Biomea Fusion Presents Phase II COVALENT-111 Data in Type 2 Diabetes at the 19th International Conference on Advanced Technologies & Treatments for Diabetes 2026

March 14, 2026

SAN CARLOS, Calif., March 14, 2026 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea,” “Biomea Fusion,” or the “Company”) (Nasdaq: BMEA), a clinical-stage diabetes and obesity company, today announced that Juan Pablo Frías, MD, delivered an oral presentation at the 19th International Conference on Advanced Technologies & Treatments for Diabetes (“ATTD”) in Barcelona on March 14, 2026 highlighting positive 52-week follow-up results from the Company’s Phase II COVALENT-111 study evaluating the efficacy, safety, and tolerability of icovamenib in patients with type 2 diabetes (“T2D”).

“We are encouraged by the durability of icovamenib’s effect observed nine months post-dosing at Week 52,” said Mick Hitchcock, Ph.D., Interim CEO and Board Member of Biomea Fusion. “We believe that we now have in hand initial evidence of durable efficacy, additional favorable safety data, a clear understanding of an effective dose, and most importantly, the target patient populations. We believe icovamenib demonstrates potential to transform the diabetes treatment landscape by effectively addressing the underlying biology. We are excited about the upcoming two new Phase II studies which are designed to specifically address those patients that had the best responses in our trial COVALENT-111.”

COVALENT-111 Study Design and Results
COVALENT-111 was a double-blind, randomized, placebo-controlled trial that enrolled adult patients diagnosed with T2D within the last seven 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. A total of 267 patients received at least one dose of icovamenib and were considered evaluable for the modified intent-to-treat population. As previously reported, study dosing was temporarily interrupted due to a clinical hold imposed by the U.S. Food and Drug Administration. The topline efficacy analysis presented here includes the patient population (N=163) who had completed at least 80% of their planned dosing prior to the clinical hold (without other significant protocol deviations) and who, at baseline, were treated with one or more antihyperglycemic agents. As prespecified in the statistical analysis plan, outcomes were prospectively evaluated by diabetes phenotype using the Ahlqvist algorithm.

The study showed positive results, while exploratory, through Week 52 across multiple subgroups, with certain groups demonstrating statistically significant and clinically meaningful reductions in HbA1c, the gold standard for assessing glycemic control in T2D, observed nine months after dosing. In the 26-week analysis, 8 weeks of dosing was found to be less effective than 12. Accordingly, the 52-week readout primarily focused on patients in Arms B and C who received 12 weeks of treatment. Among the severe insulin-deficient patients (n=10), icovamenib achieved an HbA1c reduction that improved over time reaching 1.2% at Week 52 ((p=0.01 vs placebo). The strongest performing arm for this prespecified population was Arm B (n=6; 100mg QD for 12 weeks), with a mean HbA1c reduction of 1.5% (p=0.01). Severe insulin-deficient diabetes (“SIDD”) is characterized by impaired insulin secretion, the lowest beta cell function among T2D subtypes, and rapid disease progression. This group was prospectively defined prior to unblinding and represents a population with substantial unmet need. In this subgroup, C-peptide index fold change increased by 24% from baseline, suggesting improved endogenous insulin secretion.

The 52-week analysis also showed clinically meaningful glycemic improvement in study participants who were receiving a GLP-1-based therapy but had not achieved glycemic targets at study entry (all arms n=12). In this subgroup, 8 or 12 weeks of icovamenib treatment resulted in HbA1c reduction that improved over time reaching 1.2% at Week 52 (p=0.05 vs placebo). C-peptide index fold change increased by 35% from baseline in this subgroup, further supporting improvement in beta cell function.

Icovamenib maintained a favorable safety profile throughout the 52-week observation period.
There were no treatment-related serious adverse events or discontinuations due to adverse events. Across all dosing arms, icovamenib was generally well tolerated.

ATTD 2026 Presentation:
The abstract will be published in the peer-reviewed Journal of Diabetes Technology & Therapeutics. The presentation will be available on Biomea Fusion's Investor Relations Page under the Events section https://investors.biomeafusion.com/news-events.

Key Anticipated Milestones
Icovamenib - Diabetes

- 52-week follow-up data from type 1 diabetes (“T1D”) patients in COVALENT-112 who completed ≥80% of protocol-specified dosing with the read-out expected in the second quarter of 2026.
- 26-week primary endpoint data from the Phase II COVALENT-211 and COVALENT-212 studies anticipated in the fourth quarter of 2026.

BMF-650 - Obesity

- Initial 28-day clinical weight-reduction data from Phase I GLP-131 study anticipated in the second quarter of 2026.

About Icovamenib
Icovamenib is an orally administered investigational small molecule in clinical development for the treatment of diabetes. Icovamenib targets menin, a transcriptional regulator implicated in beta-cell dysfunction, and has been observed to induce transient reductions in menin protein levels in pancreatic islets, thereby modulating pathways associated with insulin secretion and glycemic control. As a potential short course therapy, icovamenib could become an important addition to the diabetes treatment landscape particularly addressing those patients that failed their standard of care therapies.

About Menin's Role in Diabetes
Loss of functional beta cell mass is a core component of the natural history in both types of diabetes — T1D (mediated by autoimmune dysfunction) and T2D (mediated by metabolic dysfunction). Beta cells are found in the pancreas and are responsible for the synthesis and secretion of insulin. Insulin is a hormone that helps the body use glucose for energy and helps control blood glucose levels. In patients with diabetes, beta cell mass and function have been observed to be diminished, leading to insufficient insulin secretion and hyperglycemia. Menin is thought to act as a regulatory brake on beta cell turnover and growth, supporting the hypothesis that menin inhibition may enable regeneration of functional cells. Based on these and other scientific findings, Biomea is exploring the potential for icovamenib-mediated menin inhibition as a viable therapeutic approach to potentially halt or reverse progression of T2D.

About Type 2 Diabetes and Severe Insulin-Deficient Diabetes
Diabetes is considered a chronic health condition that affects how the body turns food into energy and results in excessive glucose in the bloodstream. Over time, this can cause serious health problems and damage vital organs. Most people with diabetes have a shorter life expectancy than people without this disease. According to the Centers for Disease Control and Prevention, more than 38 million Americans (~11% of the population) have diabetes, and 98 million adults have prediabetes. Diabetes also represents one of the largest economic burdens on the U.S. healthcare system, with approximately one in four healthcare dollars spent on diabetes care. Within the population of people with T2D, SIDD is a clinically recognized subtype of T2D characterized by profoundly impaired insulin secretion (significantly reduced beta cell function) and poor glycemic control. People with diabetes with severe insulin deficiency often present with higher HbA1c levels at diagnosis, lower BMI compared to insulin-resistant patients, and a rapid decline in beta cell function. This group represents a very high unmet medical need, with the highest risk of complications such as retinopathy and neuropathy and typically progresses the fastest to insulin therapy. Addressing the underlying beta cell dysfunction in this population offers an important opportunity to slow or potentially reverse disease progression.

About Biomea Fusion
Biomea Fusion is a clinical-stage biopharmaceutical company focused on the development of its 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 BMF-650, the potential of icovamenib as a treatment for T1D and T2D, the potential of BMF-650 as a treatment for obesity; 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 Phase II (COVALENT-111) study, our Phase IIb (COVALENT-211) study, our Phase IIb (COVALENT-212) study and our Phase I (GLP-131) study; 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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