

International Experts Highlight Demand for Diagnostic Innovations as PenKid's Research and Real-World Data Fuels Quest for Improved RRT Liberation Tools

- International experts recognize the need for diagnostic innovations to support more informed and standardized decisions for liberation from renal replacement therapy (RRT).
- A presentation during the 41st Vicenza Course on AKI-CRRT highlights the promising results of a real-world evaluation of kidney function under RRT with Proenkephalin A 119-159 (penKid).
- Recently published scientific data affirms that penKid remains informative under acute renal replacement therapy (RRT) and can identify patients for successful liberation.

Hennigsdorf/Berlin, Germany, September 6, 2023 – Diagnostic company SphingoTec has announced that a new study and real-world data on its kidney function biomarker penKid underline its potential to monitor kidney function during acute kidney injury (AKI) and RRT and to support liberation decisions from RRT. These findings are especially relevant in the context of a liberation failure rate of up to 50% (1), considering the lack of consensus guidelines, and tools to support clinical decision-making.

Experts advocate for improved tools in critical decision-making

RRT, a common practice in Intensive Care Units (ICUs), has long relied on clinical observations for stop decisions. However, the lack of a dependable biomarker poses challenges in accurately assessing when to discontinue RRT. Considering this, leading experts from the field have discussed in a recent advisory board the importance of identifying the right tools to improve the outcomes in AKI.

According to Claudio Ronco (Director of the International Renal Research Institute of Vicenza, Italy), "The future availability of a reliable biomarker to support stop decisions in RRT is crucial. It has the potential to minimize liberation failure rates and enhance patient care significantly." Lui Forni (Professor and Consultant in intensive care at Royal Surrey County Hospital NHS Foundation Trust and the School of Medicine, University of Surrey) highlights the ethical concerns surrounding unsuccessful liberation, stating, "When patients need to restart RRT after failed liberation, in many cases this will affect the overall patient outcome with an increase in mortality being seen. Therefore, it is imperative that we explore solutions that can help avoid such scenarios." The expert group supports the planning of a prospective study involving penKid as a potential tool to promote uniform treatment standards for RRT liberation.

Advancements in assessing kidney function under RRT

During the 41st Vicenza Course on AKI-CRRT, a presentation by Christian Nussbag (Senior Physician at the University Hospital Heidelberg, Germany) and titled "Real-world evaluation of residual kidney function under RRT - what's new?" introduced the latest insights emerging from real-world data.

Dr. Nussbag highlighted, "In the realm of AKI, there is a recognized need for relevant biomarkers that can accurately assess kidney function, especially in the context of RRT. The data we generated with penKid during our real-world evaluation at University Hospital Heidelberg, allowed us to observe that penKid seems not to be affected by RRT procedure, as standard markers are. In this case, penKid may

help to identify patients at high risk for liberation failure or patients with unnecessary prolongation of RRT, potentially supporting successful RRT liberation decisions in the future."

Recently published data support these real-world findings. The post-hoc analysis of the multicentric RICH trial show that penKid may be a competent biomarker to monitor the recovery of kidney function during continuous RRT (CRRT) and identify patients for liberation from CRRT (2). This aligns with data from the ELAIN trial, where penKid showed the potential to guide early and successful liberation of treatment (3).

Dr. Florian Uhle, Medical Director at SphingoTec comments, "PenKid's ability to provide patient-specific insights for informed clinical decision-making opens exciting possibilities in monitoring kidney function in critically ill patients, as it mirrors the real-time glomerular filtration rate in non-stable settings. The potential of penKid in kidney health assessment opens new avenues for personalized medicine in AKI."

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References:

- (1) Schiffl H, et al. Current Approach to Successful Liberation from Renal Replacement Therapy in Critically Ill Patients with Severe Acute Kidney Injury: The Quest for Biomarkers Continues. *Mol Diagn Ther.* 2021 Jan;25(1):1-8. doi: 10.1007/s40291-020-00498-z.
- (2) von Groote T et al. Proenkephalin A 119–159 predicts early and successful liberation from renal replacement therapy in critically ill patients with acute kidney injury: a post hoc analysis of the ELAIN trial. *Crit Care* 26, 333 (2022). <https://doi.org/10.1186/s13054-022-04217-4>
- (3) von Groote T, et al. Evaluation of Proenkephalin A 119-159 for liberation from renal replacement therapy: an external, multicenter pilot study in critically ill patients with acute kidney injury. *Crit Care.* 2023 Jul 10;27(1):276. doi: 10.1186/s13054-023-04556-w.

About SphingoTec

SphingoTec GmbH ("SphingoTec"; Hennigsdorf near Berlin, Germany) is a commercial-stage diagnostic company focusing on innovative critical care biomarkers for the diagnosis, prediction, and monitoring of 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.

Media contact:

Ruxandra Lenz
Head of Marketing and Communication
SphingoTec GmbH
Neuendorfstr. 15 A
16761 Hennigsdorf
Tel. +49-3302-20565-0