

sphingotec is Adding an Advanced POC Testing Platform to Portfolio

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- sphingotec GmbH will offer its next-generation sepsis, heart failure and acute kidney injury biomarkers penKid[®] and bio-ADM[®] on NEXUS IB 10 point-of-care (POC) testing platform, originally developed by Nexus Dx
- penKid[®] and bio-ADM[®] are first-in-class biomarkers to diagnose and monitor real-time kidney function and endothelial dysfunction which lead to shock in sepsis and congestion in acute heart failure
- POC testing of penKid[®] and bio-ADM[®] is set to add significant clinical benefit to emergency departments and intensive care units allowing on-site diagnosis, monitoring, and guidance in therapies of sepsis, decongestion in heart failure and acute kidney injury, thereby improving outcomes in acute heart failure, sepsis and other acute settings



German diagnostics company sphingotec GmbH (Hennigsdorf) and Nexus Dx (San Diego) have combined their technology platforms to market sphingotec's CE-marked acute biomarkers penKid® and bio-ADM® on Nexus' market-validated POC testing immunoassay platform IB10 to substantially improve decision-making in emergency departments (EDs) and intensive care units (ICUs).

This merger of technologies under the jointly owned holding company Polaris MediNet, LLC. allows emergency physicians for the first time to predict and monitor septic shock, monitor kidney function in acute settings and to monitor and diagnose congestion, including residual congestion - the major reason for re-hospitalization and post-discharge mortality in acute heart failure (AHF) - in emergency departments within a few minutes from whole blood without any sample preparation.

Each year, eight million people die from sepsis, 700,000 thereof by acute kidney injury (AKI). Sepsis causes \$24 billion in direct annual costs for the U.S. healthcare system while acute heart failure's annual cost of \$31 billion is expected to double by 2030. Details of the transaction are subject to confidentiality.

The capability of bio-ADM® to predict circulatory shock in sepsis patients and to predict and monitor residual, diuretic-resistant congestion has been clinically proven by sphingotec in clinical studies with over 20,000 Asian and Caucasian patients^{[1][2][3]}. Furthermore, the functional kidney marker, penKid®, has been shown to predict, diagnose and monitor kidney dysfunction ^{[4][5][6]}. penKid® is a real-time surrogate marker for true (actual) kidney function (true GFR) allowing emergency physicians to timely monitor real-time kidney function in acute settings.



The Nexus IB10 POC platform is an easy-to-handle POC system, allowing the detection of biomarkers from whole blood with accuracy and precision. Thus, it is a great tool to bring valuable biomarkers to the physicians in ED and ICU.

"We are delighted to shortly start European distribution of our acute care biomarkers for therapy monitoring and adjustment on a great POC testing platform," said Dr. Andreas Bergmann, founder and CEO of sphingotec GmbH.

"The addition of sphingotec's next-generation biomarkers to the IB10 platform will allow the timely introduction of a complete solution for the hospital acute point of care market in AKI, AHF and sepsis diagnosis and monitoring," said Nam Shin, CEO of Nexus Dx Inc.

About sphingotec GmbH: sphingotec GmbH develops innovative biomarkers for diagnosis, prediction and monitoring of acute medical conditions, such as acute heart failure, acute kidney injury and circulatory shock, in order to support patient management and provide guidance for treatment strategies.

Furthermore, sphingotec develops biomarkers for the risk prediction of common diseases, such as obesity, cardiovascular diseases and breast cancer, in order to support prevention strategies.

About Nexus Dx Inc.: Nexus Dx, is a global provider of Near Patient Testing systems and advanced diagnostic solutions. The company is improving patient care by providing the medical community with rapid and reliable information at the point of care (POC), delivering patient information when and where it is needed most. The company has invested over \$160 million to develop and market the IB10 analyzer system, a disc-based microfluidic immunoassay platform in which a rotating disk automatically separates plasma from whole



blood for further analyses. Results of POC testing of troponin I, a cardiac Tnl/CK-MB/Myoglobin panel, NT-proBNP, NT-proBNP/Troponin I and a D-dimer Test are available within 20 minutes.

