



Biomea Fusion Presents New Clinical and Translational Data for Icovamenib at the American Diabetes Association ("ADA") 86th Scientific Sessions and Announces Expansion of Ongoing Phase I BMF-650 Study

June 5, 2026

- *Translational data presented at ADA demonstrate icovamenib's potential to promote muscle preservation and fat reduction, supporting its broader therapeutic utility in obesity and diabetes, including as a complementary therapy alongside GLP-1 receptor agonists to enhance metabolic health outcomes*
- *Clinical data presented at ADA from COVALENT-112 show improvements in HbA1c and C-peptide in type 1 diabetes patients treated with icovamenib, with no evidence of immune activation, and inflammatory markers stable or reduced*
- *Additionally, the Company expanded its Phase I BMF-650 study to evaluate a rapid one-step titration and enhanced weight loss potential with its oral GLP-1 receptor agonist*

SAN CARLOS, Calif., June 05, 2026 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea" or the "Company") (Nasdaq: BMEA), a clinical-stage diabetes and obesity company, today announced the presentation of new clinical and translational data for icovamenib, its investigational oral menin inhibitor, at the American Diabetes Association ("ADA") 86th Scientific Sessions, taking place June 5-8, 2026, in New Orleans. The clinical data highlight icovamenib's therapeutic profile across type 1 ("T1D") and type 2 diabetes ("T2D"), including durable improvements in endogenous insulin secretion and glycemic control. In parallel, translational mechanism of action ("MOA") data demonstrated activation of biological pathways associated with metabolic health, including fat reduction and preservation of lean mass. These findings further support icovamenib's potential beyond glycemic control and its broader application across metabolic disease, including obesity.

In parallel, the Company announced the addition of an extra cohort to the ongoing Phase I GLP-131 study evaluating BMF-650, Biomea's investigational oral GLP-1 receptor agonist ("GLP-1 RA"), to explore a rapid one-step titration (200 mg QD for 1 week, then 400 mg QD for 3 weeks) and to further optimize its weight reduction potential.

"The breadth of data presented at ADA continues to strengthen our confidence in icovamenib's differentiated profile and its potential to address the significant unmet need across both type 2 and type 1 diabetes," said Mick Hitchcock, Ph.D., Interim Chief Executive Officer of Biomea Fusion. "In type 2 diabetes, we observed durable glycemic improvements and enhanced endogenous insulin secretion following treatment with icovamenib. In type 1 diabetes, the findings further support icovamenib's potential to enhance endogenous insulin secretion without causing immune activation, which is critical in ensuring lasting benefits for patients. Importantly, additional translational data presented at ADA further expands our understanding of icovamenib's broader metabolic potential by demonstrating activation of pathways associated with muscle health, fat metabolism, and GLP-1 biology, supporting its potential role in obesity and complementary use with GLP-1 therapies. In addition, we are expanding our Phase I study to not only to optimize dose selection for BMF-650 but also to evaluate a rapid up-titration schedule that could provide differentiation from other GLP-1 RAs. We continue to advance our two molecules focused on addressing the needs of patients with diabetes and obesity.

Highlights from ADA Presentations:

New Translational Data Demonstrate Mechanisms Supporting Metabolic Health (Poster 2871-LB)

Title: [Menin Inhibitor Icovamenib Activates Mechanisms That Support Metabolic Health](#)

Presented by: Mini Balakrishnan, Ph.D.

Biomea presented new translational findings from a cell model supporting icovamenib's potential to activate complementary biological pathways associated with metabolic health beyond glycemic control. The data highlight mechanisms that may support enhanced metabolic function, including pathways associated with GLP-1 biology, fat metabolism, and healthy muscle maintenance.

Key findings include:

- Icovamenib enhanced GLP-1 expression in a human colon L-cell model and increased GLP-1 receptor expression in human islets, properties that can enhance incretin effects and support complementary use alongside GLP-1 RA-based therapies
- In human skeletal muscle cells, icovamenib promoted myogenic effects, including myotube size increase, elevated myosin heavy chain expression, and enhanced myoblast fusion, supporting muscle health and maintenance
- In human adipocytes, icovamenib promoted browning and lipolysis, evidenced by reduced lipid droplet size, increased glycerol release, and modulation of key genes involved in thermogenesis and energy metabolism

Collectively, these findings suggest icovamenib can activate complementary biological pathways that may support metabolic health, including glycemic control, fat reduction, and healthy muscle maintenance, while supporting further evaluation in obesity and as part of combination treatment strategies with GLP-1 RA-based therapies.

Improved Endogenous Insulin Secretion in Type 1 Diabetes (COVALENT-112; Poster 2858-LB)

Title: [Icovamenib, a Menin Inhibitor, Improves Endogenous Insulin Secretion in T1D: Results from the COVALENT-112 Study](#)

Presented by: Juan Pablo Frías, M.D.

Biomea also presented 52-week clinical findings from the Phase II COVALENT-112 study evaluating icovamenib in adults with T1D.

