Biomea Fusion Announces First Patient Dosed in Multiple Myeloma Cohort of COVALENT-101 Trial

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- BMF-219, a covalent menin inhibitor, is the first menin inhibitor administered to patients with relapsed/refractory (R/R) multiple myeloma (MM)
- Patients with R/R MM and R/R diffuse large B-cell lymphoma (DLBCL) are eligible for enrollment in COVALENT-101
- Enrollment continuing for both acute leukemia cohorts, including AML and ALL, while initiating DLBCL and MM patient cohorts
- Site activation continuing in North America

REDWOOD CITY, Calif., June 22, 2022 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea”) (Nasdaq: BMEA), today announced that the first patient has been dosed in the MM cohort of COVALENT-101, the company’s Phase I clinical trial evaluating BMF-219, Biomea’s covalent menin inhibitor, in patients with R/R AML, ALL, DLBCL, and MM.

“From the very beginning of our journey, we have been exploring and validating the broad potential of covalently inhibiting the scaffold protein, menin, in a host of liquid and solid tumors. Menin’s broad role in a variety of tumor types is rather striking. Based on the outstanding translational work of our team, we have seen compelling preclinical activity using BMF-219 in MM subtypes, especially those that are driven by MYC, a protein essential to the growth of numerous tumor types,” said Steve Morris, MD, Chief Medical Officer of Biomea Fusion.

“Today, we have taken the first step to explore the clinical potential of BMF-219, a single-agent covalent menin inhibitor, in treating relapsed / refractory multiple myeloma patients. This represents the second cancer type, as well as the first cancer type outside of AML, to be studied with BMF-219. We are committed to delivering innovative medicine to patients in need, including those with R/R MM. I am incredibly proud of our team for their dedication as they continue to explore the boundaries of where science is leading us. Our mission is fundamentally driven by the wish to help cure patients of their disease. I would like to thank the entire Biomea team, including our participating clinical sites and wonderful collaborators, for their work quality and brilliance in achieving this very important milestone,” said Thomas Butler, CEO, Chairman of the Board and Co-Founder of Biomea.

About COVALENT-101

A Phase I, open-label, multi-center, dose escalation and dose expansion study designed to assess the safety, tolerability, and pharmacokinetics / pharmacodynamics of once daily oral dosing of BMF-219 in patients with r/r acute leukemias —including subpopulations where menin inhibition is expected to provide a therapeutic benefit (e.g., patients with MLL1/KMT2A gene rearrangements or NPM1 mutations). The study has been expanded to include cohorts for patients with R/R multiple myeloma and R/R diffuse large B-cell lymphoma. Additional information about the Phase I clinical trial of BMF-219 can be found at ClinicalTrials.gov using the identifier NCT05153330.

About Multiple Myeloma (MM)

MM is a cancer of plasma cells, which make antibodies (immunoglobulins) and are mainly located in the bone marrow. As cancerous cells proliferate and migrate from the bone marrow, organ damage occurs due to excess immunoglobulins in bones and blood and the general weakening of bones. Approximately 35,000 people in the U.S. are diagnosed with MM each year and the 5-year relative survival rate is ~56% (Source: NCI SEER Data). The need is greatest among patients with relapsed or refractory disease, with overall survival as low as 6 months in some patients. Additionally, it is estimated that more than 60% of MM patients have menin dependent genetic drivers (MYC addicted or driven) and that these drivers are more common in the relapsed or refractory setting.

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’s goal is to utilize its capabilities and platform to become a leader in developing covalent small molecules in order to maximize the clinical benefit when treating 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 our cash runway, 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, 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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