



## **Epirium Bio Presented Positive Phase 1 Safety, Pharmacokinetics and Pharmacodynamics Data for MF-300, Supporting its Role in Muscle Health, as a Late-Breaker at the Gerontological Society of America Annual Scientific Meeting 2025**

*MF-300 is a first-in-class, orally administered 15-PGDH inhibitor advancing into Phase 2 for the treatment of sarcopenia in older adults*

San Diego, November 17, 2025. Epirium Bio Inc. (Epirium), a clinical-stage biopharmaceutical company advancing medicines for neuromuscular and fibrotic diseases, presented Phase 1 data for its lead candidate, MF-300, at the Gerontological Society of America's (GSA) annual meeting held November 12-15, 2025, in Boston, MA.

MF-300 is an investigational, first-in-class, orally administered, 15-hydroxyprostaglandin dehydrogenase (15-PGDH) enzyme inhibitor in development for the treatment of sarcopenia. Inhibition of 15-PGDH enhances endogenous prostaglandin E2 (PGE2) signaling, a pathway associated with the beneficial adaptive response to exercise. Preclinical studies have demonstrated that MF-300 increases muscle force and improves muscle quality in aged mice and in other preclinical models of neurogenic atrophy.

### **Phase 1 Results**

The Phase 1 study evaluated the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of MF-300 in a total of 82 healthy adults, including 54 participants across single-ascending-dose (75–800 mg) and multiple-ascending-dose (75–200 mg daily × 5 days) cohorts. All endpoints of safety and tolerability were met. Key findings included:

- In multiple-dose cohorts (once-daily for 5 days), MF-300 showed rapid absorption and dose-dependent increases in exposure with a half-life that supports once-daily dosing.
- Observed MF-300 exposure levels were consistent with preclinical efficacy thresholds, supporting its potential to translate preclinical activity into clinical benefit.
- There were no unexpected or dose-limiting safety findings, no serious adverse events, and no early discontinuations.
- PD analyses demonstrated clear target engagement with increases in urinary PGE2, accompanied by decreases in urinary PGE-MUM – its primary metabolite – consistent with 15-PGDH inhibition. Importantly, the magnitude of PGE-MUM reduction matched levels previously associated with improved muscle quality, including gains in force, in aged mice.
- Collectively, the study met all predefined success criteria across safety, PK, and PD, providing a solid foundation for moving MF-300 forward in clinical development.

The Phase 1 results demonstrated a favorable safety profile and predictable pharmacokinetics, supporting convenient once-daily oral dosing,” said Alex Casdin, Chief Executive Officer of Epirium.

Mr. Casdin added, “As the first 15-PGDH inhibitor tested in humans to date, MF-300 also produced biomarker changes confirming target engagement and clear proof of mechanism. Together these findings support continued clinical development of MF-300 as a first-in-class potential treatment for sarcopenia, addressing a significant unmet need and targeting a pathway directly linked to improving muscle strength”.

The presentation is available in the “Posters and Publications” section of Epirium’s website, [www.epirium.com](http://www.epirium.com).

### **About MF-300**

MF-300 is an investigational, orally bioavailable small molecule that 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 clinical-stage 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](http://www.epirium.com) and follow us on [LinkedIn](#).

### **Contact**

Email: [info@epirium.com](mailto:info@epirium.com)