Biomea Fusion Presents Patient Cohorts in COVALENT-111 Displaying a Durable Placebo-Adjusted Mean Reduction of up to 1.4% in HbA1c While Off Therapy at Week-26, after BMF-219's 28-Day Treatment Cycle, Supporting Improved Pancreatic Function

March 6, 2024

Three Clinical Data Sets from the Dose Escalation Phase of COVALENT-111 to be Presented at the 17th Annual ATTD Conference Highlighting BMF-219's Novel Mechanism of Action in Patients with Type 2 Diabetes

- Patients in COVALENT-111 are displaying improved glycemic control while off therapy out to Week 26 following the 28-day treatment with BMF-219, supporting enhanced pancreatic islet function as the mechanism of action
- BMF-219 was generally well tolerated with no serious adverse events and no adverse event-related study discontinuations, and no symptomatic or clinically significant hypoglycemia
- 100mg and 200mg dose levels have been selected for the first 3 Arms of the Expansion Phase, which will dose patients up to 12 weeks (compared to 4 weeks in the Escalation Phase) and extended follow-up to Week 52
- The Expansion Phase of COVALENT-111 is currently enrolling on schedule with initial 26-week data expected during 2H24
- Biomea Fusion to announce an update on the first two patients with Type 1 Diabetes, from the COVALENT-112 Study, in the Q4 2023 Earnings Release

REDWOOD CITY, Calif., March 06, 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 three poster presentations presenting long-term 26 week follow-up data from patients treated with BMF-219, enrolled in the escalation portion of the ongoing Phase II clinical study (COVALENT-111), at the 17th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD) taking place in Florence, Italy from March 6-9, 2024. This clinical data from all dosing cohorts initiated to date as of February 12, 2024 from the Escalation Phase of COVALENT-111 will be featured during a Poster Discussion Presentation and two Poster Viewing Presentations at ATTD. Biomea will showcase the following three e-poster presentations:

- Durable Glycemic Control with BMF-219 During Off-Treatment Period at Week 26: A Phase 1/2 Trial of BMF-219 in Patients with Type 2 Diabetes (COVALENT-111) (Poster Discussion Session, March 7th, 10-10:30 am CET.)
- Case Studies from COVALENT-111, A Phase 1/2 Trial of BMF-219, a Covalent Menin Inhibitor, in Patients with Type 2 Diabetes (Poster Viewing Session)
- Key Observations from the Dose Escalation Portion of COVALENT-111, a Phase 1/2 Trial of the Covalent Menin Inhibitor BMF-219 in Patients with Type 2 Diabetes (Poster Viewing Session)

All e-Posters will be available for viewing through the conference virtual platform once the conference commences. Please find a link here to our website where the poster presentations and discussion will be available.

"We aim to cure diabetes and believe we are on the path to do so. Notably, after receiving a short, 4-week course of BMF-219, patients with type 2 diabetes are displaying durable glycemic control, and in some cases displaying continued improvement in glycemic control while off therapy. The Escalation Phase of our first in human study was quite successful, generating strong clinical data with a novel mechanism of action and importantly providing us with proof-of-concept data to support the design of the Expansion Phase which is now enrolling. The Expansion Phase will dose patients for longer treatment periods with the goal of broadening and deepening BMF-219's effect across the type 2 patient population. As presented at the ATTD conference, we believe the observations from biomarkers including HbA1c, HOMA-B, and C-peptide analysis for responders vs. non-responders, together with pharmacokinetic dose response data all point to strong evidence that BMF-219 is specifically proliferating beta cells in pancreatic islets of uncontrolled type 2 diabetes patients," said Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board. "I am also excited about the potential this pathway may provide patients with type 1 diabetes. We are enrolling our open label arm (n=40) of our Phase II COVALENT-112 study in adults with stage 3 type 1 diabetes first which will give us initial response data before embarking on a larger, potentially registrational study."

Data Highlights from ATTD Presentations

Efficacy Findings

- Patients in COVALENT-111 are displaying improved glycemic control while off therapy, supporting improved pancreatic

function following BMF-219 treatment. Patients who demonstrated the greatest HbA1c reduction at Week 26 (22 weeks off treatment), had the greatest improvement in beta cell function as measured by HOMA-B and C-peptide.

- In patients failing current standard of care medications, at Week 26, following a 28 day dose cycle of BMF-219, a general dose response was observed with placebo adjusted mean percent changes of HbA1c of -0.04% (50mg QD*), -0.2% (100mg QD with food), -0.8% (100mg), -0.4% (200mg QD), -0.4% (100mg BID), and -1.4% (200mg with food) (*50mg data out to Week 20, latest data cut).
- The efficacy seen in the 200mg with food cohort is highlighting the direct benefits of an enhanced PD effect with higher blood glucose and higher exposure, as seen in the human islet studies with BMF-219 (presented at WCIRD Dec. 2023).
- A higher proportion of patients treated with 200mg QD achieved a clinically significant reduction in HbA1c compared to 100mg QD dosing. A durable glycemic response (≥1.0% HbA1C reduction) was seen in 20% and 36% of patients in once daily 100 mg and 200 mg cohorts, respectively.
- Across 100mg QD, 200mg QD, and 100mg BID cohorts (N=40), 38% of patients had ≥0.5% HbA1c reduction (with a mean HbA1c reduction of 1.2%), and 23% of patients had ≥1.0% HbA1c reduction (with a mean HbA1c reduction of 1.5%) at Week 26.
- Patients with >7 years duration of diabetes and failing dual- or triple-agent therapy (including GLP1 RA and/or SGLT2i) (n=2) also demonstrated improved glycemic control (HbA1c -0.4%, -1.1%, and -1.1% at Weeks 4, 12, and 26, respectively) with BMF-219 dosed at 200mg with food.
- Increase in HOMA-B and C-peptide generally correlated with glycemic control, consistent with BMF-219's core mechanism of action: beta-cell proliferation and improved beta-cell function.

Safety and Tolerability Findings

- BMF-219 was generally well tolerated with no serious adverse events and no adverse event-related study discontinuations, and no symptomatic or clinically significant hypoglycemia.

Next Steps

- The Expansion Phase of COVALENT-111 is designed to further explore BMF-219's potential for long-term glycemic control by dosing BMF-219 for up to 12 weeks at various dosing levels with follow-up of 26 and 52 weeks. The Expansion Phase is currently enrolling on schedule with initial data expected in the second half of 2024.
- A PK study further assessing the optimal use of BMF-219 to ensure minimal variability of exposure is currently under way.
- Biomea is currently awaiting the read out and analysis of an additional 400 mg cohort, which will also help inform further inclusion into the Expansion Phase.

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 patients were enrolled in single ascending dose cohorts to evaluate safety at the prospective dosing levels for type 2 diabetic patients. Phase II consists of multiple ascending dose cohorts and includes adult patients with type 2 diabetes uncontrolled by standard of care medicines. Once the Escalation Phase of COVALENT-111 completes, the study advances 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 control (1:1:1) to evaluate the safety, tolerability, and efficacy of BMF-219 in persons 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 will also include 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. Additional information about the Phase II clinical trial of BMF-219 in type 1 diabetes can be found at ClinicalTrials.gov using the identifier NCT06152042.

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 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, including our pursuit of BMF-219 in metabolic diseases, the progress of our ongoing and upcoming clinical trials, including our Phase I/II COVALENT-111 study of BMF-219 in type 2 diabetes and 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 continue the evaluation of BMF-219 for type 2 diabetes in our COVALENT-111 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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