Key findings include:

- Icovamenib was associated with enhancement and preservation of endogenous insulin secretion in evaluable participants, with a directional response favoring 200 mg over 100 mg daily
- Among Cohort 1 participants diagnosed with T1D <3 years, 200 mg icovamenib increased C-peptide Area Under the Curve ("AUC") by a mean of approximately 52% at Week 12 versus baseline. At Week 52, mean C-peptide AUC remained broadly preserved (approximately 7% below baseline), compared with an approximately 47% annual decline reported in historical placebo cohorts
- Cytokine profiling showed no evidence of systemic immune activation, with inflammatory markers remaining stable or reduced through Week 52
- Icovamenib was generally well tolerated, with no new safety signals observed through Week 52 that would limit ongoing clinical development

Collectively, these findings suggest icovamenib may support enhancement and preservation of residual beta cell function in T1D without evidence of a measurable systemic inflammatory cytokine response.

Durable Glycemic Improvements in Adults with T2D Receiving Background GLP-1 RA Therapy (COVALENT-111; Poster 2857-LB)

Title: [*Glycemic Improvements with Icovamenib in Adults with T2D Receiving Background GLP-1 Therapy: Subgroup Analysis from the COVALENT-111 Study*](#)

Presented by: Juan Pablo Frías, M.D.

Subgroup analyses from the Phase II COVALENT-111 study evaluated adults with type 2 diabetes (T2D) receiving background GLP-1 RA therapy who remained above glycemic targets at baseline.

Key findings include:

- Durable HbA1c improvements through Week 52, including 40 weeks after treatment discontinuation
- 1.2% HbA1c mean reduction at Week 52 in icovamenib-treated participants versus a 0.6% mean increase with placebo, a clinically meaningful placebo-adjusted HbA1c mean reduction of 1.8% among participants inadequately controlled while receiving background GLP-1 RA therapy
- Improvements in C-peptide index, supporting enhancement of endogenous insulin secretion and restoration of beta cell function
- Icovamenib was generally well tolerated, with no serious adverse events, treatment discontinuations due to adverse events, or new safety signals observed

These findings suggest icovamenib may provide additive and durable glycemic benefit when used alongside GLP-1 RA–based therapies in patients with inadequately controlled T2D and further support its potential as a complementary treatment approach.

All abstracts will be published in Diabetes® journal and posters will be available on the [Investors & Media](#) section of Biomea's website.

Biomea Expands Ongoing Phase I BMF-650 Study to Optimize Dose Selection for Phase II Development

Biomea has completed the single ascending dose ("SAD") portion and four multiple ascending dose ("MAD") cohorts of the ongoing GLP-131 Phase I study evaluating BMF-650, the Company's next-generation oral small molecule GLP-1 RA, in otherwise healthy overweight or obese participants.

Based on the favorable safety and tolerability profile observed to date, as well as emerging pharmacokinetic and clinical observations, the Company has elected to add an additional MAD cohort to evaluate a rapid one-step titration (200 mg QD for 1 week, then 400 mg QD for 3 weeks) and to further optimize the weight reduction potential achievable with Biomea's investigational oral GLP-1 RA.

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

To date, BMF-650 has demonstrated a favorable safety and tolerability profile across completed cohorts, with no dose-limiting toxicities observed. The additional cohort is expected to provide further insight into the clinical profile of BMF-650 and support its development as a differentiated, next-generation oral GLP-1 receptor agonist for obesity and metabolic disease.

About Icovamenib

Icovamenib is an orally administered investigational small molecule currently in Phase 2 clinical development for the treatment of diabetes. Icovamenib targets menin, a transcriptional regulator implicated in beta cell biology, and has been shown in ex vivo human islet studies to induce reductions in menin protein levels, and modulated pathways associated with beta cell proliferation and insulin production and secretion. Through these mechanisms, icovamenib has the potential to restore beta cell mass and function and improve glycemic control. As a potential short-course therapy, icovamenib could represent a novel treatment approach for patients with diabetes, particularly those who have not achieved adequate control with standard-of-care therapies.

About BMF-650

BMF-650 is an investigational, next-generation oral small-molecule GLP-1 RA being developed by Biomea Fusion for the treatment of obesity. Related to the broader orforglipron chemotype, BMF-650 is designed to combine enhanced oral bioavailability and durable receptor activation to deliver robust metabolic benefits.

In preclinical studies, BMF-650 demonstrated a favorable pharmacokinetic profile with higher bioavailability, good efficacy, and less inter-individual variability compared to published third-party preclinical data on another oral GLP-1 RA. These attributes may support improved tolerability and more effective dose escalation in clinical settings. BMF-650 significantly enhanced glucose-stimulated insulin secretion in both human donor islets and in vivo in non-human primates and showed robust glucose-lowering activity and appetite suppression in cynomolgus monkey models. Notably, daily oral dosing resulted in dose-dependent reductions in food intake and progressive weight loss across the treatment period in a study with obese cynomolgus monkeys.

Biomea's development strategy for BMF-650 focuses on achieving consistent plasma levels and increased drug exposure to support a potential best-in-class profile among oral small-molecule GLP-1 therapies.

About Biomea Fusion

Biomea Fusion is a clinical-stage diabetes and obesity medicines 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 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 ongoing Phase I GLP-131 trial evaluating BMF-650; the potential clinical profile of BMF-650 and its development as a next-generation oral GLP-1 receptor agonist for obesity and metabolic disease; 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'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 explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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