## Proenkephalin (penKid®) included in the ADQI consensus statements publication as functional kidney biomarker for the management of AKI patients

- The latest consensus meeting of international experts in critical care and nephrology supports the use of novel biomarkers in the prevention and management of Acute Kidney Injury (AKI)
- The consensus recommends using a combination of damage and functional biomarkers together with clinical information for routine practice
- Proenkephalin (penKid®), the kidney function biomarker, proposed as a marker for the assessment of AKI progression and kidney recovery
- The CE-IVD marked assay for penKid® is available for point of care usage on the fully automated Nexus IB10 platform

**Hennigsdorf/Berlin, Germany, December 16, 2020** – Diagnostics company SphingoTec GmbH ("SphingoTec") announced today that the Acute Disease Quality Initiative (ADQI) recommends the use of novel biomarkers for AKI, including functional biomarkers as penKid®. Since AKI is affecting 1 in 3 Intensive Care Unit (ICU) patients [1], and the current standard of care diagnostics has considerable sensitivity and specificity limitations, there is an urgent need to implement new biomarkers to assist a better management of AKI.

The current consensus recommendations [2] support clinicians in making more informed decisions and improve outcomes with biomarker guided management of AKI patients, including triage, diagnosis, and guidance of therapy. Among the main recommendation of the ADQI meeting is the use of novel biomarkers to assess AKI progression and kidney recovery. The consensus statements highlight the performance and added value of penKid® for the prediction of duration and recovery of AKI. Based on the results of a multicenter trial (3), the presented evidence shows that penKid® concentration is significantly lower in AKI patients with improving kidney function when compared to patients without kidney recovery. Additional data (4) is used by the experts in ADQI to convey that significantly higher penKid® levels are indicating those patients with major adverse kidney events, patients with persistent AKI, and those who had worsening of kidney function. Furthermore, the consensus statement also underlines that penKid® is an earlier biomarker than today's standard of care diagnostics in identifying the patients with worsening kidney function.

Prof. Peter Pickkers (Radboud University, Nijmegen), member of the ADQI explained "Since the last evaluation of novel AKI biomarkers 9 years ago, we have collected enough evidence now to consider the usage of functional and damage biomarkers in the prediction and management of AKI. Although many novel biomarkers can measure the damage that already occurred in the kidneys, there are few choices available for measuring the kidney function. Besides Cystatin C, penKid is the only novel functional biomarker available for clinical routine practice."

The kidney function biomarker penKid® was previously validated in over 40.000 patients and published data [5] demonstrate that penKid® can detect the presence and severity of AKI and enables the identification of patients at high risk of unfavorable outcomes. Moreover, previous findings from the AdrenOSS 1, a 24-centers study, show that penKid® not only diagnoses AKI earlier than today's standard of care, but it also indicates the renal recovery. [4] The utility of penKid® has been proved both in adult and children population. [6]

Dr. Andreas Bergmann, CEO and founder of SphingoTec stated “We are excited that penKid® has been recognized by ADQI as a suitable functional kidney biomarker. Not only that penKid® reflects kidney function and true GFR independent of inflammation and comorbidities, but unpublished clinical data could complement the consensus recommendation to further evaluate the functional biomarker’s role in defining the optimal timing for initiating and stopping kidney replacement therapy.”

To support timely treatment decisions that are likely to improve patient management in critical care patients, SphingoTec makes available the CE-IVD marked assay for penKid® on its proprietary Nexus IB10 platform. The fully automated point-of-care analyzer uses whole blood, delivers results in only 20 minutes, and can be flexibly deployed in near-patient as well as laboratory settings.

