



Biomea Fusion Presents New Preclinical and Clinical Data on Icovamenib at the 85th Scientific Sessions of the American Diabetes Association (ADA)

June 23, 2025

- In a rodent model of type 2 diabetes (T2D), icovamenib in combination with low-dose semaglutide promoted enhanced glycemic control and body weight reduction with complete preservation of lean mass, outperforming the group given semaglutide alone
- Icovamenib promoted healthy myotube morphology and diminished drug-induced atrophy in ex vivo 3D-engineered human myotube cultures
- In severely insulin-deficient patients from the Phase II COVALENT-111 trial, icovamenib achieved a 1.0% placebo-adjusted mean HbA1c reduction and a 55% increase in C-peptide at Week 26, three weeks after last dose

SAN CARLOS, Calif., June 23, 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 new preclinical and clinical data for icovamenib, the company's investigational oral menin inhibitor, at the 85th Scientific Sessions of the American Diabetes Association (ADA) June 20–23, 2025 in Chicago.

Biomea presented three abstracts: one oral presentation and two posters, all highlighting icovamenib's therapeutic potential across key dimensions of T2D pathophysiology, including its impact on beta cell restoration, and synergy with glucagon-like peptide-1 (GLP-1) receptor agonists (RA) to promote metabolic health and selective fat loss with complete lean mass preservation.

"Our latest data from ADA 2025 reinforces icovamenib's differentiated therapeutic profile and highlights the potential of menin inhibition as a novel mechanism of action that can be integrated with various antihyperglycemic agents, including GLP-1-based therapies," said Ramses Erdtmann, President and Chief Operating Officer of Biomea Fusion. "The studies presented at ADA demonstrate that icovamenib enhanced glycemic control and drove additional weight loss when used in combination with GLP-1 therapies, while fully preserving lean mass. We believed these attributes set icovamenib apart in the diabetes landscape and support its potential to transform care for millions of patients."

Presentation Summaries:

Poster Presentation #870-P

Title: Combination Therapy of Icovamenib and Semaglutide Enhances Body Weight Loss and Glycemic Control While Preserving Lean Mass in a Type 2 Diabetes Animal Model

Summary: In a Zucker Diabetic Fatty (ZDF) rat model of T2D, treatment of icovamenib in combination with low-dose semaglutide (0.02 mg/kg) delivered superior metabolic benefits compared to low-dose semaglutide alone:

- 60% lower fasting blood glucose and 50% lower glucose OGTT AUC
- Greater HbA1c decline; >1% by Day 28 and >2% by Day 39
- Greater improvement in insulin sensitivity with a 75% lower HOMA-IR (marker of insulin resistance)
- 2-fold increase in C-peptide to glucose ratio indicating enhanced beta cell function
- Superior appetite suppression with a 10% greater body weight reduction than low-dose semaglutide alone
- The observed body weight loss was primarily due to fat mass reduction with complete preservation of lean mass

These findings support the potential of icovamenib to enhance the therapeutic effects of GLP-1-based therapies. The combination may allow lower doses of GLP-1-based therapies to achieve glycemic and weight loss targets and improve tolerability of these agents, offering a compelling rationale for clinical evaluation of icovamenib-based combination regimens.

Late Breaking Poster Presentation #1996-LB

Title: Icovamenib Rescues Human Myotube Atrophy Ex Vivo and Displays Complete Lean Mass Preservation in a Type 2 Diabetes Rat Model

Summary: This preclinical study evaluated icovamenib's direct effects on ex vivo human myotube cultures and the effects of icovamenib in combination with low-dose semaglutide in an in vivo rodent model of diabetes:

- In ex vivo cultures of iPSC-derived 3D-engineered human myotubes, icovamenib treatment promoted healthy myotube morphology
- Separately, icovamenib diminished drug-induced atrophy by activin A or dexamethasone, suggesting muscle health supporting effects of icovamenib
- In a ZDF rat study (data also in poster #870-P), combination treatment with icovamenib and low-dose semaglutide induced greater body weight reduction with complete preservation of lean mass, outperforming low-dose semaglutide

These early findings support icovamenib's unique potential when combined with GLP-1-based therapies to enhance body weight reduction and protect lean mass, a highly desirable feature for any long-term diabetes or obesity therapy.

Oral Presentation #272-OR

Title: COVALENT-111: 26-Week Efficacy and Safety after 8 and 12 Weeks of Daily Oral Icovamenib in Patients with Poorly Controlled Type 2 Diabetes

Summary: 26-week follow-up results from the ongoing Phase II COVALENT-111 trial highlight the potential of short-course oral icovamenib treatment (8 or 12 weeks) to deliver durable glycemic control and improved beta cell function, in patients with poorly controlled T2D, particularly in the insulin-deficient subgroup. Key findings include:

- Icovamenib achieved a 1.0% placebo-adjusted mean HbA1c reduction and a 55% increase in C-peptide in severe insulin-deficient participants at Week 26, three months after the last dose
- Over half of the C-peptide improvement occurred during the off-treatment period, indicating a durable effect on endogenous insulin production
- Short-course dosing (8 or 12 weeks) led to sustained HbA1c reductions through Week 26 across the broader study population
- Changes in HbA1c correlated significantly with changes in C-peptide, supporting the proposed mechanism of action to restore beta-cell function
- In patients inadequately controlled on baseline GLP-1 RA therapy, icovamenib added to the GLP-1 RA led up to an additional 1.0% mean HbA1c reduction
- Icovamenib was well tolerated across all dosing arms, with a low incidence of treatment-emergent adverse events (TEAEs), no clinically significant elevations in ALT or AST, and no study drug discontinuations or discontinuations from the trial due to adverse events

These data reinforce icovamenib's potential as a durable, disease-modifying treatment in T2D, both as monotherapy and in combination with existing agents such as GLP-1 RAs.

The three abstracts have been published in *Diabetes*, the peer-reviewed journal of the American Diabetes Association. Biomea remains committed to advancing novel therapies that improve patient outcomes in diabetes and obesity.

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. Based on these and other scientific findings, Biomea is exploring the potential for icovamenib-mediated menin inhibition as a 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 United States 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.

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 diabetes and obesity; our research, development and regulatory plans; 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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