

Biomarker-guided trial led by University Hospital Hamburg-Eppendorf (UKE) opens new avenues for personalized medicine in COVID-19

- *A multi-center study led by UKE is evaluating one of the first personalized approaches for moderate to severe COVID-19 patients*
- *The innovative biomarkers bio-ADM and DPP3 are guiding the enrollment of patients suffering from endothelial barrier dysfunction*
- *The biomarkers are measured with SphingoTec's point of care tests for timely decision making.*

Hennigsdorf/Berlin, Germany, April 11, 2022 - Diagnostics company SphingoTec GmbH (SphingoTec) announced the implementation of two critical care biomarkers to guide the application of a potential new drug candidate for the treatment of COVID-19 patients. The personalized approach will allow to distinguish between separate clinical pathways, requiring different treatment decisions.

This trial will implement the biomarker bioactive Adrenomedullin (bio-ADM) for early identification of endothelial dysfunction (1), which plays a central role in the pathophysiology of COVID-19 (2). The drug candidate Adrecizumab targets septic shock patients with high bio-ADM levels to restore the endothelial barrier function (3), and has already shown favorable outcomes in a case series of eight severe COVID-19 patients (4). At the same time, patients with high Dipeptidyl peptidase 3 (DPP3) levels will not be included in the trial. The biomarker DPP3 is indicating another underlying disease mechanism leading to cardiac depression and requiring different therapeutic options (5). Both critical care biomarkers are measured via SphingoTec's rapid point of care platform Nexus IB10. For more information visit <https://sphingotec.com/science/acute-care-pathways/covid-19>.

PD Dr. med. Mahir Karakas (Department of Intensive Care Medicine at UKE) said, "Not all COVID-19 patients have the same disease course and the pathology is very different. Therefore, we have to adapt the treatment to each individual patient. We will now use in a double blind randomized multicenter trial the biomarker bio-ADM and DPP3 which proved to be useful for patient enrichment in a phase II trial for treatment of septic shock."

This is one of the first personalized, biomarker-guided trials in moderately to severely ill COVID-19 patients. The multicenter study led by UKE plans to enroll more than 200 patients for treatment with the new compound (6). Adrecizumab is provided by Adrenomed AG (www.adrenomed.com), and the critical care biomarkers are determined via SphingoTec's rapid point of care platform Nexus IB10.

Dr. Andreas Bergmann, founder of SphingoTec and co-founder of Adrenomed stated: "The innovative biomarkers generate better insights into the pathophysiology of critically ill patients. This is translated into clear decisions that allow a better treatment guidance and ultimately reduce mortality. This study represents a leap from "one drug fits all" to a personalized approach in treating COVID-19."

References:

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- (3) Laterre PF, et al. *Safety and tolerability of non-neutralizing adrenomedullin antibody adredezumab (HAM8101) in septic shock patients: the AdrenOSS-2 phase 2a biomarker-guided trial*. *Intensive Care Med*. 2021 Nov;47(11):1284-1294. doi: 10.1007/s00134-021-06537-5.
- (4) Karakas, M et al. *Targeting Endothelial Dysfunction in Eight Extreme-Critically Ill Patients with COVID-19 Using the Anti-Adrenomedullin Antibody Adredezumab (HAM8101)*. *Biomolecules* 2020, 10, 1171. <https://doi.org/10.3390/biom10081171>
- (5) van Lier et al 2020, *Promotion of vascular integrity in sepsis through modulation of bioactive adrenomedullin and dipeptidyl peptidase 3*, *J. Intern. Med.*, DOI: doi.org/10.1111/joim.13220
- (6) <https://clinicaltrials.gov/ct2/show/NCT05156671>

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About SphingoTec

SphingoTec GmbH develops and markets innovative in vitro diagnostic (IVD) tests for novel and proprietary biomarkers for the diagnosis, prediction and monitoring of acute medical conditions. SphingoTec's proprietary biomarker portfolio includes bioactive Adrenomedullin (bio-ADM), a biomarker for real-time assessment of endothelial function in conditions like sepsis or COVID-19, Proenkephalin (penKid), a biomarker for real-time assessment of kidney function. Dipeptidyl Peptidase 3 (DPP3), a biomarker for cardiac depression was in-licensed from 4TEEN4 Pharmaceuticals GmbH (www.4teen4.de). IVD tests for SphingoTec's proprietary biomarkers are made available as sphingotest® microtiter plate 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). The Nexus IB10 portfolio is complemented by established and commonly used biomarker tests for acute and critical care such as PCT, Troponin, NT-proBNP, D-Dimer, TSH and others. Find out more www.sphingotec.com

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