**References**:

(1) Ponce et al (2016), Acute kidney injury: risk factors and management challenges in developing countries, Int J Nephrol Renovasc Dis., DOI: 10.2147/IJNRD.S104209

(2) Ostermann et al (2020), Recommendation on Acute Kidney Injury Biomarkers From the Acute Disease Quality Initiative Consensus Conference | Consensus Statement, Critical Care Medicine, DOI: 10.1001/jamanetworkopen.2020.19209

(3) Caironi et al (2018), Circulating proenkephalin, acute kidney injury, and its improvement in patients with severe sepsis or shock. Clin Chem; DOI:10.1373/clinchem.2018.288068

(4) Hollinger et at (2018), Proenkephalin A 119-159 (Penkid) Is an Early Biomarker of Septic Acute Kidney Injury: The Kidney in Sepsis and Septic Shock (Kid-SSS) Study, Kidney Int Rep, DOI: 10.1016/j.ekir.2018.08.006

(5) Marino et al (2015), Diagnostic and short-term prognostic utility of plasma proenkephalin (pro-ENK) for acute kidney injury in patients admitted with sepsis in the emergency department, J Nephrol, DOI 10.1007/s40620-014-0163-z

[6] Hartman et al (2020), Proenkephalin as a New Biomarker for Pediatric Acute Kidney Injury - Reference Values and Performance in Children Under One Year of Age, Clin Chem Lab Med, doi: 10.1515/cclm-2020-0381.

About penKid®

IB10 sphingotest® penKid® measures Proenkephalin (penKid®), a stable fragment of the kidney stimulating hormone Enkephalin. penKid® has been demonstrated to be a real-time surrogate biomarker for glomerular filtration rate, the gold standard to assess renal function. Measuring penKid® blood concentrations allows for timely information on kidney function in critically ill patients. Early assessment of worsening and improving of renal function on intensive care units and in emergency departments allows adjustment of nephrotoxic drug administration and the initiation of kidney-protective strategies to prevent acute kidney injury and thereby improve outcomes.

About SphingoTec

SphingoTec GmbH ("SphingoTec"; Hennigsdorf near Berlin, Germany) develops and markets innovative in vitro diagnostic (IVD) tests for novel and proprietary biomarkers for the diagnosis, prediction and monitoring of acute medical conditions, such as sepsis, acute heart failure, circulatory shock, and acute kidney injury in order to support patient management and provide guidance for treatment strategies. SphingoTec's proprietary biomarker portfolio includes bioactive Adrenomedullin (bio-ADM®), a unique biomarker for real-time assessment of endothelial function in conditions like sepsis or congestive heart failure, Proenkephalin (penKid®), a unique biomarker for real-time assessment of kidney function, and Dipeptidyl Peptidase 3 (DPP3), a unique biomarker for cardiac depression. In addition, SphingoTec develops a portfolio of novel biomarkers, which predict the risks of developing obesity, breast cancer and cardiovascular diseases. IVD tests for SphingoTec's proprietary biomarkers are made available as sphingotest® microtiterplate tests as well as point-of-care tests on the Nexus IB10 immunoassay platform by SphingoTec's subsidiary Nexus Dx Inc. (San Diego, CA, USA) alongside a broad menu of established and commonly used tests for acute and critical care.

### About Nexus Dx Inc. and the IB10 Platform

Nexus Dx Inc., a wholly-owned subsidiary of SphingoTec, headquartered in San Diego, CA, USA, is a global provider of a near patient testing system and advanced diagnostic solution. 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 $160m to develop and market the IB10 analyzer system which, without the need for sample preparation, automatically separates plasma from whole blood with subsequent reliable and quantitative detection of biomarkers in the plasma by means of antibodies. With a hands-on-time of less than 3 minutes the easy-to-use system provides in only 20 minutes test results for biomarkers that are crucial in the management of critical care patients. The portfolio of IB10 assays includes tests for established critical care parameters such as Procalcitonin, Troponin I, CK-MB, Myoglobin, NT-proBNP, and D-Dimer as well as tests for SphingoTec's proprietary biomarkers such as Proenkephalin (penKid®), a unique and proprietary biomarker for real-time assessment of kidney function, and bioactive Adrenomedullin (bio-ADM®), a unique and proprietary biomarker for endothelial function.

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