Biomea Fusion Announces Health Canada Clearance of Clinical Trial Application (CTA) for BMF-219 in Type 1 Diabetes

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

- Health Canada has cleared the initiation of COVALENT-112, a Phase II clinical trial of BMF-219 in adults living with type 1 diabetes (T1D), following FDA clearance of the initiation of COVALENT-112 in October 2023
- The randomized, double-blind, placebo-controlled (n=150) trial in adults living with T1D 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
- The trial will also include an open label portion, enrolling participants in the US and Canada with T1D up to 15 years since diagnosis

REDWOOD CITY, Calif., Dec. 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 that Health Canada has cleared Biomea's Clinical Trial Application (CTA) to study BMF-219 in adults living with type 1 diabetes.

The objective of COVALENT-112 is to evaluate the safety, efficacy, and durability of BMF-219, a novel investigational 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 restore 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.

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 will also include 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.

“Our study COVALENT-111 is currently enrolling persons with type 2 diabetes and has generated tremendous enthusiasm among investigators in Canada. We are now looking forward to examining the potential of BMF-219 in persons with type 1 diabetes with our study COVALENT-112 in this region. BMF-219 is designed to target a root cause of diabetes, a depleted pool of beta cells. Insulin-producing beta cells are necessary to establish glycemic control and are especially vital for people living with type 1 diabetes. We are very excited to explore BMF-219’s potential not only in type 2 but now also in type 1 diabetes, to successfully restore the health and function of beta cells and re-establish the body’s own mechanism to produce insulin naturally again,” stated Juan Pablo Frias, MD, Biomea Fusion’s Chief Medical Officer. He further added, “The newly added open label study is designed to enroll 40 adults living with type 1 diabetes at two different dose levels. We expect it will provide valuable insights early on to inform and apply learnings to the randomized blinded portion of the trial.”

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.

This trial will also include 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 COVALENT-111

COVALENT-111 is a multi-site, randomized, double-blind, placebo-controlled Phase I/II study. In the completed Phase I portion of the trial, healthy subjects were enrolled in single ascending dose cohorts to ensure safety at the prospective dosing levels for people with type 2 diabetes. Phase II consists of multiple ascending dose cohorts and dose durations and includes adult patients with type 2 diabetes uncontrolled by current therapies. 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 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 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.

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