Emosis
CELL-BASED HEMOSTASIS TESTING

Press Release
Strasbourg | March 2018

EMOSIS announces CE Mark approval for HIT Confirm® kit

The company is about to start marketing its first in vitro diagnostic kit in cell-based Hemostasis

Strasbourg, March 20th, 2018

Emosis, a young medical device company specializing in cell-based hemostasis diagnostics, is thrilled to announce that the company recently CE-marked its first kit, the Emo-test HIT Confirm®.

The flow cytometry-based HIT Confirm® test is a first-in-class functional test with results available in 30 minutes, 24/7, on-site and on-demand.

It is the first test that could contribute, even in emergency situations, to the diagnosis of the potentially lethal and rather frequent Heparin-Induced Thrombocytopenia (HIT) suspicion in patients treated by the common anticoagulant Heparin.

Diagnosing HIT traditionally requires laboratory tests, both screening (usually ELISA-based) and functional (platelet-based) tests.

Functional tests are technically demanding, therefore need to be batched and thus require days or weeks for most hospitals to get results from a few specialized centers.

In contrast, the HIT Confirm® test, based on selected platelet biomarkers read by flow cytometry, can timely contribute to the physician's decision to substitute or not heparin with costly and more complex to manage alternative antithrombotic drugs.

Giving an easier, faster access to HIT functional tests such as the HIT Confirm® will support many clinicians in their endeavour to treat patients more efficiently and possibly lower overall healthcare costs.

Dr. Frederic Allemand, CEO of Emosis, declared: "This CE Mark approval is a fantastic milestone in Emosis' history. It is amazing to look back and realize that it took us less than 3 years to have our first product on the market. With this first kit and several others under development, Emosis wishes to use the power of flow cytometry and cell-based hemostasis to support a better informed clinical decision for physicians facing thrombosis or bleeding risks every day".

About Heparin Induced Thrombocytopenia (HIT)

Heparin-Induced Thrombocytopenia (HIT) is a common severe health complication ("heparin allergy-like") for patients treated by Heparin, a rather cheap anticoagulant drug largely used worldwide to prevent thrombosis in many indications. With a prevalence reaching up to 8% in some cardiology patients, confirming clinically significant HIT, rapidity and specificity are paramount for physicians to stop Heparin and switch to alternative anticoagulants, or to resume safely Heparin, in order to prevent serious health complications (e.g., limb amputation or even death) for their patients, not to mention associated costs (prolonged hospital stay, unnecessary costly alternative anticoagulants).

About CE Mark

CE marking is a certification mark that indicates conformity with regulatory requirements, health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). The CE marking is another key milestone for Emosis to support the marketing of their kit in many countries accepting this regulatory certificate.

The company had previously obtained its ISO 9001:2015 and ISO 13485:2016 certifications, supporting its commitment to excellence.

ABOUT EMOSIS

Since its inception in 2015, EMOSIS, a young innovative company, is dedicated to the development and marketing of a first-in-class, high-performance and user-friendly system combining various cell- and microparticle-based assay kits to be performed on user-friendly, benchtop flow cytometers. Routinely diagnosing and differentiating various bleeding and thrombotic disorders will allow faster and better therapeutic decisions. The system will support a broad range of clinical applications such as: confirming the diagnosis of heparin–induced thrombocytopenia (first test, launch in 2017), assessing platelet function and personalizing antiplatelet therapies, testing hypercoagulable states, and others.

Frédéric Allemand, CEO of Emosis SAS,
frederic.allemand@emosis-diagnostics.com

Hashtags for LinkedIn post:

#CE #CEMark #Quality #IVD
#Diagnostics #HIT #Heparin
#Thrombosis #BloodDisorders #Emosis
#EnlighteningYourDecision.