



Biomea Fusion Releases Pre-Clinical Data with BMF-219 in Diabetes

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REDWOOD CITY, Calif., Jan. 06, 2022 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea") (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to the discovery and development of irreversible small molecules to treat and improve the lives of patients with genetically defined cancers and metabolic diseases, announced today that BMF-219 displayed remarkable activity in both the Zucker Diabetic Fatty (ZDF) Rat and the Streptozotocin-Induced Diabetes (STZ) animal models of type 2 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. Notably, it has previously been shown that knocking out the gene responsible for the creation of menin (MEN1) has been observed to produce profound glycemic control in diabetic animal models. 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.

Focusing on the hallmark of type 2 diabetes, Beta-cell dysfunction and loss of Beta-cell mass, Biomea conducted both the ZDF and the STZ experiments to measure the potential impact of BMF-219 for the treatment of type 2 diabetes. In both models, BMF-219 was able to normalize glucose levels in the majority of animals after just two weeks of treatment. Notably, the majority of the effect was maintained despite complete washout of BMF-219. Together, Biomea believes these results indicate the clinical potential for a novel menin inhibitor as a ground-breaking treatment for type 2 diabetes. Detailed reviews of both studies will be submitted to an upcoming scientific conference. The company intends to hold a meeting with regulators this quarter to discuss plans for a Phase 1/2 study.

"While the importance of menin in Beta-cell biology has been studied for some time, the normalization of insulin and glucose levels and potential repopulation of Beta-cells with a menin inhibitor in two distinct models is very unusual and noteworthy," said Rohit Kulkarni MD, PhD, Senior Investigator and Margaret A Congleton Professor; Section Head, Islet Cell and Regenerative Biology; and Professor of Medicine, Harvard Medical School. "I am looking forward to engaging with the Biomea team to support the clinical development of this exciting compound for the treatment of diabetes."

"We are a patient focused organization and we 'aim to cure.' As we reviewed the literature originally, we saw the relevance of menin in metabolic diseases and were compelled to explore the potential of our irreversible menin inhibitor for the benefit of patients," said Tom Butler, CEO and Chairman of Biomea Fusion. "We have now engaged in the standard preclinical models to validate diabetic treatments and are excited with the responses we have observed. We have shown that the use of Biomea's irreversible menin inhibitor BMF-219 has a significant impact on the progression of diabetes in several animal models. In our studies we were able to demonstrate a normalization of glucose levels and a reversal of hyperglycemia through the anticipated repopulation of Beta-cells, which is not easy to achieve. Most notably, the effect was sustained over the study period even without further dosing of BMF-219. We are now preparing the IND to support initiation of clinical trials to explore the potential benefits of BMF-219 for diabetic patients."

About Biomea Fusion

Biomea Fusion is a biopharmaceutical company focused on the discovery and development of irreversible small molecules to treat patients with genetically defined cancers and metabolic diseases. An irreversible small molecule is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional reversible 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™ discovery platform to advance a pipeline of irreversible treatments 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 irreversible 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 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 plans to discuss with regulators the potential clinical development of BMF-219 and our plans to file an IND and initiate 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 we may encounter delays in patient enrollment and in the initiation, conduct and completion of our planned clinical trials. These risks concerning Biomea Fusion's business and operations are described in additional detail in its periodic filings with the SEC, including its most recent period 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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