Biomea Fusion Announces Completion of Enrollment in COVALENT-211 Phase II Trial of Icovamenib in Insulin-Deficient Type 2 Diabetes

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- *Topline 26-week primary endpoint data from COVALENT-211 in insulin deficient type 2 diabetes ("T2D") patients who are not achieving glycemic targets despite antihyperglycemic medications anticipated in the first quarter of 2027*
- *COVALENT-212 Phase II enrollment T2D patients who are not achieving glycemic targets despite GLP-1 based therapy is still ongoing, with topline 26-week primary endpoint data anticipated in the second quarter of 2027*
- *These ongoing Phase II diabetes trials target two distinct T2D populations that demonstrated durable glycemic improvements following 12 weeks of icovamenib treatment in COVALENT-111*

SAN CARLOS, Calif., Aug. 24, 2026 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea," "Biomea Fusion" or the "Company") (Nasdaq: BMEA), a clinical-stage diabetes and obesity medicines company, today announced the completion of enrollment in COVALENT-211, a randomized, double-blinded, placebo-controlled Phase II clinical trial evaluating icovamenib in patients with insulin-deficient T2D who remain inadequately controlled on standard-of-care antihyperglycemic therapies.

COVALENT-211 enrolled 64 participants across 18 clinical sites, randomized 2:1 to receive either icovamenib 100 mg once daily or placebo for 12 weeks as an add-on to stable background therapy, followed by a 40 week off-treatment period designed to assess the durability of glycemic control and beta cell function through Week 52. The primary endpoint will be assessed at Week 26, with additional follow-up of secondary endpoints through Week 52. The Company anticipates reporting topline results for the Week 26 primary endpoint in the first quarter of 2027.

"Completing enrollment in COVALENT-211 is an important milestone for the icovamenib program as we continue to execute on our Phase II clinical trial development strategy," said Mick Hitchcock, Ph.D., Interim Chief Executive Officer and Board Member of Biomea Fusion. "Our earlier clinical data demonstrated durable glycemic improvements and increased C-peptide in insulin-deficient patients following only 12 weeks of treatment, providing the foundation for COVALENT-211 and our focus on this patient population. With COVALENT-211 now fully enrolled and our Phase II trial COVALENT-212 expected to complete enrollment over the coming months before year end, we remain focused on execution as we advance toward 26-week primary endpoint data from COVALENT-211 in the first quarter of 2027, followed by COVALENT-212 in the second quarter of 2027."

Icovamenib's Phase II Clinical Trials Diabetes Program - COVALENT-211 and COVALENT-212

COVALENT-211 (NCT07502495) is evaluating icovamenib in adult patients with insulin-deficient T2D who are not achieving glycemic targets despite treatment with antihyperglycemic medications. Eligible participants must be on a stable dose of one to three antihyperglycemic therapies for at least three months prior to screening, with HbA1c levels between 7.5% and 10.5% and a body mass index (BMI) of ≤32 kg/m². Icovamenib is administered as an add-on to stable background therapy, which is maintained throughout the study unless rescue therapy is required.

COVALENT-212 (NCT07502508) is evaluating icovamenib in adult patients with T2D who are not achieving glycemic targets despite GLP-1 based therapy. Eligible participants must be on a stable dose of GLP-1-based therapy for at least three months prior to screening and may receive up to two additional background therapies (metformin and/or an SGLT2 inhibitor). Participants must have HbA1c levels between 7.0% and 10.5% and a BMI between 25 and 45 kg/m². Icovamenib is administered as an add-on to stable GLP-1 -based therapy, which is maintained throughout the study unless rescue therapy is required. Enrollment in COVALENT-212 is expected to be completed before year end.

Both studies incorporate key learnings from the Phase II COVALENT-111 trial, including optimized dosing informed by the COVALENT-121 food-effect trial and a focus on patient populations that demonstrated the most pronounced and durable responses. Together, these trials are designed to evaluate icovamenib's potential to restore beta-cell function and provide durable glycemic control across two clinically distinct, high-need T2D populations.

Rationale for Targeted Patient Populations

COVALENT-211 and COVALENT-212 build on findings from the Phase II COVALENT-111 trial in patients with T2D who were not achieving glycemic targets despite standard-of-care therapies. The data demonstrated durable and clinically meaningful reductions in HbA1c that persisted nine months after completion of an 8 or 12 weeks treatment course.

The findings in the 52-week analysis include:

- In patients with severe insulin-deficient T2D receiving one or more antihyperglycemic agents at baseline, icovamenib achieved with a 12 weeks treatment course HbA1c reductions that improved over time reaching up to a placebo-adjusted 1.5% mean HbA1c reduction at Week 52 (p=0.01).
- In a subgroup of patients receiving GLP-1 RA-based therapy who had not achieved glycemic targets at study entry, icovamenib achieved with an 8 or 12 weeks treatment course HbA1c reductions that improved over time reaching up to a

placebo-adjusted 1.8% mean HbA1c reduction at Week 52 (p=0.05).

- In both populations, icovamenib treatment was associated with increased C-peptide levels measured off treatment, supporting the proposed mechanism of action of improvement in beta-cell function.
- Icovamenib was generally well tolerated across all dosing arms, with no treatment-related serious adverse events or treatment discontinuations observed during the 52-week observation period.

These data support the continued development of icovamenib as a potential therapy designed to address underlying beta-cell dysfunction and provide durable glycemic control following a three-month treatment period.

About Icovamenib
Icovamenib is an orally administered investigational small molecule currently in Phase 2 clinical development for the treatment of type 1 and type 2 diabetes. Preclinical evidence shows that icovamenib promotes reversible downmodulation of menin, a transcriptional regulator implicated in beta cell biology. Preclinical data also has shown that icovamenib induced glucose-dependent beta cell proliferation and enhances insulin production and secretion. Through these proposed mechanisms, icovamenib has the potential to restore beta cell mass and function and thereby improve glycemic control. As a potential beta cell restorative therapy, icovamenib represents a novel treatment approach for individuals living with diabetes.

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 — 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 regulator of beta-cell turnover and function, supporting the hypothesis that menin downmodulation or inhibition may enable regeneration of functional cells. Based on these and other scientific findings, Biomea is exploring the potential for targeting menin as a viable therapeutic approach to potentially halt or reverse progression of T2D.

About Type 2 Diabetes
Diabetes is 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, approximately one-third are insulin-dependent, a stage associated with increased complications such as kidney disease, nerve damage, vision loss, amputations and cardiovascular disease. People with insulin-deficient diabetes typically progress faster towards insulin-dependence. Insulin-deficient diabetes is a clinically recognized subtype characterized by impaired insulin secretion (significantly reduced beta-cell function). These patients typically present with higher HbA1c levels at diagnosis and lower BMIs. Separately, diabetes patients with higher BMIs often do not reach their glycemic targets even despite treatment with GLP-1RAs. Clinical research indicates that 20%-40% of people with T2D treated with GLP-1 RA-based therapies do not reach adequate levels of blood glucose control (HbA1c <7%) and often then progress to insulin-based regimens. Both of these populations, the insulin-deficient patients and GLP-1 non-responders, represent high unmet medical need and are inadequately served by current therapies.

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 BMF-650; the potential of icovamenib as a treatment for T2D; our research, development and regulatory plans; the timing of patient enrollment and dosing completion, and progress and availability of data from our clinical trials, including for the COVALENT-211 and COVALENT-212 Phase II trials; the mechanism of action of our product candidates and development programs; and the results and 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 or adverse outcomes in regulatory interactions, 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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