection of IgM and IgG antibodies. The presence of IgG antibodies to B19V indicates a previous infection, but it is estimated that approximately 25% to 45% of women of childbearing age do not possess these antibodies and are therefore susceptible to infection.

First line serology testing will indicate current active B19V infection; however, when serological test results are negative but infection is still suspected, clinicians can rapidly confirm diagnosis using the new, highly sensitive, **IAM PARVO** molecular assay on the **LIAISON® IAM**, designed by **DiaSorin** to be highly sensitive and therefore able to provide confirmation data in certain and rapid manner. This confirmation is particularly important in the 8 - 12 week period after maternal infection, when the sensitivity of IgM antibodies detection varies from 63% to 70% and serological testing alone may not give the full picture.
A **rapid diagnosis of infection** through the **IAM PARVO allows** to monitor adequately the **evolution of the infection** and to have **appropriate care referrals**.

The monitoring of the Parvovirus B19 is also important in **immunocompromised patients** or with **sickle cell anaemia**, as it can have very serious effects, sometimes fatal, and is also the leading cause of **pure red cell aplasia** in **AIDS** patients.

With the aim of simplifying and speeding up the process of diagnosis, DiaSorin has optimized the extraction of nucleic acids of Parvo B19 on its instrument DiaSorin LIAISON® IXT.

The amplification and signal detection step of the **IAM PARVO** assay utilizes the **Company's proprietary Q-LAMP technology** on the **LIAISON® IAM** platform.

REFERENCE TABLE FOR DIASORIN PRODUCTS

Assay name	Parvovirus			
Diagnosis	Infectious Diseases			
Potential market	n.d.			
Business segment	Immunodiagnostics		Molecular Diagnostics	√
Technology	CLIA		Extraction	
	ELISA		Amplification/Detection	√
	RIA		HLA Typying	
Clinical Area	Infectious Disease		Infectious Disease	√
	Hepatites and Retroviruses			
	Oncology & Endocrinolgy			
	Bone & Mineral		Onco-hematology	
	Cardiac Markers			
	GI Stool Testing			

Carlo Rosa, CEO of DiaSorin Group, commented: *"The addition of a molecular product to the IgG and IgM assays in serology already available on the LIAISON platforms, provides our customers with the opportunity to confirm the presence of Parvo B19 infection by performing both tests in the same laboratory.*

The IAM PARVO is the third assay launched by the Group on molecular technology on our LIAISON IAM instrument which reaffirms our plan to develop a strong and structured molecular business through high-quality and reliable specialty products.

I'm proud of the path taken by the Group in this regard, as well as of the new molecular assays for infectious diseases and onco-haematology we are currently working on and that we plan to commercialize in 2013 and 2014. "

About DiaSorin

Headquartered in Italy and listed in the FTSE MIB Index, DiaSorin is a global leader in the In Vitro Diagnostics (IVD) field. For over 40 years the Company has been developing, producing and marketing reagent kits for IVD worldwide. Through constant investments in research and development, and using its own distinctive expertise in the field of immunodiagnostics to deliver a high level of innovation, DiaSorin offers today the broadest range of specialty tests available in the immunodiagnostics market and new tests in the molecular diagnostics markets which identify DiaSorin Group as the IVD "diagnostics specialist".

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