Biomea Fusion Announces First Patient Dosed in Phase I Study of BMF-650 a Next-Generation Oral GLP-1 Receptor Agonist

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Initial Clinical Data Expected in the First Half of 2026

SAN CARLOS, Calif., Oct. 27, 2025 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea,” “Biomea Fusion” or the “Company”) (Nasdaq: BMEA), a clinical-stage diabetes and obesity medicines company, today announced that the first patient has been dosed in a Phase I clinical trial of BMF-650, the Company’s investigational, next-generation oral small molecule glucagon-like peptide-1 (“GLP-1”) receptor agonist (“RA”).

BMF-650 is an orally administered, next-generation small molecule GLP-1 RA being developed by Biomea for the treatment of obesity. Structurally related to the chemotype class of orforglipron, BMF-650 was designed to combine enhanced oral bioavailability with less PK variability and high plasma protein binding with good intrinsic potency to achieve more patient-friendly weight reduction outcomes.

In preclinical studies with obese cynomolgus monkeys, once-daily oral administration of BMF-650 (10 mg/kg and 30 mg/kg) resulted in clear, dose-dependent reductions in daily food intake and continuous, progressive weight loss over a 28-day treatment period. Animals receiving 10 mg/kg and 30 mg/kg doses achieved average body weight reductions of approximately 12% and 15%, respectively, from baseline. BMF-650 was well tolerated and maintained a good safety profile. These results compare favorably with published preclinical data from another leading oral GLP-1 receptor agonist in development.

“Dosing the first patient represents a major milestone for the BMF-650 program and the dedicated team behind it,” said Thorsten Kirschberg, Ph.D., Executive Vice President of Research at Biomea Fusion and program lead for BMF-650. “We are very pleased to advance BMF-650 into clinical evaluation, building on the compelling preclinical results in primates that demonstrated robust appetite suppression, weight loss, and glucose-lowering benefits. With its enhanced pharmacokinetic profile, including improved oral bioavailability and consistent plasma exposure, we believe BMF-650 has the potential to deliver distinct metabolic benefits in a convenient, once-daily oral form. We look forward to sharing initial data from this study, which is anticipated to be announced in the first half of 2026.”

The Phase I clinical trial will assess the safety, tolerability, and preliminary efficacy of BMF-650 in otherwise healthy overweight or obese participants, with 28-day weight loss data at the highest dose expected in the first half of 2026.

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 pharmacokinetic profile with higher bioavailability, good efficacy, 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 consistent plasma levels and increased drug exposure to support a potential best-in-class profile among oral small-molecule GLP-1 therapies.

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.

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 molecule product candidates, 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, and our expectations regarding the optimal dose and target patient population; our research, development, partnership and regulatory plans, the mechanism of action of our product candidates and development programs; the progress and initiation of our ongoing and upcoming clinical trials, including our Phase I study for BMF-650, 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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