

# Ipsogen announces the CE marking of its "ProfileQuant® WT1" kit

- WT1 is a valuable biomarker in the prognosis and follow-up of Acute Myeloid Leukemia (AML) patients.
- The ProfileQuant® WT1 kit was developed and validated in the context of an international collaborative study coordinated by the European Leukemia Network (ELN) consortium.
- With its WT1 kit, Ipsogen continues its CE marking strategy and confirms its leadership position in molecular diagnosis of leukemia.

Marseille, France, March 16, 2009 - IPSOGEN SA (Alternext - FR0010626028 - ALIPS), a molecular diagnostic company specialized in the development, manufacturing and commercialization of diagnostic assays for breast cancer and leukemias, today announces the CE marking of its ProfileQuant WT1 kit.

The WT1 (for "Wilms' tumor gene") biomarker is used in the prognosis and follow-up of normal karyotype AML patients, who account for nearly half of AML adult patients. Quantification of WT1 expression level helps predict disease aggressiveness and determine patient response to treatment. In a recent large European study, WT1 proved to be a reliable indicator that can be used for Minimal Residual Disease monitoring distinguishing patients at differing risk of relapse.

The WT1 assay has been developed in the context of a collaborative project coordinated by the ELN consortium, systematically evaluating 9 different available assays to identify the best performing one.

"The WT1 gene has been reported to be switched on in the majority of cases of AML making it an attractive target for novel treatment approaches and monitoring response to therapy" says David Grimwade, leader of the Minimal Residual Disease working group of ELN. "Therefore, there was a pressing need to develop a highly reproducible and reliable assay that quantifies WT1 transcript levels. IPSOGEN's collaboration and industrial support were key to the success of this international collaborative study coordinated by ELN."

The CE marking obtained by Ipsogen for the ProfileQuant®WT1 kit, confirms the quality of its validation and manufacturing processes. With this kit, Ipsogen continues to contribute to the standardisation efforts in place in Europe in order to reduce inter-laboratory variability and provide consistent results over time.

"The CE marking of our ProfileQuant® WT1 will further increase the adoption of this marker by European laboratories" says Vincent Fert, founder and CEO of Ipsogen. "This test provides oncologists and hematologists with a more precise picture of pathological processes and disease evolution, and will help them to tailor their treatment strategy for each individual AML patient, a critical need in a disease where only 60% of normal karyotype AML patients survive on the long term".



### **About IPSOGEN**

Ipsogen, Cancer Profiler, develops and markets molecular diagnostic tests designed to map diseases in order to guide patients and oncologists decisions along their complex therapeutic path.

With more than 70 tests already used routinely worldwide for the diagnosis, prognosis and follow-up of thousands of patients with leukemia, Ipsogen is now also targeting breast cancer. Its initial goal will be to provide diagnostic information that remained unavailable until now.

Strengthened by its first-rate scientific, clinical and technological partnerships, in addition to its highly skilled multidisciplinary team in France and the USA, Ipsogen is striving to become the leader in the molecular profiling of cancers. It is pursuing its development and promotion of diagnostic standards that have a significant impact on patients, medical professionals and society.

Ipsogen employed 48 people as of December 31, 2008. Its headquarters are located in Marseille, France. The company has also a subsidiary, Ipsogen Inc., in New Haven, CT, USA.

For more information, visit: www.ipsogen.com

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