OMEICOS Therapeutics Announces Positive Phase 2 Study Outcome Demonstrating OMT-28's Potential in Primary Mitochondrial Diseases (PMD)

Trial Results Support Transition into Late-Stage Development with Program Expected to be Phase 2b/3-ready in H2 2026

BERLIN, GERMANY, January 29, 2026 – OMEICOS, a clinical-stage biopharmaceutical company developing first-in-class small molecule therapeutics for mitochondrial and inflammatory disorders, announced the successful conclusion of its multi-centre, open-label Phase 2a PMD-OPTION Study evaluating its lead program OMT-28 in patients with Primary Mitochondrial Disease (PMD). The study results demonstrate OMT-28's therapeutic potential to improve the physical condition in PMD based on significant recovery of the impaired mitochondrial fitness in the responding patients. The study further underscored the excellent safety and tolerability profile of OMT-28, which has now been evaluated in more than 220 individuals. OMEICOS is preparing for a potentially pivotal Phase 2b/3 study in PMD patients with myopathy and/or cardiomyopathy across EU and US sites and expects to be ready to initiate this study later this year, subject to the completion of partnering discussions.

PMD represents a heterogeneous group of conditions including the more prevalent subtypes MELAS, non-MELAS, and MIDD. 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. OMT-28, an orally available biased modulator, targets the GPCR-receptor S1PR1 (Sphingosine-1-Phosphate Receptor 1 thereby driving downstream activation of the mitochondrial sirtuin family members SIRT1 and SIRT3. By targeting S1PR1 and activating SIRT1/SIRT3, OMT-28 combines immunomodulation with mitochondrial protection—a dual mechanism to tackle inflammation and energy deficits in primary mitochondrial diseases.

"Improving physical performance through enhanced mitochondrial metabolism and reduced oxidative stress holds great promise in PMD. Our PMD-OPTION study results indicate a strong correlation between OMT-28 treatment, the observed positive impact on mitochondrial bioenergetics and fitness, and relevant clinical improvements in functional measures, which could translate into significant patient benefit," said Dr. Robert Fischer, CEO/CSO of OMEICOS Therapeutics. "The profound effects on NAD^+ and GSH levels, as well as simultaneous improvement of the NAD^+/NADH and GSH/GSSG ratios we have seen in the responder group, are integrative indicators of electron transport chain function improvements and cellular redox homeostasis. Overall, the results offer a robust path for late-stage development."

Study Design and Results Summary

The PMD-OPTION study enrolled a total of 29 PMD patients with mitochondrial tRNA point mutations or single mtDNA deletions across nine expert sites in Germany, Italy, and The Netherlands. The study generated strong interest among patients and key opinion leaders (KOLs), resulting in timely recruitment and a high degree of compliance with the study protocol and follow-up appointments. The study included a 12-week untreated run-in phase as an integrated control, capturing the patients' natural history and baseline parameters for evaluating treatment results. Subsequently, all patients received a 24 mg once-

daily dose of OMT-28 for a treatment period of up to 24 weeks. The study ended after a subsequent four-week follow-up period. The level of GDF-15, a prospective biomarker for reflecting cellular stress and inflammation, was used as a screening and inclusion criteria, while reduction of GDF-15 was used as a primary endpoint next to demonstrating safety and tolerability in PMD patients. The study outcome did not support the choice of GDF-15 in this setting suggesting that OMT-28 is acting downstream of the release mechanism of GDF-15.

To assess clinically meaningful improvements in the study population, the PMD-OPTION study utilized a combination of objective exercise endpoints and patient-reported outcomes. Using these measures, the study demonstrated a response rate of more than 60%. In the 12-Minute Walk Test (12 MWT) and the 5x Sit-to-Stand Test (5xSST), both accepted endpoints for pivotal studies, the entire study population showed improvements over baseline, while OMT-28 responders exhibited profound and statistically significant (12 MWT) clinical improvements compared to non-responders.

These results strongly correlated with a highly significant increase in total NAD+ levels in the responder group compared to baseline, and a clear separation between responders and non-responders in NAD+/NADH ratios over the course of the study. In patients responding to OMT-28 treatment, mean NAD+ levels were approximately 30% higher compared to baseline, bringing this crucial indicator of mitochondrial energy metabolism and redox status close to healthy ranges. Similarly, OMT-28 demonstrated a significant improvement in total GSH and GSH/GSSG ratios—key indicators of reduced oxidative stress in mitochondrial diseases—thereby reestablishing normal, healthy levels and even showing a trend toward further enhancement. Together, these results demonstrate that OMT-28's ability to normalize both NAD^+/NADH and GSH/GSSG ratios addresses the core pathologies of PMD—energy deficiency and oxidative stress—differentiating it from single-mechanism approaches and supporting its potential as a first-in-class therapy.

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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