New Formula Leverages Proenkephalin A 119-159 (penKid) for Improved GFR Estimation in Steady-State and Critically Ill Patients

- *PenKid is a kidney function biomarker that correlates with gold standard GFR measurements in stable and acute kidney injury (AKI) patients.*
- *Based on penKid, a new formula was developed to estimate the GFR, outperforming widely used conventional equations based on creatinine alone.*
- *Scientists from Radboud University and Mayo Clinic developed and validated this formula in a large cohort of stable, as well as critically ill patients, laying the foundation for future increased clinical vigilance in kidney health assessment.*

Hennigsdorf/Berlin, Germany, October 5, 2023 - Diagnostic company SphingoTec GmbH ("SphingoTec") announces that a new, improved formula has been developed for estimating the GFR using its kidney function biomarker penKid (1). According to the data, penKid strongly correlates with the measured GFR (mGFR), while the penKid-based formula for estimating GFR performs better than routinely used equations.

In clinical practice, kidney dysfunction is monitored using creatinine-based estimates of GFR. Creatinine is recognized as a late and insensitive biomarker of GFR, with consensus guidelines emphasizing that a more timely and accurate estimation of GFR in AKI is a relevant unmet medical need (2,3,4).

Researchers from the Radboud University Medical Centre, Netherlands, and Mayo Clinic, USA, have included a cohort of over 1,300 patients in a data-driven approach for developing an equation to estimate the GFR using the kidney function biomarker penKid (1). According to the findings, this novel equation performs better in calculating eGFR compared to creatinine-based equations. The formula can be applied to a wide range of patients since the cohort used for its development and validation included a broad spectrum of patients, such as patients with established chronic kidney disease, and critically ill patients. The compelling data is further strengthened by the fact that gold-standard methods to determine the true mGFR were used in all patients, and penKid concentration was most strongly correlated with mGFR.

Prof. Peter Pickkers (Head of Research in Intensive Care Medicine at Radboud University Nijmegen Medical Centre) summarized, "The innovative biomarker penKid has previously demonstrated significant potential in increasing the clinical vigilance and supporting the management of AKI patients. The penKid-based formula will facilitate in future its implementation in the clinical routine since it translates penKid concentrations into a more accurate GFR estimation that can now be implemented by physicians worldwide."

Dr. Florian Uhle, Medical Director at SphingoTec, added, "With this landmark research, the first formula using penKid has been successfully established in chronic and acute kidney impairment. Starting from this evidence base, we will focus on further validating this formula in critically ill patients and aiming to overcome the shortcomings of our current diagnostic standards in AKI management. We are looking

forward to interacting closely with global healthcare providers in the future to drive this concept to clinical reality."

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References:

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About SphingoTec

SphingoTec GmbH ("SphingoTec"; Hennigsdorf near Berlin, Germany) is a commercial-stage diagnostic company focusing on innovative critical care biomarkers for diagnosing, predicting, and monitoring acute medical conditions. SphingoTec's innovative markers are made available on different IVD platforms. SphingoTec's proprietary biomarker portfolio includes Proenkephalin A 119-159 (penKid), a biomarker for the assessment of kidney function in critical diseases, and bioactive Adrenomedullin 1-52 (bio-ADM), a biomarker for the assessment of endothelial function in conditions like sepsis.

About penKid

Proenkephalin A 119-159 (penKid) is a blood-based biomarker for assessing kidney function in acute and critical conditions. The biomarker offers a blood-based alternative for the complex and time-consuming in vivo measurement of true glomerular filtration rate (GFR). PenKid is independent of common comorbidities (e.g., hypertension and diabetes) and the frequently occurring inflammation in critically ill patients. Rising penKid blood levels predict acute kidney injury earlier than today's standard of care, and decreasing penKid blood levels indicate the improvement of kidney function, even under dialysis. Scientific evidence shows that penKid also reflects kidney function in children, representing a potential biomarker for pediatric AKI.

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