Biomea Fusion Selected for Two Oral Presentations at the European Association for the Study of Diabetes Annual Meeting Describing BMF-219's Potential as a Novel, Oral, Long-Acting, Acute Treatment for Type 2 Diabetes

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- Biomea to present two oral abstracts across multiple animal models highlighting the ability of BMF-219, a covalent menin inhibitor, to significantly lower HbA1C (approximately two-fold greater reduction than active control, liraglutide) and to increase beta cell function.
- BMF-219 showed prolonged glycemic control in two standard diabetes animal models, the Zucker Diabetic Fatty (ZDF) and Streptozotocin-induced (STZ) Rat models, throughout the dosing period and, additionally, glycemic control was maintained after the dosing period ended.
- Oral Presentations to include additional data not released in the two posters presented at the American Diabetes Association Scientific Sessions on June 4, 2022.
- Biomea expects to initiate a Phase I/II clinical trial of BMF-219 in type 2 diabetes in the second half of 2022, subject to IND submission and clearance.

REDWOOD CITY, Calif., July 01, 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, announced today that two BMF-219 preclinical abstracts were chosen for oral presentations at the European Association for the Study of Diabetes (EASD) Annual Meeting. The EASD, one of the largest networks for diabetologists worldwide, holds its Annual Meeting in a different European city each year with more than 15,000 delegates from over 130 countries attending. This year's 58th EASD Annual Meeting will be held in Stockholm, Sweden, 19 - 23 September 2022.

During the 2022 EASD annual meeting, Biomea's abstract "Oral menin inhibitor, BMF-219, displays a significant and durable reduction in HbA1c in a type 2 diabetes rat model" has been accepted for Short Oral Discussion with presentation number 590 and "Oral long-acting menin inhibitor normalizes type 2 diabetes in two rat models" will be presented orally with presentation number 197. Both abstracts can be viewed as of today at www.easd.org.

Both presentations highlight BMF-219's robust and prolonged glycemic control, insulin sensitization, and HbA1c reduction in two preclinical rat models of diabetes. These preclinical data support the potential utility of BMF-219 as a novel and acutely dosed oral, long-acting treatment for type 2 diabetes.

"We are honored to be selected for two oral presentations at the European Association for the Study of Diabetes Annual Meeting. The burden of diabetes remains unprecedented, with close to 10% of adults worldwide suffering from this disease and 1 in 3 Americans being prediabetic. Currently, diabetes typically requires daily treatment with multiple agents with various mechanisms of action in order to achieve glycemic control, however after several years they typically fail to maintain blood glucose control. The preclinical data that we have generated with oral BMF-219 to date and presented for the first time at the American Diabetes Association, may provide a true alternative as we are exploring to proliferate the beta cell mass and restore the body's own ability to produce insulin, thereby reversing the downward spiral of type 2 diabetes," said Thomas Butler, Biomea's Chief Executive Officer, and Chairman of the Board. "In the STZ rat model, a model that displays a significant reduction in beta cell mass, and where non-insulin based therapies have been ineffective, BMF-219 is the first single agent treatment to show glycemic control after 14 days of treatment. A therapy that can generate glucose responsive beta cells would be a major break-through for patients with diabetes. We are excited about these results and look forward to submitting our IND in the second half of this year."

Oral Presentation #197: (Thursday, September 22, 2022, 2:30 to 4:00 pm CEST) Oral Long-Acting Menin Inhibitor Normalizes Type 2 Diabetes in Two Rat Models

Abstract Text:

Background and aims: Menin is a scaffold protein that has been recognized for its role in T2DM as a key regulator of b-cell proliferation. Menin inhibition has previously been shown to improve glycemic control in diabetic mice. Herein, we report the first evidence that BMF-219, an orally bioavailable, selective, irreversible menin inhibitor, restores glycemic control in Zucker Diabetic Fatty (ZDF) Rat and Streptozotocin-induced (STZ) Rat models of T2DM.

Materials and methods: Rats were treated daily with BMF-219, vehicle, or pioglitazone for 16 days and analyzed for fasting and non-fasting blood glucose levels, insulin, c-peptide, and blood lipemic levels. Oral Glucose Tolerance Test (OGTT) was conducted up to Day 15 in both models and two-weeks post-treatment in the ZDF model. Body weight of all rats was also monitored.

Results: BMF-219 was well tolerated throughout the conduct of the study. BMF-219 treatment resulted in a significant 50% reduction in fasting and non-fasting blood glucose levels, reduced serum insulin and c-peptide levels ($p<0.05$), and reduced HOMA-IR ($p<0.001$) after two weeks of treatment

in ZDF rats. BMF-219 decreased glucose levels at all timepoints during an OGTT at Day 15 (AUC reduction of 54%, $p<0.001$) and at Day 29 (AUC reduction of 40%, $p<0.05$), ~2 weeks after the last dose in the ZDF model, indicating prolonged glycemic control. Strikingly, BMF-219, but not pioglitazone, reduced blood glucose levels during an OGTT in STZ animals (AUC reduction of 41%, $p<0.05$, see figure). Significant reductions in blood lipemic levels ($p<0.01$) and body weight were observed in both models.

Conclusion: Collectively, our data indicate the novel and marked potential of BMF-219 as an oral, long-acting treatment for T2DM.

Short Oral Discussion #590: (Tuesday, September 20, 2022, 12:00 pm CEST) Oral Menin Inhibitor, BMF-219, Displays A Significant and Durable Reduction in HbA1c in a Type 2 Diabetes Rat Model

Abstract Text:

Background and aims: Menin is an epigenetic regulatory protein that plays a key role in beta-cell proliferation and function, as previously demonstrated though increased beta-cell mass generation in Men1 knockout mice. The menin-MLL interaction also plays a major role in suppressing islet cell growth through control of cell cycle inhibitor expression. Here, we demonstrate the marked potential of an oral menin inhibitor, BMF-219, in durable glycemic control following a short course treatment in a Type 2 Diabetes Mellitus (T2DM) Zucker Diabetic Fatty (ZDF) Rat model.

Materials and methods: Rats were treated daily with BMF-219, liraglutide or vehicle for 28 days and monitored for an additional 28 days post-treatment for fasting and non-fasting blood glucose levels, HbA1C levels, insulin and c-peptide levels, HOMA-IR and HOMA-B quantitation and oral glucose tolerance test (OGTT).

Results: All animals tolerated BMF-219 well throughout the study. Notably, BMF-219 treatment resulted in a significant reduction in HbA1C at Day 21, which reached 3.5% absolute reduction in HbA1C versus vehicle ($p < 0.0001$), compared to liraglutide (1.7% at Day 29, $p < 0.05$) and remained reduced throughout the entire study, including post-treatment. The high-dose arm of BMF-219 showed a strong reduction in 4-hour fasting blood glucose during the treatment up to Day 29 ($p < 0.0001$). Both BMF-219 dose groups showed improved glycemic control by OGTT on day 25, whereas vehicle and liraglutide-treated animals continued to show high glucose levels. Additionally, insulin levels, HOMA-IR, HOMA-B, OGTT, HbA1C, and C-peptide levels measured at Day 57 across all groups will be reported.

Conclusion: Collectively, our data demonstrate the novel long-acting potential of menin inhibitor, BMF-219, as an oral treatment for T2DM, in maintaining glycemic control after short-term dosing.

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 is exploring 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, our plans to submit an IND application and to initiate a Phase I/II clinical trial of BMF-219 in type 2 diabetes, 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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