Epirium Bio Announces Follow-on Phase 1 Results in Older Adult Participants for MF-300 A First-In-Class, Oral 15-PGDH Enzyme Inhibitor, For the Treatment of Sarcopenia

As with the younger study participants, no safety concerns or dose limiting toxicities were observed in older adults and pharmacodynamic analysis continued to demonstrate evidence of target engagement together with a biologic effect

San Diego, CA, January 8, 2026. Epirium Bio Inc. (Epirium), a clinical-stage biopharmaceutical company advancing medicines for neuromuscular and fibrotic diseases, today announced additional results from the older adult follow-on cohorts from its completed Phase 1 trial evaluating MF-300, a novel therapy in development for primary or age-related sarcopenia. In the older cohorts, the study met its primary safety endpoint, and the evaluated dose of MF-300 - corresponding to the maximum estimated pharmacologic effect - was generally well tolerated, with no early discontinuations. In older adults, MF-300 continued to demonstrate the desired pharmacodynamic (PD) responses with a profile consistent with the younger study participants. PD responses were observed early and sustained over time, with effects that differentiated from placebo, supporting target engagement and biologic activity. Pharmacokinetic (PK) analyses demonstrated exposures consistent with younger adults, the observed half-life supporting convenient once-daily oral dosing.

“We are encouraged by the success of our Phase 1 study. In the age group targeted for our planned Phase 2 study in age-related sarcopenia, MF-300 results were consistent with the favorable safety, PK and PD findings observed in younger adults. Notably, all older participants receiving MF-300 demonstrated reductions in urinary PGE2 metabolites consistent with levels associated with maximal gains in muscle force in aged mouse models, along with substantial increases in urinary PGE2 that were comparable to increases observed in human muscle tissue after exercise,” said Alex Casdin, Chief Executive Officer of Epirium.

Mr. Casdin added, “These Phase 1 results in older adults support advancing MF-300 into a Phase 2 safety and efficacy study in patients with age-related sarcopenia, a disease affecting over 20 million seniors, for which there are no FDA-approved therapies.”

Phase 1 Study Details

The randomized, double-blind, placebo-controlled single and multiple-ascending dose (SAD and MAD) trial was designed to assess the safety, tolerability, PK and PD of MF-300 in

healthy adults, including younger (≥18 to ≤65 years of age) and older (>65 to ≤75 years of age) participants.

A total of 100 healthy participants were enrolled and received oral administration of MF-300 or placebo as part of single- and multiple-ascending (once daily dosing for 5 days) dose cohorts. MF-300 was well tolerated across all cohorts, with no serious adverse events and all participants completed the study. Most adverse events were assessed as mild. PK analyses demonstrated a half-life supporting a convenient once-daily oral administration. Evidence of on-target biological activity was observed, in a dose-dependent manner, as measured by changes in PGE2 and its metabolites, guiding dose selection for Phase 2. Findings were consistent between younger and older participants.

The company plans to initiate a randomized, placebo-controlled, Phase 2 clinical trial in patients with sarcopenia in mid-2026.

About MF-300

MF-300 is an investigational, first-in-class, orally administered, 15-hydroxyprostaglandin dehydrogenase (15-PGDH) enzyme inhibitor currently in development for the treatment of sarcopenia, or age-related muscle weakness. MF-300 reversibly occupies the prostaglandin E2 (PGE2) binding site of 15-hydroxyprostaglandin dehydrogenase (15-PGDH). 15-PGDH metabolically degrades PGE2, generating non-functional PGE2 metabolites, and is transcriptionally upregulated in aged muscle. Preclinical data show that PGE2 plays a crucial role in promoting aged muscle strength by improving muscle quality (i.e., muscle strength independent of muscle mass) as well as function of the neuromuscular junction. In preclinical studies, oral administration of MF-300 increases physiologic levels of PGE2 in skeletal muscle in rats and it increases muscle force and improves muscle quality in aged mice. Inhibiting 15-PGDH in aged muscle may be a strategy to increase physiologic levels of PGE2 to improve muscle quality and function in sarcopenia.

About Sarcopenia

The U.S. Food and Drug Administration (FDA) estimates that up to a third of Americans over the age of 60 are affected by sarcopenia, a disease that increases the risk of falls, fractures, disability and all-cause mortality. Despite sarcopenia's widespread prevalence and serious health implications, there are currently no FDA-approved therapies available to treat sarcopenia, highlighting the significant unmet medical need for this disease.

About Epirium Bio

Epirium, a biopharmaceutical company based in San Diego, California, has identified and established an IP-protected platform of orally bioavailable small molecules that constitute a new class of therapeutics with the potential to improve function in neuromuscular diseases, including sarcopenia and spinal muscular atrophy. Epirium has

generated preclinical data in a broader scope of indications with significant unmet medical need, including fibrosis, which Epirium's development pipeline has the potential to address.

To learn more about Epirium, please visit www.epirium.com and follow us on LinkedIn.

Contact

Email: info@epirium.com