



Epirium Bio Announces FDA Clearance of Investigational New Drug Application for MF-300 and Appointment of Alex Casdin as New Chief Executive Officer and Russell Cox as Executive Chairman

MF-300 Phase 1 Patient Screening Commencing

Expected First Patient Dosed in Q1 2025

San Diego, December 23, 2024. Epirium Bio, Inc. (Epirium), a biopharmaceutical company advancing medicines for neuromuscular and fibrotic diseases, is pleased to announce two significant milestones that mark a new chapter for the Company. The U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for MF-300, a first-in-class orally administered, 15-hydroxyprostaglandin dehydrogenase (15-PGDH) enzyme inhibitor in development for the treatment of sarcopenia, or age-induced muscle weakness. The first study under this IND will be a Phase 1 randomized, double-blinded, placebo controlled, dose escalation clinical trial of MF-300 in healthy adults. The primary objective of the Phase 1 trial is to evaluate the safety and tolerability of orally administered MF-300 in healthy volunteers. Additional objectives of the trial will be to study the pharmacokinetics of MF-300 and determine a recommended Phase 2 dose. In December 2024 Epirium will commence patient recruitment for the dose escalation portion of this Phase 1 study.

Simultaneously, Epirium announced today the transition of Russell Cox, President and Chief Executive Officer (CEO) to the role of Executive Chairman and the appointment of Alex Casdin, Epirium's current Chief Operating Officer, as its new CEO, both effective January 1, 2025. "Becoming a clinical stage company is a transformation event for Epirium, and I am pleased to pass the reins of CEO to Alex, who has been instrumental in leading the Company's progress to date," said outgoing CEO, Russell Cox.

With a 25-year track record of creating value across a wide range of companies in the biotech, biopharmaceutical and healthcare sectors, Mr. Casdin brings a wealth of knowledge and expertise to his new role. "I am honored to take on the role of CEO at such an exciting time for our company. I look forward to leading Epirium as we move into the clinic. I am also grateful to our dedicated and talented team for their continued hard work and strong executional focus on our goal of delivering first-in-class oral therapies targeting neuromuscular diseases with significant unmet medical needs, such as sarcopenia," said Mr. Casdin. "I also look forward to continuing my work with Russ and our Board to create significant value for Epirium's stakeholders as the company progresses in its next chapter."

Building on its operational momentum, Epirium secured a bridge financing round earlier this month, led by its current investor syndicate. “This infusion of capital will enable Epirium to deliver MF-300 Phase 1 results in H2’25 while making the necessary investments to ensure the timely initiation of a Phase 2 study in patients with sarcopenia in H1’26,” said Paul Berns, Chairman of the Board of Directors.

“We are very encouraged by the preclinical data demonstrating an improvement in muscle force and now look forward to generating data in humans. I would also like to express my gratitude to Russ for the dedication and commitment at Epirium towards achieving the goal of getting MF-300 into the clinic,” said Patrick Enright, Co-Lead investor, Longitude Capital.

About MF-300

MF-300 is an investigational, orally bioavailable small molecule that reversibly binds to the Prostaglandin E2 (PGE2)-binding site of 15-hydroxyprostaglandin dehydrogenase (15-PGDH), an enzyme that converts PGE2 to an inactive metabolite. MF-300 target engagement inhibits 15-PGDH activity in biochemical assays, stabilizing and increasing levels of PGE2 in a cell-based assay and in skeletal muscle in preclinical studies of healthy animals.

In humans and rodents, 15-PGDH gene expression is elevated in muscle coincident with the onset of age-induced muscle weakness. PGE2, a lipid signaling molecule with multiple beneficial effects on the motor unit, including enhanced muscle quality and improved function of the neuromuscular junction, is reduced in skeletal muscle of aged mice due to increased activity of 15-PGDH. Inhibiting 15-PGDH in aged muscle may be a strategy to increase physiologic levels of PGE2 to improve muscle quality and function.

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](#).

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