Biomea Fusion Announces Dosing of First Patient with Type 2 Diabetes and Completion of Phase I Healthy Volunteer Portion of Phase I/II (COVALENT-111) Study of BMF-219

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- BMF-219 is the first menin inhibitor to reach the clinic for type 2 diabetes. The Phase II portion of COVALENT-111 is designed to examine the capacity of BMF-219 to provide long-term glycemic control by restoring the patient's pool of beta cells
- Beta cell loss is a critical component of the etiology and pathogenesis of type 1 and type 2 diabetes; menin is thought to function as the brakes on beta cell recovery in the pancreas. BMF-219 was designed to specifically inhibit menin. Preclinical studies have shown the potential of BMF-219 to restore functional beta cells
- The Phase I portion of COVALENT-111 in healthy volunteers is now completed and was designed to assess safety, tolerability, and pharmacokinetics; BMF-219 was well tolerated and showed a favorable PK and PD profile
- The study is ongoing following clearance of the CTA by Health Canada; alignment has been reached with the FDA on the contents of the IND, filing is on track for Q4 to support expansion of COVALENT-111 to U.S. sites, subject to FDA clearance
- Initial data from the Phase II portion of the study is expected in the first half of 2023

REDWOOD CITY, Calif., Oct. 31, 2022 (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 the dosing of the first patient with type 2 diabetes in the Phase II portion of COVALENT-111, a Phase I/II clinical trial underway in Canada. Biomea has completed the Phase I portion of the trial in healthy volunteers.

"With the dosing of our first patient with BMF-219, we have reached an important milestone for the nearly 500 million patients worldwide with type 2 diabetes. We are pursuing BMF-219 with the aim to cure this disease. Beta cell preservation, reactivation and regeneration are the core components in providing diabetes patients with long term benefit," stated Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board. "The burden of diabetes is rapidly increasing, and we are faced with a global unmet need for treatments with novel mechanisms of action. With BMF-219, a potentially first-in-class, covalent menin inhibitor, we are aiming to address and reverse the root cause of this epidemic."

Mr. Butler continued, "We leveraged an opportunity to begin clinical development earlier by initiating the COVALENT-111 study in Canada. With the completion of the Phase I portion in healthy volunteers, we have now swiftly progressed to dosing type 2 diabetes patients in the Phase II. In the meantime, we have been in active discussions with the FDA and plan to file an IND before the end of the year. We expect to report initial Phase II data in the first half of 2023."

Rohit N. Kulkarni MD, PhD, Senior Investigator and Margaret A Congleton Professor; Section Head, Islet Cell and Regenerative Biology; and Professor of Medicine, Harvard Medical School, commented: "Based on the promising preclinical data presented at the European Association for the Study of Diabetes in September of this year, showing BMF-219's ability to restore and balance beta cell mass in two distinct animal models of type 2 diabetes, it is very exciting to now see BMF-219 being evaluated in type 2 diabetes patients. While the importance of menin in beta cell biology was researched academically, we have not seen menin being clinically inhibited in type 2 diabetes patients. I am very excited to see a novel menin inhibitor, designed to address a key pathway to beta cell regeneration, advance into clinical development for the first time."

About COVALENT-111
COVALENT-111 is a multi-site, randomized, double-blind, placebo-controlled Phase I/II study. In the Phase I portion of the trial, healthy subjects were enrolled in single ascending dose cohorts to ensure 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 current therapies.

About Menin 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 are 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 permanently halt or reverse progression of type 2 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. The company is utilizing its proprietary FUSION™ System to advance a pipeline of covalent-binding therapeutic agents against key oncogenic drivers of cancer and metabolic diseases. Biomea Fusion's goal is to utilize its capabilities and platform to become a leader in developing covalent small molecules in order to maximize the clinical benefit when treating various cancers and metabolic diseases.

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 submit an IND application and to initiate a Phase I/II clinical trial of BMF-219 in type 2 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 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.

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