Biomea Fusion to Present Late Breaking Data from Ongoing Phase II Trial, COVALENT-111, Evaluating BMF-219 in Patients with Type 2 Diabetes, at the ADA 83rd Scientific Sessions 2023 in June

April 19, 2023

- New clinical data from COVALENT-111 will be featured during the Late-Breaking Poster Presentations at the Scientific Sessions
- Biomea to hold an investor and KOL event during the Scientific Sessions

REDWOOD CITY, Calif., April 19, 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 that it will present new clinical data from the ongoing Phase II portion of its COVALENT-111 trial, which is evaluating BMF-219 as a treatment for patients with type 2 diabetes, in a late-breaking poster presentation at the 2023 American Diabetes Association (ADA) 83rd Scientific Sessions, to be held June 23 – 26, 2023 in San Diego, CA. The company will also host an investor and KOL event during the Scientific Session.

Biomea will disclose additional information about the late-breaking presentation in accordance with ADA’s abstract embargo policies. In addition, the company will provide further details on the investor and KOL event at a later date.

The loss of insulin-producing beta cells is a root biological cause of type 2 diabetes and its progression. BMF-219, a novel covalent menin inhibitor, is designed to regenerate, preserve, and reactivate healthy, insulin-producing beta cells, thereby normalizing glycemic control and halting or reversing type 2 diabetes disease progression. Biomea is evaluating BMF-219’s potentially novel mechanism of action with an intended treatment goal of re-establishing a pool of healthy beta cells, which may allow for continued glycemic control for prolonged periods even after treatment is stopped.

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 ensure 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 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.

In March 2023, Biomea announced initial positive safety and efficacy data for the first two cohorts of patients with type 2 diabetes enrolled in the Phase II portion of the trial. A link to the press release can be found here and a link to webcast can be found here.

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 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 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, 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.

Contact: Chunyi Zhao, PhD Sr. Manager of Investor Relations & Corporate Development czhao@biomeafusion.com