Biomea Fusion Enters 2026 Focused on Executing Key Icovamenib and BMF-650 Milestones

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- ***Advancing icovamenib toward late-stage clinical development in two Phase II clinical trials in patients with insulin-deficient type 2 diabetes ("T2D") and in T2D patients currently failing glucagon-like peptide-1 ("GLP-1") based therapies***
- ***Successfully completed icovamenib food-effect study, establishing optimal dosing conditions to support late-stage clinical studies***
- ***Successfully completed icovamenib chronic toxicology studies, supporting potential flexibility to evaluate clinical dosing beyond the validated 12-week regimen***
- ***Advancing BMF-650 through clinical development as an oral next-generation GLP-1 receptor agonist candidate designed to deliver effective and patient-friendly metabolic benefits***
- ***Company to share 2026 strategy at the 44th Annual J.P. Morgan Healthcare Conference***

SAN CARLOS, Calif., Jan. 12, 2026 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea," "Biomea Fusion" or "the Company") (Nasdaq: BMEA), a clinical-stage diabetes and obesity company, today outlined its execution priorities for 2026. The Company enters the year with strong operational momentum and a defined plan across its investigational metabolic programs, led by icovamenib, a potentially first-in-class investigational covalent menin inhibitor for diabetes, and BMF-650, an oral next-generation GLP-1 receptor agonist candidate in clinical development for obesity and metabolic disorders. Biomea remains focused on disciplined execution of its development strategy, advancing medicines designed to modify the underlying biology of diabetes and obesity with the goal of delivering durable clinical benefits.

"We are entering 2026 with clarity, alignment, and a commitment to execution," said Mick Hitchcock, Ph.D., Interim Chief Executive Officer and Board Member. "We know what needs to be done and we are focused on doing it. We believe icovamenib has the potential to redefine the treatment for insulin-deficient diabetes and those type 2 diabetes patients currently failing on GLP-1 therapies. We are also excited with our clinical progress with BMF-650 which strengthens our position in obesity care with a potentially more patient-friendly designed oral GLP-1 therapy. Our objective this year is straightforward, execute on our clinical plans and to deliver against the clinical milestones we have set out."

Icovamenib: Advancing Toward Late-Stage Clinical Development
Icovamenib is a potentially first-in-class investigational small molecule covalent menin inhibitor that has been shown to promote beta-cell proliferation and improve beta-cell function, addressing an underlying disease driver in diabetes. The therapy continues to demonstrate meaningful and durable clinical benefits in patients with insulin deficiency, a subgroup of T2D associated with reduced beta-cell function, higher complication risk, and limited treatment options. Recently reported 52-week data further supports icovamenib's potential to deliver sustained glycemic improvement in this subgroup following a finite 12-week dosing period, reinforcing its differentiated approach focused on beta-cell health.

Importantly, the 52-week data analysis also demonstrated clinically meaningful benefit in patients who were receiving GLP-1-based therapy at study entry but had not achieved glycemic targets, supporting the potential use of icovamenib alongside incretin-based treatment. Together with mechanistic data, showing enhancement of GLP-1 receptor and insulin expression, we believe these results continue to strengthen the rationale for advancing icovamenib as both a standalone option in severe insulin-deficient diabetes and a complementary treatment approach in patients who are not adequately controlled on GLP-1-based therapies.

During the fourth quarter of 2025, Biomea completed the COVALENT-121 food-effect study in 60 participants. The study demonstrated that icovamenib achieved optimal pharmacokinetic exposure, while demonstrating a generally favorable safety profile in line with prior clinical data when administered within 30 minutes after a meal. These data play an important role in our future clinical plans potentially ensuring consistent drug exposure and appropriate dosing as the Company prepares to dose the first patients in its Phase II studies, COVALENT-211 and COVALENT-212.

In addition, Biomea has successfully completed chronic toxicology studies in two species for icovamenib, further strengthening the program's safety foundation. These studies demonstrated a favorable safety profile consistent with previously reported preclinical and clinical data. To date, more than 400 subjects have been dosed with icovamenib, with results indicating that the compound has been generally well-tolerated.

BMF-650: Progressing Oral GLP-1 Development
BMF-650 represents Biomea's commitment to advancing next-generation accessible metabolic care through patient-friendly therapy options. BMF-650 is an orally administered, next-generation small molecule GLP-1 receptor agonist endowed with enhanced oral bioavailability, favorable pharmacokinetic profile, and reduced variability to support effective, patient-friendly treatment.

Biomea plans to continue clinical advancement of BMF-650 in 2026, with initial 28-day weight loss clinical data expected in the second quarter of 2026 from the Phase I study in obese otherwise healthy volunteers.

Biomea's anticipated 2026 milestones include:

- COVALENT-211, Phase IIb, icovamenib in insulin-deficient type 2 diabetes, with first patient enrollment expected in the first quarter of 2026 and readout of the 26-week primary endpoint evaluating HbA1c reduction in approximately 60 patients expected in the fourth quarter of 2026.
- COVALENT-212, Phase II, icovamenib in type 2 diabetes patients inadequately controlled on GLP-1-based therapies (i.e., semaglutide), with first patient enrollment expected in the first quarter of 2026 and readout of the 26-week primary endpoint evaluating HbA1c reduction in approximately 60 patients expected in the fourth quarter of 2026.
- GLP-131, Phase I, BMF-650 in obese, otherwise healthy volunteers, with completion of single- and multiple-ascending dose cohorts and final 28-day weight-loss data expected in the second quarter of 2026.
- Continued proactive regulatory engagement and collaboration with clinical and scientific experts to support progression toward late-stage development.
- Anticipate completion of additional preclinical studies in relevant diabetes models to further evaluate the potential of icovamenib and BMF-650 across selected diabetes and obesity subpopulations.

Mick Hitchcock, Ph.D., will present at the 44th Annual J.P. Morgan Healthcare Conference on Wednesday, January 14, 2026 from 5:15 PM to 5:55 PM Pacific Time. A live audio webcast of the presentation can be accessed here or by visiting the Investors & Media section of Biomea's website at biomeafusion.com. A replay of the webcast will be available following the live presentation.

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, 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 icovamenib and BMF-650, the potential of icovamenib as a treatment for T2D, the potential of BMF-650 as a treatment for obesity; our research, development and regulatory plans, the timing of initiation, patient enrollment and dosing, progress and availability of data from our clinical trials; the mechanism of action of our product candidates and development programs; our engagement with regulatory authorities and collaboration with clinical and scientific experts; 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 preclinical 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, preclinical 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
Sr. Director of Investor Relations and Corporate Development
ir@biomeafusion.com