Biomea Fusion Announces Oral and Poster Presentations of Icovamenib at the 22nd World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC)

December 12, 2024

- In preclinical experiments, icovamenib enhanced beta cell function and responsiveness of human islets to GLP-1-based therapies. These effects were associated with an increase in the expression levels of both the GLP-1 receptor (GLP-1R) as well as intracellular insulin.
- Overall results showed synergy of the combination therapy, which may allow lower doses of GLP-1-based therapies to achieve glycemic targets, potentially reducing side effects and improving tolerability of GLP-1 based therapies.

REDWOOD CITY, Calif., Dec. 12, 2024 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea” or “Biomea Fusion” or “the Company”) (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing oral covalent small molecules to improve the lives of patients with diabetes, obesity, and genetically defined cancers, today announced the Company will present one oral presentation, one poster presentation, and host an oral symposium at the 22nd World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC) taking place in Los Angeles, California on December 12-14, 2024.

“The data we will present during the WCIRDC this year show that there may be complementary mechanisms of action between icovamenib and approved GLP-1-based therapies that have the potential to provide a synergistic response and improved efficacy for patients. We observed in preclinical experiments that icovamenib not only increased beta cell mass but also enhanced the responsiveness to the GLP-1-based therapies. These complementary effects may ultimately have the potential to increase the effectiveness of current GLP-1 based agents,” said Juan Pablo Frias, Biomea Fusion’s Chief Medical Officer. “The increase in beta cell mass from icovamenib may also potentially allow for lower doses of approved GLP-1-based therapies to achieve glycemic targets, potentially reducing side effects and improving tolerability of these agents. Icovamenib also has a proposed mechanism of action that has been shown to be complementary to metformin and SGLT2 inhibitors, two very commonly used agents in type 2 diabetes (T2D). We look forward to further exploring clinically the potential benefits icovamenib may provide to persons with diabetes.”

Oral Presentation Abstract #0069
Combination of Icovamenib and GLP-1-Based Therapeutic Agents Improves Beta Cell Function and Insulin Secretion
Presentation Time
Oral Presentation: December 13th, 2024, at 7:30pm – 9:00pm PST

Poster Presentation Abstract #0063
Investigating the Effects of Icovamenib on Poorly Managed Severe Insulin-Deficient Diabetes (SIDD): Insights from COVALENT-111 Case Studies
Presentation Time
Poster Presentation: December 12, 2024, at 6:30pm – 7:30pm PST

Breakfast Symposium
Unlocking the Potential of Menin Inhibition: Icovamenib and a look into the Future of Diabetes Management
Presentation Time
December 13, 2024, at 7:00am – 7:45am PST

Please find a link here to our website where the poster and presentations will be available.

Data Highlights for Presentations at WCIRDC
Icovamenib is an investigational covalent menin inhibitor in development to address the root cause of diabetes: the progressive decline in beta cell mass and function. The data published at the WCIRDC annual meeting showed a selective proliferation of beta cells and an increase in the expression levels of both GLP-1 receptors and intracellular insulin in human islets treated ex-vivo with icovamenib, effects reproducible in multiple donors.

Menin has been shown to regulate GLP-1R expression and, consequently, the GLP-1R pathway. Effects on GLP-1R and insulin gene expression were evaluated in islet cultures from 8 independent healthy donors. Icovamenib enhanced the responsiveness of human islets to the GLP-1-based therapies, semaglutide and tirzepatide and induced enhancement in beta cell function correlated with an increase in the expression levels of both the GLP-1R as well as intracellular insulin. Both transcript and protein levels were increased. In these experiments, icovamenib promoted controlled proliferation and enhanced insulin content in beta cells in human islet microtissues ex vivo, in a glucose- and dose- dependent manner. The overall results showed synergy of the combination therapy utilizing icovamenib together with a GLP-1 based therapy. We believe the increase in beta cell mass and improved beta cell function induced by icovamenib may allow lower doses of GLP-1-based therapies to achieve glycemic targets, potentially reducing side effects and improving tolerability of these agents.

In addition, data from earlier presentations were published at the 22nd WCIRDC, showing how covalently inhibiting menin may be particularly relevant for diabetes patients with a depleted pool of beta cells. Whereby the severe insulin-deficient diabetes (SIDD) and mild age-related diabetes (MARD) subgroups in relevant dose escalation cohorts reviewed, showed approximately a 2.5-fold improvement in HbA1c reduction versus the insulin resistant

diabetes (SIRD) and the mild obesity related diabetes (MOD) subgroups. T2D subtyping reveals distinct risk profiles and provides a framework for precision medicine. In addition, data presented from clinical case studies showed the potential of short-term icovamenib treatment to modify disease progression and provide lasting effects in patients with uncontrolled T2D. In these case studies icovamenib was generally well tolerated, there were no treatment related adverse events, no dose discontinuations or modifications reported, and no symptomatic or clinically significant hypoglycemia was observed.

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 (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 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 US 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 US health care costs spent on caring for people with diabetes. Despite the current availability of many diabetes medications, there remains a significant need 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 Fusion'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.

About Biomea Fusion
Biomea Fusion is a clinical-stage biopharmaceutical company focused on the discovery and development of oral covalent small molecules to improve the lives of patients with diabetes, obesity, and genetically defined cancers. A covalent small molecule is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional non-covalent drugs, including greater target selectivity, lower drug exposure, and the ability to drive a deeper, more durable response.

We are utilizing our proprietary FUSION™ System to discover, design and develop a pipeline of next-generation covalent-binding small-molecule medicines designed to maximize clinical benefit for patients. We aim to have an outsized impact on the treatment of disease for the patients we serve. We aim to cure.

Visit us at 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, their mechanism of action, and their potential relative to approved products marketed by third parties; the potential benefits to future trial design and program development of subtyping diabetes patients; our research, development and regulatory plans, the progress of our ongoing and upcoming clinical trials 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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