Biomea Fusion Announces Near Doubling the Percentage of Patients with Durable HbA1c Reduction in the 200 mg Dose Cohorts

December 9, 2023

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

- At Week 26, 22 weeks after the last dose of BMF-219, the 200 mg cohorts increased the percentage of patients to approximately 40% with durable HbA1c reduction of 1% or more as compared to the 100 mg cohorts which reported earlier as 20%.
- To date, the dose escalation portion has shown after only 4 weeks of dosing with BMF-219 that patients across all dosing cohorts have consistently experienced generally meaningful HbA1c reductions and no serious adverse events or study discontinuations.

REDWOOD CITY, Calif., Dec. 09, 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 top line data of the 200 mg dose cohorts from the ongoing Phase II clinical study (COVALENT-111) which will be presented in more detail at the International Conference on Advanced Technologies and Treatments of Diabetes (ATTD) in March 2024.

“At WCIRDC over the past days, we had the opportunity to lay out the foundational preclinical work and the data sets which supported that beta cell proliferation and their functional improvement is tractable to BMF-219, not only in animals, but also in the human islets, which we studied together with the Harvard Medical School, Joslin Diabetes Center. When inhibiting menin covalently, we observed some of the key signaling pathways and genes that are known to influence beta cell proliferation and function. As presented at the conference, we have shown for the first time the long-term follow-up data of our 100 mg patient cohorts. At ATTD next March, we will further discuss the long-term follow-up data from the 200 mg cohorts,” said Thomas Butler, Biomea Fusion’s Chief Executive Officer and Chairman of the Board. “Today, we can confidently say that we are specifically proliferating beta cells in pancreatic islets. By increasing the dose from 100 mg to 200 mg, we are excited about nearly doubling the percentage of patients treated with BMF-219 having a robust HbA1c reduction of 1% or more, 22 weeks after the last dose. We are now methodically going through the kinetics and durability of the responses that we have seen to better understand how we can support the various patients, and in particular those that have failed to reach their target HbA1c while on multiple agents including GLP-1s. Our goal with BMF-219 is to create a short-term treatment regimen for patients with diabetes that results in long term glycemic improvement and control. We believe we have made significant progress in reaching this goal, as reported over the past few days, and we look forward to further updates in 2024.”

At Week 26, 22 weeks after the last dose of a 4-week treatment with BMF-219, approximately 40% of patients from the 200 mg QD cohorts (4/11) displayed durable reduction in HbA1c of 1% or more; effectively near doubling the percentage of patients as compared to 20% observed in the 100 mg QD cohorts (n=20) presented this week at the World Congress Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC). At the ATTD taking place in Florence, March 2024, Biomea will present in an oral poster discussion session, further details of the long-term follow-up data (22 weeks after the last dose of BMF-219) to show durable glycemic control with BMF-219 during the off-treatment period of the 100 mg and 200 mg dose cohorts.

To date, the dose escalation portion has shown, after only 4-weeks of dosing with BMF-219, that patients across all dosing cohorts (n=52) have consistently experienced generally meaningful HbA1c reductions. Patient cohorts at higher dose levels have seen greater pharmacokinetic exposure of BMF-219. Variability seen in HbA1c reduction is viewed as being related to several factors including patients’ prior lines of therapies, years since diagnosis, beta cell function scores (Homa-B) and others. Based on the preclinical data, including the WCIRDC published presentations, we believe the responses seen to date will improve with longer dose durations and higher dose levels.

The best performing dosing cohort announced so far is cohort 3 (100 mg without food, n=10), where we reported a mean HbA1c reduction of 0.81% after only 4 weeks of dosing. In cohort 3, we enrolled 90% frontline patients on a single diabetic therapy with a mean HbA1c level reported of 8.1% at baseline; here only 10% of the patients were on two or more therapeutic agents. The dose cohorts we enrolled in addition to the 100 mg cohorts (50 mg, 100 mg BID, 200 mg, n=32) had between approximately 30%-100% of patients on two or more background agents, while failing with above normal HbA1c levels (baseline HbA1c ranging from 7.9% to 8.4%). In these cohorts the mean HbA1c reduction was observed between 0.4% to 0.5%, after four weeks of dosing. Considering the consistency of our responses, we believe we have confirmed clinically meaningful activity across all dosing cohorts.

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 patients were enrolled in single ascending dose (SAD) cohorts to evaluate safety at the prospective dosing levels for type 2 diabetic patients. Phase II consists of multiple ascending dose (MAD) cohorts 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 type 1 and type 2 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, the availability of future data from the Phase II portion of the study, our plans to complete dose escalation, identify optimal dose levels, initiate dose expansion, explore longer duration of treatment and additional dosage forms and explore the potential utility of BMF-219 in type 1 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 initial results may not be indicative of final results in later clinical trials, we may encounter delays, regulatory challenges or unforeseen and/or adverse results in preclinical or clinical development, we may face difficulties in patient enrollment and in the initiation, conduct and completion of our ongoing and 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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