# Biomea Fusion Presents Data Demonstrating Enhanced Preclinical Activity of Icovamenib in Combination with Semaglutide in Type 2 Diabetes (T2D) Animal Model at the 61st EASD Annual Meeting and Provides Additional Corporate Update

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- In a rodent model of T2D, icovamenib in combination with low-dose semaglutide promoted enhanced glycemic control and body weight reduction with preservation of lean mass, outperforming the group given semaglutide alone.
- U.S. Food and Drug Administration (FDA) clearance of the Investigational New Drug Application (IND) for BMF-650, Biomea's next-generation investigational oral glucagon-like-peptide-1 (GLP-1) receptor agonist (RA), was recently received. Initiation of a Phase I clinical trial in obesity is on track with 28-day weight loss data expected in the first half of 2026.

SAN CARLOS, Calif., Sept. 16, 2025 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (Biomea or Biomea Fusion) (Nasdaq: BMEA), a clinical-stage diabetes and obesity medicines company, today announced the presentation of preclinical data from its investigational menin inhibitor icovamenib in combination with semaglutide in a T2D animal model. The oral presentation titled "Icovamenib and Semaglutide Combination Therapy Enhances Body Weight Loss and Glycemic Control While Preserving Lean Mass in a Type 2 Diabetes Animal Model" (Presentation #66), was presented at the 61st European Association for the Study of Diabetes (EASD) Annual Meeting, which takes place September 15 - 19, 2025, in Vienna, Austria.

The Biomea presentation highlighted icovamenib's therapeutic potential across key dimensions of T2D pathophysiology, including its impact on beta cell function, and synergy with GLP-1 RAs to promote metabolic health and muscle-sparing body weight reduction.

"We are very encouraged by these preclinical results, which show that icovamenib combined with semaglutide not only improved glycemic control but also enhanced weight loss while preserving lean mass," said Mick Hitchcock, Interim CEO of Biomea Fusion. "This growing body of evidence reinforces icovamenib's unique mechanism of action in beta cell regeneration and highlights the potential of combining icovamenib with GLP-1 receptor agonists to deliver meaningful benefits for patients with type 2 diabetes."

**Presentation Summary**

- **Study design:** Zucker diabetic fatty (ZDF) rats were treated with icovamenib (200 mg/kg, PO, QD) or vehicle for 28 days, and low-dose semaglutide (0.02 mg/kg, SC, QD) was administered daily during weeks three and four. Outcomes from the combination treatment were compared to semaglutide alone.
- **Results:** Combination therapy produced significant reductions in fasting and fed blood glucose levels as early as one week, with a 60% mean reduction in fasting blood glucose after two weeks versus semaglutide alone. Oral glucose tolerance test (OGTT) results showed a 50% lower mean glucose AUC compared to semaglutide alone, and a >1% mean reduction in HbA1c by Day 28. Combination therapy also reduced insulin resistance (measured by HOMA-IR) and improved beta cell function (as measured by HOMA-B and C-peptide index). Importantly, combination therapy resulted in greater mean body weight loss compared to semaglutide alone (-12.5% vs -3.4%), and was driven entirely by fat mass reduction, with preservation of lean mass.
- **Conclusion:** We believe these results support the potential of icovamenib to enhance the effectiveness of GLP-1-based therapies by enabling lower doses to achieve the glycemic and weight loss targets, while also preserving lean mass, a highly desirable profile for the potential long-term management of diabetes and obesity.

**Key Preclinical Findings**
In the ZDF rat model of T2D, combination therapy with icovamenib and low-dose semaglutide demonstrated superior preclinical activity versus low-dose semaglutide alone, including on average:

- 60% lower fasting blood glucose
- 50% lower glucose AUC during OGTT
- Greater reduction in HbA1c; >1% by Day 28 and >2% by Day 39
- Greater improvement in insulin sensitivity; 75% lower HOMA-IR
- Significant improvement in beta cell function as measured by C-peptide to glucose ratio
- ~10% greater reduction in body weight, driven by fat loss with full preservation of lean mass

Biomea plans to advance clinical evaluation of icovamenib in combination with GLP-1 therapies, with a Phase II study expected to begin in the second half of 2025. The abstract has been published in *Diabetologia*, the peer-reviewed journal of the EASD.

**Pipeline Update**
In addition to the presentation at EASD, Biomea also announced progress of its BMF-650 program:

- BMF-650: FDA clearance of the IND was recently received for Biomea's next-generation investigational oral GLP-1 RA. Initiation of a Phase I clinical trial in obesity is on track with 28-day weight loss data expected in the first half 2026.

**About Menin's Role in Diabetes**
Loss of functional beta cell mass and function is a core component of the natural history in both types of diabetes —type 1 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 brake on beta cell turnover and growth, supporting the notion that inhibition of menin could lead to the regeneration of normal, healthy beta cells and the recovery of beta cell function. 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**
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. The Centers for Disease Control and Prevention estimates about two in five adults in the United States are now expected to develop diabetes during their lifetime. More than 37 million people of all ages (about 11% of the United States population) have diabetes today. 96 million adults (more than one in three) have pre-diabetes, blood glucose levels that are higher than normal but not high enough to be classified as diabetes. Diabetes is also one of the largest economic burdens on the United States health care system with one dollar out of every four dollars in health care costs spent on caring for people with diabetes. Despite the current availability of many diabetes medications, there remain significant unmet needs in the treatment and care of patients with diabetes.

**About Icovamenib**
Icovamenib is an investigational, orally bioavailable, potent, and selective covalent inhibitor of menin. The molecule was built using Biomea's FUSION™ System and is designed to regenerate insulin-producing beta cells with the aim to cure diabetes. Icovamenib's proposed mechanism of action in diabetes is to enable the proliferation, preservation, and reactivation of a patient's own healthy, functional, insulin-producing beta cells. As the potentially first disease-modifying therapy for T1D and T2D, icovamenib could become an important addition and complement to the diabetes treatment landscape once it has successfully completed its ongoing clinical studies and received regulatory approval.

**About Biomea Fusion**
Biomea Fusion is a clinical-stage diabetes and obesity medicines company focused on the development of its oral small molecules, icovamenib and BMF-650, both designed to significantly improve the lives of patients with diabetes, obesity, and metabolic diseases. We aim to cure.

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**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 diabetes and obesity; our research, development and regulatory plans, the intuition, progress and availability of data from our clinical trials; the mechanism of action of our product candidates and development programs 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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