Biomea Fusion Presents New Translational Data at the European Association for the Study of Diabetes (EASD) 2022 in Animal Models and Ex-vivo Human Donor Islets Further Supporting BMF-219's Potential as an Oral, Long-Acting Treatment for Type 2 Diabetes

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- Treatment with BMF-219 led to an increase in beta cell mass in ex-vivo experiments with human donor islets
- BMF-219 showed improved pancreatic beta-cell function and beta cell area, insulin sensitivity, blood lipid levels, weight decline, and glycemic control in the rat models (ZDF (Zucker Diabetic Fatty Rat) and the STZ (streptozotocin)) during the dosing period, and importantly, both glycemic and lipemic control were maintained after the dosing period ended
- BMF-219 treatment resulted in a sustained increase in beta cell area and function in the ZDF diabetic rats observed at the end of treatment and two weeks following succession of therapy, compared to rats treated with vehicle or active control pioglitazone, which showed a decline in beta cell area and function
- BMF-219 demonstrated, after 16 days of treatment, a recovery of beta-cell activity in STZ rats compared to rats treated with vehicle control or pioglitazone
- Biomea remains on track to file an IND to explore the utility of BMF-219 in type 2 diabetes in the second half of 2022

REDWOOD CITY, Calif., Sept. 22, 2022 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (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, presented "Oral long-acting menin inhibitor normalizes type 2 diabetes in two rat models" at the European Association for the Study of Diabetes Annual Meeting (EASD).

The presentation highlighted BMF-219's ability to improve pancreatic beta cell area and function in two preclinical rat models of diabetes. This data showed BMF-219's robust and prolonged glycemic control, insulin sensitization, and reduction of weight and lipid levels in preclinical rat models.

In addition, and for the first time, Biomea Fusion presented data showing an increase in beta cell function based on HOMA-B determination in the two rat models and an increase in beta-cell area in the ZDF rat model and an increase in beta cell mass in an ex-vivo human donor beta-cell islet model. This data provides further support for the potential of BMF-219 as a long-acting, disease modifying treatment for type 2 diabetes. The preclinical presentations from EASD can be viewed on Biomea's website at https://biomeafusion.com/publications.

"Today we reported direct evidence of BMF-219's ability to increase beta cell area, another key feature of the novel mechanism. BMF-219 also displayed the ability to restore and preserve beta cell function in various type 2 diabetes models. In addition, we have continued to expand our translational work and presented a preview of the results today, showing treatment with BMF-219 led to a substantial expansion of human beta cells in an ex-vivo donor islet model," said Thomas Butler, CEO and Chairman of Biomea Fusion.

Diabetes is a multi-factorial disease that typically requires daily treatment with multiple agents with various mechanisms of action to achieve glycemic control. The global burden of diabetes has been rapidly increasing with over 400 million people currently struggling with diabetes globally.

"These results, along with additional work, increases our understanding and our confidence in BMF-219's ability to restore and balance beta cell mass effectively and efficiently. We are excited about the potential impact a treatment like this can have on the lives of the millions of patients worldwide with diabetes. Today, available therapies only provide symptomatic control whereas BMF-219 has the potential to be disease modifying. We look forward to updating you on our clinical development plan in diabetes in the coming months," commented Mr. Butler

The data presented at EASD shows that BMF-219 was superior to pioglitazone in an oral glucose tolerance test (OGTT), an assessment of glucose metabolism and processing, in the STZ beta cell ablation model during the treatment period. In this model, BMF-219 but not active comparator, pioglitazone, restored non-fasting glucose levels to near normal baseline by treatment day eight and significantly reduced blood glucose levels vs. vehicle and pioglitazone during the OGTT in STZ rats (mean AUC reduction of 41%, $p<0.05$) at day 15, suggesting that BMF-219 rapidly induced pancreatic beta cell regrowth and function. Furthermore, BMF-219 administration resulted in a near doubling of HOOMA-B value compared to vehicle control and pioglitazone in the STZ rat model.

In the other gold standard type 2 diabetes model, ZDF rats treated with BMF-219 exhibited an increase in beta cell mass and function while on BMF-219 and for two weeks after BMF-219 was removed. ZDF rats treated with vehicle and pioglitazone saw a reduction in IHC-Insulin staining, a proxy for beta cell mass of -33% and -28%, respectively, while rats treated with BMF-219 saw an increase of +2%.

Two weeks after BMF-219 treatment, the ZDF rats continued to see a normalization of their HOMA-B score, with approximately 350% improvement compared to vehicle treated ZDF rats, which remained highly diabetic with poor beta cell function (~75% below the normal range). In the ZDF model, BMF-219 and pioglitazone showed similar glycemic control during an OGTT while drug was present (AUC reduction of 54%, $p<0.001$) but only BMF-219 treated rats saw weight loss during treatment with BMF-219 and maintained glycemic control two weeks after washout (AUC reduction of 40%, $p<0.05$), indicating prolonged glycemic control. In addition to OGTT, blood glucose, insulin, C-peptide, Hemoglobin A1C (HbA1c), lipemic levels, and weight were also assessed.

We believe these data collectively demonstrate the novel, long-acting potential of BMF-219 as a single agent, disease modifying oral treatment for type 2 diabetes.

About Menin 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 are diminished, leading to insufficient insulin secretion and hyperglycemia. Menin is thought to act as a brake on beta-cell turnover / beta-cell 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 explored the potential for menin inhibition as a viable therapeutic approach to permanently halt or reverse progression of type 2 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. The company is utilizing its proprietary FUSION™ System to advance a pipeline of covalent-binding therapeutic agents against key oncogenic drivers of cancer and metabolic diseases. Biomea Fusion's goal is to utilize its capabilities and platform to become a leader in developing covalent small molecules in order to maximize the clinical benefit when treating various cancers and metabolic diseases.

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 our cash runway, the clinical and therapeutic potential of our product candidates and development programs, including BMF-219, the potential of BMF-219 as a treatment for various types of cancer and diabetes, our research, development and regulatory plans, including our pursuit of BMF-219 in metabolic diseases, 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.

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