About Polaris MediNet, LLC: Polaris MediNet (San-Diego) is a holding company jointly owned by Nam Shin, CEO of Nexus Dx and sphingotec GmbH.

About penKid®: penKid® is the very first functional kidney marker that works in plasma, is independent from comorbidities and inflammation and provides timely information about the changing kidney function in critically ill patients. sphingotest® penKid® is non-inferior to the gold standard in vivo measurement of glomerular filtration rate (GFR) and penKid® indicates two days earlier than the gold standard serum creatinine in patients developing acute kidney injury (AKI). These features enable physicians to predict, diagnose and closely monitor worsening and improving kidney function in critically ill patients. In congestive heart failure, penKid® allows to adjust diuretics dosage to the situation in individual patients.

About bio-ADM®: As a marker of acute vascular dysfunction, bio-ADM® enables both prediction of circulatory shock 48 h before blood pressure breakdown, e.g. in septic patients, and diagnosis of diuretic resistant congestion in acute heart failure patients.

A biomarker-assisted diuretics therapy in patients with congestive heart failure/cardio-renal syndrome, by simultaneous measurement of bio-ADM® and penKid®, targets lower re-hospitalization and mortality rates. Since 2017, sphingotest®bio-ADM® and sphingotest®penKid® immunoassays are distributed in Germany and Austria by bestbion Dx and marketed in China under an agreement with Shuwen Biotech Co. Ltd.



About congestive heart failure: About 26 million people globally suffer from congestive heart failure. The characteristic loss of pump function of the heart triggers cardiac remodeling - the heart gets stiffer, fibrotic, and cannot pump enough blood into the circulatory system. The lower pump efficacy causes lower oxygen saturation and results in congestion, which means that blood returning to the heart through the veins backs up, resulting in higher venous pressure and causing fluids to build up in the tissues (edema). About 80% of patients with congestive heart failure are also at risk to develop edema, because their microvasculature becomes leaky due to venous hypertension. Physicians try to prevent the worst case - deadly lung edemas - by administration of loop diuretics, which can reduce hypertension by increasing water excretion. However, not all patients fully respond to diuretics. Incomplete response to diuretics therapy is the most common cause of re-hospitalization and post discharge mortality in patients with congestive heart failure. It's not yet fully understood why patients with congestive heart failure often experience acute kidney injury (AKI). However, there is growing evidence that AKI can be attributed to congestion ("cardio-renal syndrome") and that, vice versa, AKI can trigger heart problems. Management of fluid balance with loop diuretics is challenging - if too much fluid is excreted from tissues, this will support development of AKI. On the other hand, if too little fluid is excreted, lung edemas could return. Besides that, a large proportion of patients with congestive heart failure does not fully respond to diuretics treatment, leading to undetected residual congestion. To date, physicians have no means to identify these patient group at discharge, resulting in high re-hospitalization and post-discharge mortality rates.

Septic shock is defined as a life-threatening organ dysfunction due to dysregulated host response to a proven or suspected infection which leads to a decline of Mean Arterial Pressure (MAP) < 65 mmHg, which is refractory to fluid resuscitation and requires vasopressors. Refractoriness to fluid resuscitation is



defined as a lack of response to the administration of 30 mL of fluid per kilogram of body weight or is determined according to a clinician's assessment of inadequate hemodynamic results.

[1] Caironi et. al (2017) Circulating Biologically Active Adrenomedullin (bio-ADM) Predicts Hemodynamic Support Requirement and Mortality During Sepsis

[2] Marino et al. (2014) Plasma adrenomedullin is associated with short term mortality

[3] Kremer et al. (2017) bio-ADM: a novel marker of congestion in patients with acute heart failure

[4] Beunders et al. (2017) Proenkephalin (PENK) as a Novel Biomarker for Kidney Function

[5] Siong Chan et al. (2018) Proenkephalin in Heart Failure

[6] Ng et al. (2017) Proenkephalin, Renal Dysfunction, and Prognosis in Patients with Acute Heart Failure

Contact

sphingotec GmbH

Neuendorfstr. 15a

16761 Hennigsdorf

Tel. +49-(0)3302 20565-0

info@sphingotec.de

<http://www.sphingotec.com>

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