Biomea Fusion Announces First Patient Dosed in Newly Initiated Phase II Programs Enrolling Type 2 Diabetes Patients Failing on Standard-of-Care Therapies

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COVALENT-211 Phase II enrolling insulin-deficient type 2 diabetes patients
COVALENT-212 Phase II enrolling type 2 diabetes patients uncontrolled with a GLP-1 receptor agonist-based therapy
Topline 26-week primary endpoint data from both Phase II studies anticipated 4Q 2026

SAN CARLOS, Calif., March 31, 2026 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea" or "Biomea Fusion" or "the Company") (Nasdaq: BMEA), a clinical-stage diabetes and obesity medicines company, today announced that the first patient has been dosed in its newly initiated Phase II programs, COVALENT-211 and COVALENT-212, evaluating icovamenib in patients with type 2 diabetes ("T2D"), marking a key step in advancing icovamenib into Phase II development in targeted patient populations failing standard-of-care therapies as established in the clinical trial COVALENT-111.

"These studies represent an important step forward as we advance icovamenib into later-stage Phase II development in the two clearly defined patient populations in which we had observed sustained glycemic improvements in our prior study. We are planning to enroll these two studies within the second quarter to achieve an initial readout before year-end." said Mick Hitchcock, Ph.D., Interim Chief Executive Officer and Board Member of Biomea Fusion. "The design of COVALENT-211 and COVALENT-212 is informed by the durability, safety profile, and subgroup responses observed in our Phase II COVALENT-111 study, where we saw clinically meaningful glycemic improvements following a limited 12-week course of therapy with effects sustained nine months post the dosing period. These studies address patients who would otherwise require insulin therapy as one of their next therapeutic choices while existing alternatives are no longer providing glucose control. We believe icovamenib can provide significant benefits to these patients."

Icovamenib's Phase II 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 antihyperglycemic medications. Eligible participants must be on a stable dose of one to three antidiabetic 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 remain inadequately controlled while receiving GLP-1 ("RA")-based therapy but have not achieved glycemic targets. Eligible participants must be on a stable dose of GLP-1 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 ≥7.5% and ≤9.5% and a BMI between 25 and 40 kg/m². Icovamenib is administered as an add-on to stable GLP-1 RA-based therapy, which is maintained throughout the study unless rescue therapy is required.

Both studies are planned to enroll approximately 60 participants each (2:1 randomization; icovamenib to placebo) across approximately 20 clinical sites. Participants will receive icovamenib 100 mg once daily or placebo for 12 weeks, followed by a 40-week off-treatment period designed to assess durability of glycemic control and beta-cell function beyond the dosing period, assessed at Week 26 (primary endpoint) and at Week 52 (secondary endpoint).

Both studies incorporate key learnings from the Phase II COVALENT-111 study, including optimized dosing informed by the COVALENT-121 food-effect study and a focus on patient populations that demonstrated the most pronounced and durable responses. Topline data from both studies are anticipated in the fourth quarter of 2026. Together, these studies are designed to evaluate icovamenib's potential to restore beta-cell function across two clinically distinct, high-need T2D populations.

Rationale for Targeted Patient Populations

The initiation of COVALENT-211 and COVALENT-212 builds on findings from the all-comers Phase II COVALENT-111 study in patients with T2D not achieving glycemic targets despite standard-of-care therapy. The data demonstrated durable and clinically meaningful reductions in HbA1c that persisted nine months after completion of a 12-week 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 up to a placebo-adjusted 1.5% mean reduction in HbA1c (p=0.01) that was maintained through Week 52 following 12 weeks of dosing.
- In a subgroup of patients receiving GLP-1 RA-based therapy who had not achieved glycemic targets at study entry, icovamenib achieved a 1.8% placebo-adjusted mean reduction in HbA1c (p=0.05) that was maintained through Week 52 following 12 weeks of dosing.
- In both populations, icovamenib treatment was associated with increased C-peptide levels measured off treatment,

supporting the proposed mechanism of action of restoration of 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 in Phase II 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 who failed 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 — 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 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
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 though treated 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 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 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!

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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 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 II COVALENT-211 study, and our Phase II COVALENT-212 study; the anticipated availability of data from our clinical trials; our planned interactions with regulators, and the timing of such events; and our expected cash runway 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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