



Biomea Fusion Announces Phase 1 Results for BMF-650, its Investigational Next-Generation Oral Small Molecule GLP-1 Receptor Agonist

October 13, 2026

- Mean weight reduction ranged from 1.5% to 3.2% at Day 29 across Cohorts 1-4, compared with 0.1% for pooled placebo.
- No severe or serious TEAEs, no TEAE-related dose modifications, and no TEAE-related discontinuations among all BMF-650-treated MAD participants.
- A rapid one-step titration to the target dose of 400 mg QD in Cohort 5 was equally well tolerated with all TEAEs being mild, with nausea and vomiting each reported in only 12.5% of participants, supporting further evaluation of “no titration” dosing for patients.
- Company to host conference call on October 13 at 4:30 p.m. ET (1:30 p.m. PT).

SAN CARLOS, Calif., Oct. 13, 2026 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea” or the “Company”) (Nasdaq: BMEA), a clinical-stage biopharmaceutical company, today announced Phase 1 GLP-131 clinical trial results for BMF-650, its investigational oral small-molecule glucagon-like peptide-1 receptor agonist (“GLP-1 RA”), which demonstrated consistent weight reduction across five multiple ascending dose (“MAD”) cohorts over four weeks and encouraging tolerability even when reaching 400 mg QD in the highest dosing cohort after only a single one-week titration step. Together, these findings provide encouraging early evidence of BMF-650’s clinical activity, sustained weight-reduction trajectory, and, importantly, its tolerability.

“BMF-650 is the culmination of a program we initiated approximately four years ago, and these Phase 1 results provide important clinical validation of the work behind its design,” said Mick Hitchcock, Ph.D., Interim Chief Executive Officer and Board Member of Biomea Fusion. “We observed consistent weight reduction across multiple dose cohorts, encouraging tolerability and the ability to reach 400 mg after just one brief titration step. We believe these findings warrant further evaluation, including through potential collaborations. At the same time, our primary development focus remains firmly on menin inhibition with icovamenib in type 1 and type 2 diabetes, where we have several important clinical milestones ahead.”

The randomized, double-blind, placebo-controlled Phase 1 GLP-131 study evaluated safety and tolerability measures as co-primary endpoints and pharmacokinetics, pharmacodynamics and weight reduction in overweight or obese, otherwise healthy adults as key secondary endpoints. The study included a single ascending dose part followed by five MAD cohorts. In Cohorts 1-4, mean Day 29 weight reduction ranged from 1.5% to 3.2%, compared with 0.1% for pooled placebo from those cohorts. Across Cohorts 1-4, the mean weekly weight reduction at doses of 200 mg or higher once daily was approximately 0.97 kg. Additional data analysis remains ongoing, and we expect to present those results at a future medical meeting.

To ensure dosing compliance and better characterize the safety and tolerability profile of BMF-650, an additional fifth MAD cohort was conducted under confinement. Participants received 200 mg BMF-650 once daily for one week followed by 400 mg once daily for three weeks. At Day 29, mean weight reduction was 6.1% (6.2 kg), averaging approximately 1.55 kg per week, without observed attenuation during treatment. A similar weight reduction was observed by the two placebo patients. While all participants were provided 2,100 kcal/day, the 2 placebo participants consumed only approximately 33% of the presented food. As confinement appeared to have affected eating behavior for the Cohort 5 participants, we believe the results of Cohort 5 should be interpreted separately from the outpatient Cohorts 1-4.

Safety and Tolerability

Across the five active-dose MAD cohorts (n=40), all reported treatment-emergent adverse events (TEAEs) were mild or moderate. There were no severe or serious TEAEs, TEAE-related dose modifications, or TEAE-related study discontinuations. In the highest dosing group, Cohort 5, nausea and vomiting were each reported in one of eight BMF-650-dosed participants (12.5%), constipation in two (25%) and diarrhea in none (0%); these gastrointestinal (“GI”) events were all Grade 1. Across all active MAD cohorts, nausea occurred in 17.5%, vomiting in 7.5%, constipation in 10%, and diarrhea in 5% of participants. No adverse events of increased Alanine Aminotransferase (“ALT”)/Aspartate Aminotransferase (“AST”) were reported. These findings are preliminary and reflect outcomes from four weeks of treatment.

