Biomea Fusion Highlights Initial Data from the First Two Type 1 Diabetes Patients Dosed with BMF-219

April 1, 2024

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

- The first two type 1 diabetes patients enrolled in COVALENT-112 both demonstrated early signs of clinical activity with improved measures of beta-cell function after initial treatment with BMF-219
- BMF-219 has been well tolerated by both patients
- Open label portion of Phase II COVALENT-112 study readout of 40 patients with type 1 diabetes dosed for 12 weeks with BMF-219 expected in 2024
- First type 2 diabetes patient dosed with BMF-219 for 4 weeks in COVALENT-111 being taken off background therapy (metformin) after week 40, displaying improved glycemic control

REDWOOD CITY, Calif., April 01, 2024 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea”) (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing oral covalent small molecules to treat and improve the lives of patients with metabolic diseases and genetically defined cancers, today announced initial response data from the first two type 1 diabetes patients treated with BMF-219 in the ongoing Phase II study (COVALENT-112).

“We are very excited to announce the initial response data from the first two type 1 diabetes patients enrolled in the COVALENT-112 study. Both patients showed improvement in measures of beta-cell function after only 4 weeks of dosing with BMF-219. We are rapidly gathering significant proof points we believe validate that covalent inhibition of menin leads to the regeneration of beta cells which has been shown to provide disease-modifying patient benefits,” stated Juan Pablo Frias, MD, Biomea Fusion’s Chief Medical Officer. “With BMF-219, we are learning about the potential of restoring the health and function of the beta cell pool in persons with diabetes and how this may lead to the restoration of the ability to produce and secrete insulin, and control blood glucose. These data are preliminary and we look forward to building upon them as we continue enrollment in the open-label portion of COVALENT-112.”

Dr. Tom Elliott, Medical Director of BC Diabetes (Vancouver, Canada), Clinical Associate Professor of Medicine at the UBC Division of Endocrinology, and a key investigator in the type 1 COVALENT-112 study added, “In my 32 years of practice as an endocrinologist I have never before seen a type 1 diabetes agent achieve such immediate increases in C-peptide secretion. We need longer-term follow up in a greater number of patients to validate these early signals, but I am very excited for the potential BMF-219 may provide for people with type 1 and type 2 diabetes. This is an unparalleled opportunity to address the root cause of diabetes.”

COVALENT-112 is a randomized, placebo-controlled, double-blind Phase II study (n=150) designed to examine the safety, efficacy, and durability of BMF-219 in adults diagnosed with type 1 diabetes within 3 years at two oral dose levels, 100 mg and 200 mg, for 12 weeks of treatment followed by a 40 week off-treatment period. The trial includes an open label portion for adults with type 1 diabetes up to 15 years since diagnosis. The open label portion (n=40) will also examine the safety, efficacy, and durability of BMF-219 at two oral dose levels, 100 mg and 200 mg, for 12 weeks of treatment followed by a 40 week off-treatment period.

We are highlighting initial response data from a data cut-off of March 7, 2024 from our first two patients with Stage 3 type 1 diabetes who have received BMF-219 in the open-label portion of COVALENT-112

Case Study Patient 1 Highlights

- A 58-year-old, diagnosed with type 1 diabetes 3 years ago
- BMF-219 200 mg once-daily
- Week 4: Fasting C-peptide increased by 57% compared to Baseline (study Day 1). During a mixed-meal tolerance test (MMTT) the C-Peptide Index (AUC) increased by 12%. The C-peptide index is the ratio of serum C-peptide to plasma glucose levels and is used to evaluate β-cell function
- Week 8: Fasting C-peptide increased by 80% compared to Baseline. During a MMTT, C-peptide increased up to 200%. The C-Peptide Index (AUC) increased by 40% compared to Baseline

- Data on any changes in daily insulin usage are pending

Case Study Patient 2 Highlights

- A 24-year-old, diagnosed with type 1 diabetes 7 years ago
- BMF-219 100 mg once-daily
- Week 4: Fasting C-peptide increased by 16% compared to Baseline. During a MMTT the C-peptide Index (AUC) increased by 30%
- Patient had a near-normal glucose response during the MMTT without receiving any meal-time insulin
- Patient had a reduction in daily insulin usage during the first four weeks of the study

Dr. Alexander Abitbol, Endocrinologist & Assistant Medical Director at the LMC Healthcare (Ontario, Canada), a key investigator in the type 2 diabetes COVALENT-111 study, and also participating in the type 1 diabetes COVALENT-112 study, provided further color on his experience with the follow-up of his patients after completion of the 26-week COVALENT-111 study, "The majority of my patients responded to 4 weeks of BMF-219 and continued to see an improvement in A1c over time. Some patients have now completed the 26-week study, and I am pleased to report that I recently discontinued a former study patient's background antidiabetic medication. This patient is doing particularly well and had an additional 1% HbA1c reduction after he completed the study. It has been exciting to participate in this study and explore this new pathway for the benefit of our patients. I look forward to continuing the enrollment."

About 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, where about 35 million people have type 2 diabetes and about 2 million people have type 1 diabetes. 96 million adults (more than 1 in 3) have prediabetes, 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 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 volunteers were enrolled in single ascending dose cohorts to evaluate safety at the prospective dosing levels for patients with type 2 diabetes. Phase II consists of multiple ascending dose cohorts and includes adult patients with type 2 diabetes uncontrolled by standard of care medicines. Following the Escalation Phase of COVALENT-111, the study has advanced into an Expansion Phase (n>200) consisting of multiple cohorts dosing type 2 diabetes patients for longer dose durations. 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 COVALENT-112

COVALENT-112 is a multi-site, randomized, double-blind, placebo-controlled Phase II study in adults with stage 3 type 1 diabetes. This stage describes the period following clinical diagnosis of type 1 diabetes when symptoms are present due to significant beta cell loss. COVALENT-112 will be a multi-arm trial comparing two different doses of BMF-219 to placebo (1:1:1) to evaluate the safety, tolerability, and efficacy of BMF-219 in adults with type 1 diabetes. Approximately 150 patients will be enrolled in the trial and will receive either BMF-219 or placebo for 12 weeks, followed by a 40-week off-treatment period.

This trial also includes an open-label portion for adults with type 1 diabetes up to 15 years since diagnosis. The open-label portion (n=40) will examine the safety, efficacy and durability of BMF-219 at two oral dose levels, 100 mg and 200 mg, for 12 weeks of treatment followed by a 40-week off-treatment period.

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 maintain normal 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 1 and type 2 diabetes.

About Biomea Fusion

Biomea Fusion is a clinical stage biopharmaceutical company focused on the discovery and development of oral covalent small molecules to treat patients with metabolic diseases 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, 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 type 1 and type 2 diabetes, our research, development and regulatory plans, the progress of our ongoing and upcoming clinical trials, including our Phase II COVALENT-112 study of BMF-219 in type 1 diabetes, the anticipated enrollment of patients and availability of data from our clinical trials, our plans to advance BMF-219 into a larger, potentially registrational 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 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 (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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