NEWS RELEASE

OMEICOS Therapeutics Completes Enrollment of PMD-OPTION Study in Primary Mitochondrial Disease

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Interim data confirms OMT-28's strong safety profile in PMD patients, top-line data expected mid-2025

BERLIN, GERMANY, September 26, 2024 – OMEICOS, a biopharmaceutical company developing first-in-class small molecule therapeutics, today announced the completion of enrollment in its multi-center, open-label Phase 2a PMD-OPTION study of OMT-28 in Primary Mitochondrial Disease (PMD) patients suffering from myopathy and cardiomyopathy. OMEICOS expects
top-line data to become available by mid- 2025.

"Meeting our PMD-OPTION enrollment target about a year after including the first patient is a significant milestone for the OMT-28 development program. We are very grateful for the commitment by patients and investigators for our study," said Dr. Robert Fischer, CEO/CSO of OMEICOS Therapeutics. "Initial data analysis confirms the strong safety profile and very good tolerability of OMT-28 in the target population. Furthermore, the clinical data obtained so far looks promising for relevant endpoints, which bodes well for our goal to provide a much-needed new treatment option for patients underserved by current therapies."

The primary endpoints of the PMD-OPTION study are safety and tolerability of OMT-28 and the response rate of patients showing a reduction of Growth differentiation factor 15 (GDF-15) levels by at least 20% compared to baseline. GDF-15, which is produced in response to mitochondrial stress, inflammation or hypoxia, is emerging as a strong risk predictor in many diseases including cardiometabolic and PMD. The study also evaluates a range of secondary and exploratory endpoints to determine the effect of OMT-28 on relevant clinical symptoms, standard functional parameters of physical strength, heart function, quality of life, and key metabolic biomarkers.

PMD patients suffer from debilitating and life-threatening health consequences, such as severely limited physical stamina and disease-related changes in the heart and skeletal muscles, as well as associated neurological disorders. OMEICOS' therapeutic strategy with OMT-28 could translate into improved cell metabolism and mitochondrial function, which in turn would bring significant quality of life benefits to PMD patients and their families. The PMD-OPTION study has enrolled a total of 28 PMD patients and features a 12-week untreated run-in phase, capturing the patients' natural history and baseline parameters. Subsequently, all patients receive a 24 mg once-daily dose of OMT-28 for a treatment period of up to 24 weeks.

About OMT-28

OMT-28 is a first-in-class small molecule that has demonstrated cell protective, anti-inflammatory and anti-atherosclerotic properties. OMEICOS has generated comprehensive preclinical and clinical datasets demonstrating the compounds strong safety profile and tolerability as well as its therapeutic potential in cardiovascular diseases targeting inflammation in atherosclerosis and cardiomyopathy, as well as other age-related diseases including AMD. In the active PMD-OTION Phase 2 clinical study, OMEICOS is evaluating OMT-28 in Primary Mitochondrial Disease patients.

+++ Meet OMEICOS Therapeutics at the BIO-Europe 2024 International Partnering Conference from November 4-6, 2024, in Stockholm, Sweden +++

About OMEICOS

OMEICOS Therapeutics has discovered a series of metabolically robust synthetic analogues of omega-3 fatty acid-derived epoxyeicosanoids that have the potential to treat mitochondrial dysfunction, inflammatory, cardiovascular and other diseases. Epoxyeicosanoids activate cell type-specific endogenous pathways that promote organ and tissue protection. OMEICOS' small molecules are orally available and show improved biological activity and pharmacokinetic properties compared to their natural counterparts. For more, please visit: **www.omeicos.com**

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Attachment

- **240926_OMEICOS_Recruitment_Completion_ENG_**

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