Pharmacokinetics and Simple Titration

BMF-650 was designed with a medicinal chemistry strategy to separate GI adverse events from weight loss objectives. BMF-650 in Cohort 5 demonstrated sustained systemic exposures supporting once-daily oral administration with a low peak to trough ratio. Participants who advanced from 200 mg once daily to 400 mg once daily after one week remained at 400 mg for the subsequent three weeks (Cohort 5) and demonstrated similar GI tolerability as the other patients who underwent slower titration. We believe these data may provide sufficient support to test for a potential ‘no titration’ regimen. Further longer-duration studies and additional clinical data will be needed to fully characterize the optimal patient dosing regimen for BMF-650.

“Our objective in designing BMF-650 was not to maximize weight loss compared to other oral GLP-1s, but rather we specifically designed the molecule for less acute GLP-1 receptor agonism in the GI tract, with the goal of improving GI tolerability while maintaining weight loss consistent with industry standards weight loss. Our goal was to eliminate titration steps which can take 5 months or more with other GLP-1s and are typically required to avoid over-agonism. BMF-650 was designed to ultimately increase persistence with chronic therapy,” said Thorsten Kirschberg, Ph.D., Executive Vice President of Research at Biomea Fusion and program lead for BMF-650. “BMF-650 demonstrated good oral absorption in this study with consistent and sustained systemic exposure. We believe these Phase 1 results provide initial clinical evidence supporting our design strategy, with meaningful weight reduction, a well-tolerated safety profile, and rapid one-step titration to the 400 mg target dose without increasing local GI agonism and side effects.”

BMF-650 Development Considerations

After finalizing data collection from the Phase 1b clinical trial, additional clinical development of BMF-650 will require longer-term toxicology studies. Biomea intends to continue that work while positioning the program for a strategic partnership, which could include a licensing arrangement for late-stage development and commercialization.

Conference Call and Webcast Details

Biomea’s management will host a conference call on October 13, 2026, at 4:30 p.m. ET (1:30 p.m. PT). The live webcast will be available under the Investors and Media section of the Company’s website at <https://investors.biomeafusion.com/news-events/events>. A replay of the webcast will be archived on Biomea’s website following the event.

About the Phase 1 Study

The GLP-131 Phase 1 ([NCT07223216](#)) study is a randomized, double-blind, placebo-controlled, single and MAD study evaluating safety, tolerability, pharmacokinetics, pharmacodynamics and effects on body weight of BMF-650 in otherwise healthy overweight or obese adult participants. The study includes a single ascending dose portion and five MAD cohorts. The fifth MAD cohort was added to evaluate a rapid one-step titration regimen, with participants receiving 200 mg once daily for one week followed by 400 mg once daily for three weeks.

About Biomea Fusion

Biomea Fusion is a clinical-stage biopharmaceutical company advancing oral small molecule therapies, icovamenib and BMF-650, for diabetes and obesity. These programs target metabolic disorders, a global health challenge affecting nearly half of Americans and one-fifth of the world’s population. Biomea’s mission is to deliver transformative treatments that restore health for patients living with diabetes, obesity and related conditions. We aim to cure.

Visit us at biomeafusion.com and follow us on [LinkedIn](#), [Twitter](#) 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 icovamenib and BMF-650; the potential of icovamenib as a treatment for T1D and T2D; our research, development and regulatory plans; the timing of patient enrollment and dosing completion, and progress and availability of data from our clinical trials, including for the COVALENT-211 and COVALENT-212 Phase 2 trials; and our ongoing Phase 1 trial evaluating BMF-650; the potential clinical profile of BMF-650 and its development as a next-generation oral GLP-1 RA for obesity and metabolic disease; the mechanism of action of our product candidates and development programs; and the results and 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 preliminary or interim results of nonclinical studies or clinical trials may not be predictive of future or final results in connection with future clinical trials and the risk that we may encounter delays or adverse outcomes in regulatory interactions, nonclinical or clinical development, patient enrollment and in the initiation, conduct and completion of our ongoing and planned clinical trials and other research and development activities. These risks concerning Biomea Fusion’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.

Contact:

Meichiel Jennifer Weiss
Senior Director of Investor Relations and Corporate Development
ir@biomeafusion.com