Epirium Bio Announces Positive Type C (End-of-Phase 1) Meeting with FDA Supporting Advancement of MF-300 to a Phase 2b Clinical Trial in Sarcopenia

- Alignment gained on Phase 2b inclusion/exclusion criteria, primary and secondary endpoints, and trial design, including sample size and dosing regimen
- Company expects to begin enrolling patients in Phase 2b in the second half of 2026

San Diego, CA, January 27, 2026. Epirium Bio Inc. (Epirium), a clinical-stage biopharmaceutical company advancing medicines for neuromuscular, immunological and fibrotic diseases, today announced outcomes from its Type C meeting with the Food and Drug Administration (FDA). Epirium has received written feedback from the FDA on its Phase 2b trial plan to evaluate MF-300, an oral 15-PGDH enzyme inhibitor for the treatment of age-related sarcopenia. Epirium has previously completed a positive Phase 1 clinical trial of MF-300, including older adult cohorts.

Key Outcomes from the FDA Type C Meeting

- Reached concurrence with FDA on the patient population, primary and secondary efficacy endpoints, treatment duration and dosing regimen of MF-300.
- Agreement that the efficacy endpoints evaluated in the Phase 2b study will inform Phase 3 endpoint selection.
- Agreement that a Fast Track Designation request may be submitted for MF-300 as a treatment for sarcopenia.

Based on the positive outcome of this Type C meeting, Epirium will continue its plans to initiate a 6-month, randomized, double-blind, placebo-controlled, multi-center Phase 2b study designed to assess the safety and efficacy of MF-300 in patients diagnosed with age-related sarcopenia in the second half of 2026. The Company also plans to file an application for Fast Track Designation which, if accepted, will allow greater access to FDA interaction during MF-300 development for sarcopenia and enable priority review.

“We are pleased with the positive outcome of our End-of-Phase 1 meeting with the FDA, which provided constructive guidance on our development strategy for MF-300 in sarcopenia,” said Alex Casdin, Chief Executive Officer of Epirium. Mr. Casdin added, “Epirium and the FDA are in broad agreement on the major aspects of the proposed Phase 2b clinical trial for MF-300, a first-in-class oral treatment for sarcopenia. With alignment on key elements of our trial, we plan to advance MF-300 into the next stage of clinical evaluation to further assess its safety and efficacy in support of a future Phase 3 program.”

“In the absence of approved pharmacologic therapies or established regulatory pathways for sarcopenia, alignment with the FDA on a Phase 2b trial design represents an important

milestone for the field," said Dr. Jose Garcia, M.D., Ph.D., Professor, Department of Medicine, Division of Gerontology and Geriatric Medicine, University of Washington School of Medicine. "As sarcopenia represents a significant and growing unmet medical need, this agreement is a meaningful step toward advancing therapeutic options for patients affected by age-related muscle loss and weakness."

Phase 2b Study Details

The planned Phase 2b study is a 6-month, randomized, double-blind, placebo-controlled, multi-center trial designed to assess the safety and efficacy of MF-300 in approximately 200 patients diagnosed with sarcopenia. A comprehensive package of efficacy endpoints will assess the effect of MF-300 on muscle function, muscle strength and quality of life. The Company expects to begin enrolling patients into the trial in the second half of 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. In a Phase 1 trial evaluating the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of MF-300 in younger and older adults, the primary safety endpoint was achieved, the PD profile demonstrated dose-related target engagement and biologic activity, and the PK profile of MF-300 supports once daily dosing.

About Sarcopenia

The 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 also generated preclinical data across multiple therapeutic areas with significant unmet medical need, including immunology and 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.

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