Biomea Fusion Announces Dosing of First Type 1 Diabetes Patient in Phase II Study (COVALENT-112) with BMF-219

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BMF-219 is an investigational novel covalent menin inhibitor developed to regenerate insulin-producing beta cells with the aim to cure diabetes

- The clinical study, COVALENT-112, has initiated enrollment of adults living with type 1 diabetes in the US and Canada.
- Eligible patients include those who have been diagnosed with type 1 diabetes for up to 15 years.
- Data from the Phase II study are expected in 2024.

REDWOOD CITY, Calif., Jan. 08, 2024 (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 1 diabetes in the U.S. in its ongoing Phase II study (COVALENT-112) evaluating BMF-219, a novel, investigational covalent menin inhibitor, as a potential treatment for patients with type 1 diabetes.

The objective of COVALENT-112 is to evaluate the safety, efficacy, and durability of BMF-219 in potentially restoring beta cell function in adults with type 1 diabetes. Beta cell loss is thought to be 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 proliferate insulin-producing beta cells in animal models of type 1 and type 2 diabetes.

The randomized, placebo-controlled, double-blind portion of the COVALENT-112 trial (n=150) will examine the safety, efficacy, and durability of BMF-219 in adults diagnosed with type 1 diabetes within 3 years at two oral dose levels, 100 mg and 200 mg, for 12 weeks of treatment followed by a 40 week off-treatment period. The trial includes an open label portion for adults with type 1 diabetes up to 15 years since diagnosis. The open label portion (n=40) will also examine the safety, efficacy, and durability of BMF-219 at two oral dose levels, 100 mg and 200 mg, for 12 weeks of treatment followed by a 40 week off-treatment period.

“We are very excited to announce this milestone of starting the enrollment in our clinical trial for adults with type 1 diabetes, where a great unmet need exists. Persons with type 1 diabetes require exogenous insulin therapy, which entails intensive management and can result in important morbidity, including hypoglycemia and weigh gain. With the encouraging data from our preclinical and early-phase clinical studies of BMF-219 in type 2 diabetes, we believe that by targeting one of the root causes of diabetes, this oral agent has the potential to restore the health and function of the body’s own mechanism to produce insulin, the beta cells,” stated Juan Pablo Frias, MD, Biomea Fusion’s Chief Medical Officer. He added, “We look forward to presenting initial data in 2024 as we march toward our goal of delivering a transformational therapy for patients with diabetes.”

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 (1:1:1) to evaluate the safety, tolerability, and efficacy of BMF-219 in adults 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.

This trial also includes an open-label portion for adults with type 1 diabetes up to 15 years since diagnosis. The open-label portion (n=40) will examine the safety, efficacy, and durability of BMF-219 at two oral dose levels, 100 mg and 200 mg, for 12 weeks of treatment 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 type 1 and type 2 diabetes, our research, development and regulatory plans, the progress of our ongoing and upcoming clinical trials, including 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.

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