Biomea Fusion Announces Dosing of First Patient with Type 2 Diabetes in the United States in Ongoing Phase I/II (COVALENT-111) Study of BMF-219

January 4, 2023

- COVALENT-111, now underway in the US, has completed Phase I and is currently enrolling type 2 diabetes patients in the Phase II randomized, placebo-controlled portion of the trial
- BMF-219, an orally available covalent menin inhibitor, is being evaluated for its potential to enable the proliferation, preservation, and reactivation of healthy, functional beta cells capable of producing insulin, thereby leading to long-term glycemic control
- Disease modification via the restoration of healthy beta cells in patients with type 2 diabetes would potentially address a root cause of the disease
- Initial Phase II data from this trial is expected in the first half of 2023

REDWOOD CITY, Calif., Jan. 04, 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 dosing of the first patient with type 2 diabetes in the Phase II portion of COVALENT-111 in the U.S. This trial is a randomized, double-blinded, placebo-controlled study evaluating the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of six dose levels of BMF-219 administered orally daily in 28-day cycles followed by a 26-week evaluation period.

“We are thrilled to announce this milestone so soon after receiving IND clearance from the FDA in December. BMF-219 is potentially capable of addressing and modifying a major driver of type 2 diabetes, beta cell health and function. We believe that this oral agent has the potential to obviate the need for multiple concurrent treatments, including insulin injections,” stated Thomas Butler, Biomea Fusion’s Chief Executive Officer, and Chairman of the Board. “We look forward to presenting initial data from the Phase II portion of COVALENT-111 later this year as we march toward our goal of delivering a transformational therapy for patients with diabetes.”

Beta cells in the pancreas are responsible for producing, storing, and releasing insulin. Adequate insulin production helps ensure glucose homeostasis. Menin is thought to function as the brake and a key regulator for beta cell growth in the pancreas, acting as a checkpoint, to prevent excessive beta cell proliferation in healthy individuals. Low beta cell mass is a root cause of type 2 diabetes; without enough healthy, functional beta cells, people with type 2 diabetes are unable to produce sufficient amounts of insulin.

BMF-219 was designed to specifically inhibit menin’s capacity to interact with transcriptional partners that drive the expression of cell cycle protein regulators, including those that prevent the replication and expansion of beta-cells. Preclinical studies have shown the potential of BMF-219 to restore and balance beta cells mass.

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 enrolling adult patients with type 2 diabetes uncontrolled by current therapies. COVALENT-111 is designed to examine the capacity of BMF-219 to potentially provide long-term glycemic control to patients by restoring their pool of beta cells.

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 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 1 in 3 Americans will develop diabetes at some point in their life. 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 availability of current medication, there is 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. 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 is a leader in advancing next-generation covalent small molecule medicines designed to maximize clinical benefit to treat 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 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 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.

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