Biomea Fusion to Present Long-Term Follow-Up Data from Ongoing Phase II Study (COVALENT-111) of BMF-219 in Adults with Type 2 Diabetes and Results from Ex-Vivo Human Islet Experiments at the World Congress Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC)

December 7, 2023

BMF-219 is an investigational novel covalent menin inhibitor developed to regenerate insulin-producing beta cells with the aim to cure diabetes

- In a poster presentation on Thursday, Dec. 7th at 6:30pm and an oral presentation on Friday, Dec. 8th at 7:30pm, Biomea to present new preclinical and clinical data highlighting:
    - A sustained HbA1C reduction of ≥0.5% and ≥1.0% in 40% and 20% of patients, respectively, 22 weeks after the last dose from the 4-week BMF-219 treatment period from the initial two 100mg QD dose cohorts investigated in COVALENT-111
    - BMF-219 was generally well tolerated; there were no dose reductions, dose discontinuations, or severe or serious adverse events
    - BMF-219 displayed glucose-controlled beta cell proliferation in a preclinical ex-vivo human islet model, supported by on-target cell-cycle gene expression changes
    - The poster will present additional data on the reduction of A1c at Week 26, twenty-two weeks after last dose, change in C-peptide and Homa-B compared to baseline
- Biomea will kick-off the WCIRDC meeting by hosting a congress symposium titled, “BMF-219: An oral menin inhibitor in clinical development as a short-term treatment to address the root cause of diabetes, beta-cell dysfunction” on Thursday, December 7th at 7am PST.
- COVALENT-111 trial is ongoing and currently enrolling the expansion phase of the study. The company will share topline data from the escalation portion of COVALENT-111 at the conclusion of WCIRDC.

REDWOOD CITY, Calif., Dec. 07, 2023 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea”) (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing novel covalent small molecules to treat and improve the lives of patients with genetically defined cancers and metabolic diseases, today announced the full abstract, titled “BMF-219: A novel therapeutic agent to reestablish functional beta cells and provide long-term glycemic control”, will be presented during the Abstract Oral Presentation Session as well as the Poster Session of the 21st World Congress Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC) taking place in Los Angeles, California on December 7-9, 2023.

“We are honored to be selected as one of the six oral presentations by the WCIRDC Abstract Committee. We’ve seen truly promising data to date with BMF-219’s novel proposed mechanism of action which is designed to address an underlying cause of type 2 diabetes – the loss of healthy, insulin-producing beta cells. BMF-219 is the first investigational agent to show durable glycemic control during off-treatment period after four weeks of dosing. Together with the evidence in ex-vivo human islet experiments, we believe these data validate the proposed mechanism of action for BMF-219 – disruption of menin drives beta cell-specific proliferation. These data also further support the potential for BMF-219 as a disease modifying agent in type 2 diabetes. We are excited about these early findings and look forward to presenting the data during the conference,” said Juan Pablo Frias, M.D., Chief Medical Officer at Biomea.

Details for the abstract are listed below and can be viewed online on the WCIRDC conference website. Presentation slides from the Breakfast Symposium will be made available after the event on Biomea’s website. There will be a replay of the presentation once available through the WCIRDC.

Abstract #0088

BMF-219: A novel therapeutic agent to reestablish functional beta cells and provide long-term glycemic control

Presentation Time:

Poster Presentation: Thursday, December 7, 2023, 6:30pm – 7:30 pm PST

Oral Presentation: Friday, December 8, 2023, 7:30 pm – 9:00 pm PST

Abstract Text:

Background: Inhibition of menin drives an increase in beta-cell proliferation and function. BMF-219, an oral menin inhibitor, is being developed to manage diabetes. Herein we summarize BMF-219 ex-vivo human islet and T2D clinical data.

Methods: BMF-219 was evaluated in ex-vivo human islet cultures to assess beta-cell function and proliferation. In T2D, a randomized, double-blind, placebo-controlled study is ongoing. We report patients treated with BMF-219 100mg QD for 4 weeks, followed until Week 26. Endpoints include glycemic efficacy and safety.

Results: With human islet microtissues cultured for 2-3 weeks under high glucose conditions, BMF-219 increased the fraction of proliferating beta cells resulting in an increase in insulin content and glucose-stimulated insulin secretion. Gene expression changes with CCNA2 and PbK were observed, supporting beta cell proliferation, consistent with published data.

Twenty T2D patients received BMF-219 100mg QD for 4 weeks (with or without food). A reduction in HbA1C of 0.5% or greater was seen in 50% patients at Week 4, which improved to 60% at Week 12. A sustained reduction ≥0.5% was seen in 40% patients at Week 26. At this timepoint, 20% of patients experienced ≥1% HbA1c reduction, with a maximum reduction of 2.5%. BMF-219 was well tolerated (no SAEs or dose discontinuations).

Conclusions: In ex-vivo cultured islets, BMF-219 improved human beta-cell function and proliferation. In T2D, BMF-219 for 4 weeks resulted in meaningful HbA1c reductions at treatment completion (Week 4) and during the 26-week follow-up. Combined results support BMF-219 mechanism of action of beta-cell preservation, reactivation, and proliferation.

COVALENT-111

COVALENT-111 is a multi-site, randomized, double-blind, placebo-controlled Phase I/II study. In the completed Phase I portion of the trial, healthy subjects were enrolled in single ascending dose cohorts to ensure safety at the prospective dosing levels for people with type 2 diabetes. Phase II consists of multiple ascending dose cohorts and dose durations and includes adult patients with type 2 diabetes uncontrolled by current therapies. Additional information about the Phase I/II clinical trial of BMF-219 in type 2 diabetes can be found at ClinicalTrials.gov using the identifier NCT05731544.

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 type 2 diabetes (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 BMF-219-mediated menin inhibition as a viable therapeutic approach to potentially halt or reverse progression of type 2 diabetes.

About Type 2 Diabetes

Diabetes is considered a chronic health condition that affects how the body turns food into energy and results in too much sugar 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 CDC estimates about 2 in 5 of the adult population in the USA 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 1 in 3) have pre-diabetes, blood sugars 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 $1 out of every $4 in US health care costs being 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 Biomea Fusion

Biomea Fusion is a clinical stage biopharmaceutical company focused on the discovery and development of covalent small molecules to treat patients with genetically defined cancers and metabolic diseases. 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 with various cancers and metabolic diseases, including diabetes. 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, Twitter 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 BMF-219, the potential of BMF-219 as a treatment for diabetes, our research, development and regulatory plans, including our pursuit of BMF-219 in metabolic diseases, our plans to continue the evaluation of BMF-219 for type 2 diabetes in our COVALENT-111 study, that initial results may not be indicative of final results in later clinical trials, the availability of future data from the Phase II portion of the study, 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 we may encounter delays or unforeseen results in preclinical development, IND-filing and acceptance, patient enrollment and in the initiation, conduct and completion of our planned clinical trials and other research, development and regulatory 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 (the "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.

Contact: Investor Relations Chunyi Zhao, PhD Sr. Manager of Investor Relations & Corporate Development czhao@biomeafusion.com Media Relations Neera Chaudhary, PhD Chief Commercial Officer – Diabetes nchaudhary@biomeafusion.com