Biomea Fusion Announces FDA Clearance of Investigational New Drug (IND) Application for BMF-219 in Type 1 Diabetes

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BMF-219 is a novel covalent menin inhibitor designed to regenerate insulin-producing beta cells with the aim to cure type 1 diabetes

- The FDA has cleared the initiation of COVALENT-112, a Phase II clinical trial of BMF-219 in adults with type 1 diabetes (T1D).
- The randomized, double-blind, placebo-controlled (N=150) trial in adults with T1D will examine the safety and efficacy of BMF-219 at two oral dose levels, 100 mg and 200 mg unfed, for 12-weeks of treatment followed by a 40 week off-treatment period.

REDWOOD CITY, Calif., Oct. 05, 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 the U.S. Food and Drug Administration (FDA) has cleared Biomea's IND application to study BMF-219 in adults with type 1 diabetes.

The objective of COVALENT-112 is to evaluate the safety, efficacy, and durability of BMF-219, a covalent menin inhibitor, in potentially restoring beta cell function. Beta cell loss is a root cause of type 1 and type 2 diabetes. Menin inhibition has been demonstrated to improve beta cell function. Preclinical studies have shown the potential of BMF-219 to specifically regenerate and retain insulin-producing beta cells in animal models of type 1 and type 2 diabetes.

“We are excited to evaluate the potential impact BMF-219 may have in people with type 1 diabetes. Currently, the only available therapy for these patients is exogenous insulin which requires intensive management with chronic multiple daily insulin injections or treatment with an insulin pump, and has a risk of hypoglycemia, increased morbidity and mortality,” stated Juan Pablo Frias, MD, Biomea Fusion’s Chief Medical Officer. He added, “By targeting one of the root causes of diabetes, we may successfully restore the health and function of the body’s own mechanism to produce insulin, the beta cells. I’m excited for patients as BMF-219 has shown a significant ability to regenerate and retain those critical cells in preclinical and early-phase clinical studies in type 2 diabetes.”

“Our initial clinical data has demonstrated that BMF-219 is potentially disease modifying for people with type 2 diabetes. We have been diligent to build a program that will evaluate most people with diabetes, including those with type 1 diabetes. Last week we announced the expansion of our existing Phase I/II study enrolling approximately 300 additional patients with type 2 diabetes. Today, we are thrilled to announce that the FDA has also cleared our IND to study BMF-219 in type 1 diabetes. Our new study, COVALENT 112, is designed to enroll 150 patients with type 1 diabetes,” stated Thomas Butler, Biomea Fusion’s Chief Executive Officer and Chairman of the Board. He further added, “I am immensely proud that Team Fusion has achieved these clinical and regulatory milestones more than 3 months ahead of our guided timelines. We have now established a clinical development plan that we believe will fully explore the potential of BMF-219 across the spectrum of diabetes. The next quarters will be very exciting as we expect these studies will begin to read out.”

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.

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 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, the progress of our ongoing and upcoming clinical trials, including COVALENT-101, COVALENT-102, COVALENT-103 and 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 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, 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: Investor Relations Chunyi Zhao, PhD Sr. Manager of Investor Relations & Corporate Development czhao@biomeafusion.com Media Relations Neera Chaudhary nchaudhary@biomeafusion.com