Biomea Fusion Reports Preclinical Data for BMF-650, a Next-Generation Oral GLP-1 Receptor Agonist Candidate, Demonstrating Robust Weight Loss and Appetite Suppression in Obese Non-Human Primates

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- ***Dose-dependent, marked reductions in food intake and significant weight loss observed in obese cynomolgus monkeys***
- ***BMF-650 compared favorably to published data of a leading GLP-1 RA candidate***
- ***IND filing on track for the second half of 2025; with Phase I study initiation in obese, otherwise healthy volunteers anticipated late 2025***

REDWOOD CITY, Calif., June 18, 2025 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea,” “Biomea Fusion” or the “Company”) (Nasdaq: BMEA), a clinical-stage diabetes and obesity medicines company, today announced new preclinical findings from a 28-day weight loss study in obese non-human primates evaluating BMF-650, the Company’s investigational, next-generation oral small molecule glucagon-like peptide-1 receptor agonist (GLP-1 RA).

The weight reduction study was conducted in 15 obese cynomolgus monkeys. The study demonstrated a clear, dose-dependent reduction in daily food intake and pronounced and continuous weight loss over a 28-day treatment period. BMF-650 was administered orally once daily at 10 mg/kg and 30 mg/kg and resulted in marked reductions in food intake and progressive body weight reductions, with the respective dose groups achieving a 12% and 15% average weight reduction from baseline over 28 days. These effects compared favorably to published preclinical data of another leading oral GLP-1 RA candidate in development.

“These new findings are especially relevant given the functional similarities between monkey and human GLP-1 receptors. These data disclosed today further support our goal of developing a next-generation oral GLP-1 receptor agonist with enhanced pharmacokinetic properties, specifically a more consistent plasma exposure and improved bioavailability, while preserving the potent metabolic effects observed with injectable therapies,” said Thorsten Kirschberg, Executive Vice President of Chemistry at Biomea and program lead for BMF-650. “These data reinforce BMF-650’s potential as a best-in-class oral GLP-1 RA with robust metabolic effects. We believe the pronounced and consistent appetite suppression and weight loss observed in primates, together with earlier data on glucose-lowering and oral bioavailability, provide strong support for advancing BMF-650 into clinical development.”

Study Design and Key Preclinical Findings

- The study assessed 15 obese cynomolgus monkeys, randomized into three groups receiving vehicle, BMF-650 at 10 mg/kg, or BMF-650 at 30 mg/kg daily for 28 days.
- Daily food intake was reduced to an average of 35g/day (10 mg/kg) and 16g/day (30 mg/kg) versus 109 g/day for the vehicle control group.
- BMF-650 induced rapid and durable weight loss during the study, with reductions of 12% (10 mg/kg) and 15% (30 mg/kg) from baseline at Day 28.
- BMF-650 was generally well tolerated, with no aminotransferase (AT) elevations.

BMF-650 Preclinical Highlights

- Similar to the broader orforglipron chemotype class, designed to improved PK properties, enhance oral bioavailability, achieve less variability and higher plasma protein binding for a potentially enhanced safety and tolerability profile.
- Goal to achieve a more patient-friendly dose escalation profile than current GLP-1 RAs.
- Demonstrated robust glycemic control and appetite suppression in multiple preclinical models resulting in pronounced and dose-dependent weight reduction.
- Generally well tolerated without safety concerns outside of the observed class effects.

Next Steps

- Investigational New Drug (IND) submission on track for the second half of 2025.
- Phase I trial in obese, otherwise healthy volunteers anticipated to begin in late 2025, subject to IND clearance.
- A full set of preclinical data for BMF-650 is planned for submission and presentation at an upcoming medical conference.

About BMF-650
BMF-650 is an investigational, next-generation oral small-molecule GLP-1 RA being developed by Biomea Fusion for the treatment of obesity. Related to the broader orforglipron chemotype, BMF-650 is designed to combine enhanced oral bioavailability and durable receptor activation to deliver robust metabolic benefits.

In preclinical studies, BMF-650 demonstrated a favorable PK profile with higher bioavailability and less inter-individual variability compared to published third-party preclinical data on another oral GLP-1 RA. These attributes may support improved tolerability and more effective dose escalation in clinical settings. BMF-650 significantly enhanced glucose-stimulated insulin secretion in both human donor islets and in vivo in non-human primates and showed robust glucose-lowering activity and appetite suppression in cynomolgus monkey models. Notably, daily oral dosing resulted in dose-dependent reductions in food intake and progressive weight loss across the treatment period in a study with obese cynomolgus monkeys.

Biomea's development strategy for BMF-650 focuses on achieving steady plasma levels and increased drug exposure (AUC) to support a potential best-in-class profile among oral small-molecule GLP-1 therapies. BMF-650 is currently advancing through IND-enabling studies, with submission of an IND application on track for the second half of 2025.

About Obesity
Obesity is a chronic disease necessitating long-term management, associated with diminished life expectancy and a spectrum of severe health complications. These include metabolic disorders such as type 2 diabetes and metabolic liver disease; cardiovascular diseases such as coronary artery disease, cerebrovascular disease, and hypertension; and increased risks of chronic kidney disease, certain cancers, and chronic inflammation. The Centers for Disease Control and Prevention estimates that over 40% of adults in the United States suffer from obesity, contributing to a significant burden on public health and healthcare systems. Globally, over 650 million adults are living with obesity, and these numbers are steadily rising.

About GLP-1 Receptor Agonists
GLP-1 is a naturally occurring incretin hormone that plays a vital role in glucose homeostasis and appetite regulation. GLP-1 RAs are a class of medications that bind to and activate GLP-1 receptors, mimicking the effects of native GLP-1. These agents have demonstrated robust clinical efficacy in improving glycemic control, promoting weight loss, and enhancing insulin sensitivity in individuals with type 2 diabetes and obesity.

About Biomea Fusion
Biomea Fusion is a clinical-stage diabetes and obesity medicines company focused on the development of its oral small molecules, icovamenib and BMF-650, both designed to significantly improve the lives of patients with diabetes, obesity, and metabolic diseases. We aim to cure.

Visit us at biomeafusion.com and follow us on LinkedIn, X, and Facebook.

Forward-Looking Statements

Statements we make in this press release may include statements which are not historical facts and are considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact, including statements regarding the clinical and therapeutic potential of our product candidates and development programs, including BMF-650, the potential of BMF-650 as a treatment for type 2 diabetes and obesity, our research, development, partnership and regulatory plans, the mechanism of action of our product candidate and development programs; the progress and initiation of our ongoing and upcoming clinical trials, including our planned IND submission for BMF-650 and our anticipated initiation of a Phase I study for BMF-650 following IND clearance, the anticipated availability of data from our clinical trials; our planned interactions with regulators and the timing of such events may be deemed to be forward-looking statements. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. Any forward-looking statements in this press release are based on our current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, including the risk that results of preclinical studies may not be predictive of future preclinical results or clinical results in connection with planned clinical trials and the risk that we may encounter delays in preclinical or clinical development, interactions with regulatory authorities related to clinical development, and in the initiation, conduct and completion of our planned clinical trials and other research and development activities. These risks concerning Biomea's business and operations are described in additional detail in its periodic filings with the U.S. Securities and Exchange Commission (SEC), including its most recent periodic report filed with the SEC and subsequent filings thereafter. Biomea Fusion explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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