OMEICOS' OMT-28 Headed for Phase 3 in Primary Mitochondrial Diseases (PMD) Following Positive End-of-Phase 2 Meeting with the FDA

- *Feedback from the U.S. Food and Drug Administration (FDA) supports acceleration of OMT-28's development path directly into a pivotal Phase 3 study*
- *With the vast majority of PMD patients having no FDA-approved therapeutic option, OMT-28 addresses a significant unmet medical need in mitochondrial disease space*
- *Results from Phase 2a PMD-OPTION Study were recently presented at Euromit 2026 and Mito MED 2026, the two largest international conferences on mitochondrial pathologies*

BERLIN, GERMANY, July 21, 2026 – OMEICOS, a late-stage clinical biopharmaceutical company developing first-in-class small-molecule therapeutics for mitochondrial and inflammatory disorders, today announced the successful completion of the End-of-Phase 2 (EOP2) meeting with the FDA regarding the development of OMT-28 in Primary Mitochondrial Diseases (PMD). During the meeting, the FDA expressed strong support for OMEICOS' plans to advance the program into late-stage clinical development and provided clear, constructive guidance to structure the next steps efficiently. As a result, OMEICOS is now positioned to advance its proprietary, fully owned lead product candidate OMT-28 directly into a pivotal Phase 3 study.

The EOP2 meeting with the FDA was supported by results from the successfully concluded multicentre, open-label Phase 2a PMD-OPTION Study in patients with PMD. The PMD-OPTION Study demonstrated OMT-28's therapeutic potential to improve physical condition in patients with PMD based on significant recovery of the impaired mitochondrial function in the responding patients. The study also further underscored the excellent safety and tolerability profile of OMT-28, which has been evaluated in more than 190 individuals to date.

OMT-28 has the potential to be a first-in-class and best-in-class therapy and is clearly differentiated from competing approaches in PMD through its unique dual mechanism, targeting both redox balance and mitochondrial restoration, addressing core disease biology more comprehensively than single-pathway approaches. OMT-28 leverages the activation of mitochondrial sirtuin family members SIRT1 and SIRT3, mainly through biased modulation of S1PR1 (Sphingosine-1-Phosphate Receptor 1) signalling.

As a once-daily oral small molecule, OMT-28 would offer superior convenience and adherence compared to currently evaluated injectables or twice-daily future alternatives. Moreover, cardiomyopathy patients—a subgroup often excluded in other clinical development programs—highlights OMT-28's potentially broader target population further reinforcing its best-in-class product profile. Beyond PMD, OMEICOS is pursuing a 'pipeline-in-a-drug' strategy with OMT-28 and sees potential for expansion into larger disease areas.

"The strong endorsement from the FDA marks a significant milestone for OMEICOS as a company and for our mission to address Primary Mitochondrial Disease. The meeting's outcome even surpassed our expectations, as we are now able to advance directly from our concluded Phase 2a study into a pivotal

Phase 3 study," said Dr. Robert Fischer, CEO/CSO of OMEICOS Therapeutics. "Our goal now is to bring a much-needed new treatment option into the final stages of development—and hopefully into medical practice—as quickly as possible. We are currently evaluating the best possible infrastructure, strategic partners, and resources to achieve this goal efficiently."

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. The disease represents a heterogeneous group of conditions including the most prevalent subtypes MELAS, non-MELAS, and MIDD. The upcoming pivotal Phase 3 study is planned to enrol up to 160 adult patients stratified by these three common PMD subgroups and will evaluate the efficacy of OMT-28 at a 24 mg once-daily dose over 24 weeks, with an option to extend treatment up to 104 weeks. The trial will employ an adaptive design, allowing adjustments to sample size and treatment duration based on interim analyses, ensuring flexibility and efficiency in this rare disease setting. The primary endpoint is a composite measure combining the 12-Minute Walk Test (12MWT) and the 5x Sit-to-Stand Test (5xSST), with secondary endpoints including quality-of-life assessments and exploratory biomarkers such as NAD^+, GSH, and their ratios. This design reflects the FDA's constructive guidance and underscores the potential of OMT-28 to transform the treatment landscape for patients in need.

About OMEICOS

OMEICOS Therapeutics, a late-stage clinical biopharmaceutical company, 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. The Company's most advanced development program OMT-28 is headed for a pivotal Phase 3 clinical study in Primary Mitochondrial Diseases (PMD). For more, please visit: www.omeicos.com

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