



Biomea Fusion Presents COVALENT-111 Study Results at the 23rd World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC)

December 5, 2025

Durable Glycemic and C-Peptide Improvements with Icovamenib in Insulin-Deficient Type 2 Diabetes

SAN CARLOS, Calif., Dec. 05, 2025 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea" or "Biomea Fusion" or "the Company") (Nasdaq: BMEA), a clinical-stage diabetes and obesity company, today announced that it presented COVALENT-111 study results at the 23rd WCIRDC which took place December 3-6, 2025 in Los Angeles, California. The data showed durable glycemic and c-peptide improvements with icovamenib, a menin inhibitor targeting beta-cell restoration in insulin deficient type 2 diabetes.

"I am very pleased that our data was selected for an oral presentation at the WCIRDC meeting this year. Over the past 24 months, our clinical studies have shown that selective inhibition of menin can meaningfully influence the clinical response of patients with insulin deficient diabetes. The results we presented at this meeting highlight the lasting and continuous benefits observed in our study, with durable glycemic and C-peptide improvements 9 months after the last dose," said Mick Hitchcock, Ph.D., Interim CEO and Board Member of Biomea Fusion. "Targeting menin offers promise for people living with diabetes, with the potential to support the natural insulin producing capacity of the pancreatic beta cells. Icovamenib, as a selective menin inhibitor, represents a first in class approach in this area of research."

Key Highlights from WCIRDC showing HbA1c and C-peptide responses at week 52 – 9 months post the last dose:

- Icovamenib demonstrated durable and continuous treatment effect in severe insulin-deficient type 2 diabetes (T2D)
- Higher HbA1c reduction was associated with higher icovamenib exposure
- Icovamenib improved long-term insulin secretion in severe insulin-deficient T2D
- Treatment effect in GLP-1 "failures" continued to improve with durable and clinically significant improvements in HbA1c
- Icovamenib was generally well-tolerated, with no adverse-event related discontinuations and no related serious adverse events

The abstract will be published in the peer-reviewed *Metabolism: Experimental and Clinical*. The presentation will be available on Biomea Fusion's Investor Relations Page under the Events. Please find a link [here](#) to our website where the poster will be available.

COVALENT-111 Study Design

COVALENT-111 is a double-blind, randomized, placebo-controlled trial that enrolled adult patients diagnosed with T2D within the last 7 years. Eligible participants had HbA1c levels between 7.0% and 10.5%, and a body mass index (BMI) between 25 and 40 kg/m². At baseline, all participants were treated with lifestyle management, including diet and exercise, with or without antidiabetic medications and had inadequate glycemic control despite treatment with up to three antidiabetic medications. The study evaluated icovamenib in three dosing regimens: Arm A at 100mg QD (once daily) for 8 weeks, Arm B at 100mg QD for 12 weeks, and Arm C at 100 mg QD for 8 weeks and 100mg BID (twice daily) for 4 weeks.

About Icovamenib

Icovamenib is an investigational, orally bioavailable, potent, and selective covalent inhibitor of menin. The proposed mechanism of action for icovamenib in diabetes is selective and partial inhibition of menin, a regulator of beta cell quantity and function, thereby enabling the proliferation, preservation, and reactivation of a patient's own healthy, functional, insulin-producing beta cells. As the first non-chronic therapy for T2D, icovamenib could become an important addition to the diabetes treatment landscape once it has successfully completed its ongoing clinical studies.

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 www.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 the potential of icovamenib as a treatment for T1D and T2D, and our expectations regarding the optimal dose and target patient population; our research,

development 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 Food Effect Study (COVALENT-121), the initiation of our Phase IIb trial (COVALENT-211) in severe insulin-deficient type 2 diabetes patients, to initiate in fourth quarter of 2025 and the initiation of our Phase II trial with GLP-1 therapy (COVALENT-212) in type 2 diabetes patients, in the fourth quarter of 2025; 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 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 in 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.

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