Biomea Fusion Announces Completion of Enrollment of First 3 Arms in Phase 2 Expansion Cohorts of COVALENT-111 Study for BMF-219 in Type 2 Diabetes

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BMF-219 is an investigational novel covalent menin inhibitor developed to regenerate insulin-producing beta cells

REDWOOD CITY, Calif., May 30, 2024 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea”) (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing oral covalent small molecules to treat and improve the lives of patients with metabolic diseases and genetically defined cancers, today announced the completion of enrollment of the first three dose expansion arms of COVALENT-111, with a total of over 260 type 2 diabetes patients enrolled.

The COVALENT-111 study is a multi-site, randomized, double-blind, placebo-controlled Phase I/II study. Phase II consists of multiple dose escalation and dose expansion cohorts including adult patients with type 2 diabetes uncontrolled by standard of care medicines. The dose escalation phase is evaluating BMF-219 dosed over 4 weeks with 22 weeks follow-up off treatment. The first three arms (A, B, C) of the expansion phase are evaluating BMF-219 dosed over 8 and 12 weeks at 100 mg and 200 mg with up to 40 weeks of follow-up off treatment.

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.

“We are thrilled to announce the important milestone of completing enrollment of the first three expansion arms of COVALENT-111. In the dose escalation arms, after only 4 weeks of BMF-219 dosing, many participants demonstrated durable glycemic control at Week 26. To date, we have not seen an agent with such a profound impact on type 2 diabetes while off therapy. BMF-219 is unique in that it directly addresses the root cause of diabetes by proliferating the failing pool of beta cells. We are now excited to see how the impact of BMF-219 may be improved by a longer, 8 to 12-week dosing regimen.” stated Juan Pablo Frias, MD, Biomea Fusion’s Chief Medical Officer. He added, “The expansion phase builds upon our early learnings and supports a more patient centric approach to treatment as we investigate the heterogeneity of type 2 diabetes. We look forward to presenting our topline Week 26 data of our first three expansion arms of COVALENT-111 in Q4 2024.”

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 patients were enrolled in single ascending dose cohorts to evaluate safety at the prospective dosing levels for the patients with type 2 diabetes. Phase II consists of multiple ascending dose cohorts and includes adult patients with type 2 diabetes uncontrolled by standard of care medicines. Once the escalation phase of COVALENT-111 completed, the study advanced into an expansion phase consisting of multiple cohorts dosing type 2 diabetes patients for longer dose durations. 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 oral covalent small molecules to treat patients with metabolic diseases and genetically defined cancers. 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. 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 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, the 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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