

## DIASORIN LAUNCHES THE LIAISON FGF 23 TEST, THE FIRST INNOVATIVE AND FULLY AUTOMATED MARKER FOR CHRONIC KIDNEY DISEASE

**January 26, 2017 - Saluggia (VC)** - DiaSorin (FTSE Italia Mid Cap: DIA) is pleased to announce the launch of the first fully automated quantitative assay for the FGF 23 protein on CLIA platform, available worldwide with the exception of the U.S.

This test expands DiaSorin Bone and Mineral product line and allows the Group to enter the clinical area of chronic kidney disease, which represents a sector of great interest for the clinical community, where it is crucial using an automated system and, consequently, providing quick, fast and high-quality results.

DiaSorin R&D team has, thus, generated a test that can determine FGF 23 protein concentration in human plasma in just 48 minutes.

The FGF 23 protein has two main functions: inhibition of renal phosphate reabsorption and decrease of 1,25 Vitamin D. Hence, the presence of the FGF 23 protein is closely associated with chronic kidney disease (CKD) and diseases related to bone tissue calcification.

According to data reported by CARHES (*Cardiovascular risk in Renal patients of the Health Examination Survey*) study carried out by the Italian Society of Nephrology in cooperation with *Istituto Superiore di Sanità* and the *Associazione Nazionale Medici Cardiologi Ospedalieri*, CKD in Italy affects about 7.5% of men and 6.5% of women aged 35-79 years.

On the basis of epidemiological data collected from the National Health and Nutrition Examination Survey III (NHANES III), CKD is a global public health problem. It is estimated that about 10% of the population is affected by CKD, both in developing and developed countries. In most cases, this disease is unknown.

High cardiovascular risk associated with CKD and high social and economic costs related to substitution treatments, such as dialysis and kidney transplant, increase exponentially from early to more advanced stages representing a key aspect in terms of healthcare expenditure.

In Italy, the annual direct cost per patient under dialysis is estimated to be up to € 44,000. In addition to direct costs, this estimate should include indirect costs or costs associated with kidney transplant (about € 50,000 in the first year and € 15,000 in each subsequent year).

On the basis of these data it has been estimated the National Healthcare Service could save 2.5 billion euros by slowing down the progression of kidney disease, for at least 5 years, in 10% of patients at stages III - IV as well as postponing dialysis treatment for 5 years.

Currently the FGF 23 marker is mainly used for research purposes and is complementary to other markers such as parathyroid hormone (PTH) and 1,25 Vitamin D, which are both available on LIAISON analyzers.

Carlo Rosa, CEO of DiaSorin Group, commented *"The development and launch of the FGF 23 test confirm DiaSorin's focus on innovation. We have been the first to launch this assay on CLIA automated platform in Europe, providing an extremely high-quality product that can contribute to the medical research and expand, in future, the diagnostic tools for diseases related to phosphate metabolism in human plasma. As presented during the Investor Day held in May 2015, our decision to address a portion of our resources to the development of innovative markers*



The Diagnostic Specialist

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## Press Release

*represents a very important pillar for our strategy aimed at maintaining our leadership position in the diagnostic field and our pioneering role in the specialty sector”.*

### **About DiaSorin**

*Headquartered in Italy and listed in the FTSE Mid Cap, 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 immunodiagnosics to deliver a high level of innovation, DiaSorin offers today the broadest range of specialty tests available in the immunodiagnosics market and new tests in the molecular diagnostics markets, which identify DiaSorin Group as the IVD “diagnostics specialist”.*

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