Biomea Fusion Announces FDA and Health Canada Clearance of the Expansion Cohorts of the Ongoing COVALENT-111 Phase II Study

September 28, 2023

- The FDA and Health Canada have cleared the initiation of the expansion portion of COVALENT-111, which will evaluate BMF-219 administered at 100 mg and 200 mg, with dosing durations up to 12 weeks in type 2 diabetes patients
- The expansion portion will consist of approximately 300 patients and will begin to enroll three cohorts immediately, with a fourth cohort following the completion of the escalation portion
- Compared to baseline, 84% of all patients dosed for four weeks with BMF-219 (n=32) in the escalation portion of COVALENT-111 showed a reduction in HbA1c at Week 4 and 74% at Week 12, two months after the final dose of BMF-219
- Topline results of the escalation portion anticipated in Q4 2023

REDWOOD CITY, Calif., Sept. 28, 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 FDA and Health Canada clearance of the expansion portion of the ongoing COVALENT-111 Phase II study. The objective of the expansion portion is to continue to investigate BMF-219 with treatment durations up to 12 weeks.

“We’ve seen truly groundbreaking data to date with BMF-219’s novel mechanism of action focused on addressing an underlying cause of type 2 diabetes – the loss of healthy, insulin-producing beta cells,” said Juan Pablo Frias, M.D., Chief Medical Officer at Biomea. “As we learned from our preclinical studies and now with the early clinical data, patients present with various levels of beta cell function, which supports extending the treatment period beyond four weeks in order to maximize the degree and durability of improvement in glycemic control. The expansion portion of COVALENT-111 is designed to build on the impressive findings thus far, and more deeply interrogate and define BMF-219 as a potential treatment for a large portion of the type 2 diabetes patient population.”

Thomas Butler, Biomea’s Chief Executive Officer and Chairman of the Board, commented, “We are excited to begin the expansion portion of COVALENT 111. It is an important milestone as the data from this trial will further inform development plans and our discussions with the FDA and Health Canada.” He further added, “BMF-219 has continued to show durable HbA1c lowering even after the dosing period has ended, which helps validate the postulated mechanism of action for BMF-219 - the regeneration of beta cells - and supports the potential for disease modification of type 2 diabetes. The momentum of our study is continuing to build with new sites coming onboard quickly and enrollment surpassing internal expectations. We look forward to reporting results from this study in the coming year.”

During the escalation phase of COVALENT-111, a total of 32 type 2 diabetes patients completed 4-weeks of dosing with BMF-219 to date (10 active patients per arm, with dose levels 100mg with food, 100mg without (w/o) food, 200mg w/o food, and 200mg with food (n=2)). An additional 30 type 2 diabetes patients will complete the escalation phase with 4 weeks of BMF-219 dosing in Q4 2023 (10 active patients per arm, with 50mg w/o food, 100mg BID w/o food, and 400mg w/o food). Biomea anticipates providing topline data from the escalation phase of COVALENT-111 later this year and a more detailed presentation at a medical conference in 2024.

About COVALENT-111
COVALENT-111 is a multi-site, randomized, double-blinded, placebo-controlled Phase I/II study. In the completed Phase I portion of the trial, healthy subjects were enrolled in single ascending dose cohorts. As previously reported, the Phase I portion of COVALENT-111 has been completed, and BMF-219 was generally well tolerated with an encouraging PK and PD profile in healthy volunteers. The Phase II portion, ongoing in Canada and the U.S., consists of multiple ascending dose cohorts (escalation portion) enrolling adult patients with type 2 diabetes uncontrolled by current therapies. During the expansion portion of COVALENT-111, multiple dose level cohorts will enroll adult patients to investigate BMF-219 with treatment durations up to 12 weeks. COVALENT-111 is designed to examine BMF-219’s potential to provide long-term glycemic control to patients by restoring their pool of healthy, insulin-producing beta cells. 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 in Diabetes
Loss of functional beta cell mass is a core component of the natural history in 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 adults in the USA are 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 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 and BMF-500, the potential of BMF-500 as an FLT3 inhibitor and as a treatment for various types of cancers, the potential of BMF-219 as a treatment for various types of cancer and diabetes, our research, development and regulatory plans, the progress of our ongoing and planned clinical trials, including COVALENT-101, COVALENT-102, COVALENT-103 and our Phase I/II COVALENT-111 study of BMF-219 in type 2 diabetes, our plans to provide clinical updates on additional data from the initial dosing cohorts in COVALENT-111, our plans to provide future data from the Phase II portion of COVALENT-111 and the expansion of the Phase II portion, complete dose escalation, identify optimal dose levels, initiate dose expansion, our plans to explore longer duration of treatment and additional dosage forms and our plans to 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 we may encounter delays in preclinical or clinical development, the preparation, filing and clearance of INDs, 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.

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