Biomea Fusion Announces First Patient Dosed

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- BMF-219 is the first irreversible covalent menin inhibitor to enter the clinic
- Phase I trial is enrolling patients with relapsed/refractory acute leukemias, including those with MLL1/KMT2A gene rearrangements or NPM1 mutations
- Phase I trial is expected to include up to 20 clinical sites at leading US medical centers

REDWOOD CITY, Calif., Jan. 25, 2022 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea”) (Nasdaq: BMEA), today announced that the first patient has been dosed in its Phase I clinical trial evaluating BMF-219, the company’s irreversible covalent menin inhibitor, in patients with relapsed/refractory (r/r) acute leukemias, including those with MLL1/KMT2A gene rearrangements or NPM1 mutations.

“We are honored and deeply humbled by this significant milestone, which marks our successful transition to a clinical stage company. Just over four years ago, we took the concept of designing a small molecule that targets menin and brought forward BMF-219 to the clinic to significantly improve the lives of patients,” said Thomas Butler, Biomea’s Chief Executive Officer and Chairman of the Board. “I’m incredibly proud of our team for their ability to execute on this aggressive timeline. This signals how we intend to operate as a drug discovery and development organization – advancing world-class science with rapid momentum and driven by an unwavering mission to improve patient outcomes and save lives. We are pursuing a novel approach to developing best-in-class molecules with our FUSION™ System across multiple indications and anticipate announcing our next pipeline candidate in the first half of 2022.”

“Since 2017, we have focused on building a world-class discovery and development team at Biomea Fusion. We have internally developed our FUSION™ System, which allows us to expeditiously target validated cancer biology with breakthrough covalent chemistry. Our pipeline assets are designed to achieve higher selectivity, deeper target inactivation and thereby afford patients a greater therapeutic window. BMF-219 is just our first asset graduating now into clinical development. Our team has evolved significantly and is set up today not only to explore the full potential of BMF-219 and the inhibition of the menin pathway but also to advance several other programs into the clinic,” said Ramses Erdtmann, President of Biomea Fusion. “We are an integrated biotech company engaged in all phases of drug discovery and clinical development. We have come a long way and are now set up to fully explore pre-clinically and clinically innovative therapies for the benefit of patients.”

The current Phase I, open-label, multi-center, dose escalation and dose expansion study is 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). Additional information about the Phase I trial of BMF-219 can be found at ClinicalTrials.gov using the identifier NCT05153330.

Acute Myeloid Leukemia (AML) and Acute Lymphocytic Leukemia (ALL)

AML is the most common form of acute leukemia in adults and is responsible for the largest number of annual leukemia deaths in the U.S. and Europe. AML originates within the white blood cells in the bone marrow and can rapidly move to the blood and other parts of the body, including the lymph nodes, spleen, and central nervous system. Approximately 20,000 people in the U.S. are diagnosed with AML each year, and the five-year overall survival rate in adults is roughly 29% (Source: NCI SEER Data). Among patients with relapsed/refractory disease, the need is greatest, as the overall survival is approximately 3 to 9 months. It is estimated that upwards of 45% of AML patients have menin dependent genetic drivers (e.g., MLL1/KMT2A gene rearrangements or NPM1 mutations). ALL is a less common leukemia, with approximately 6,000 new cases in the U.S. each year and a higher five-year survival rate of nearly 70% (Source: NCI SEER Data). Between 10-15% of adult ALL patients and 60-70% of pediatric ALL patients have MLL1/KMT2A gene rearrangements.

About Biomea Fusion

Biomea Fusion is a biopharmaceutical company focused on the discovery and development of irreversible small molecules to treat patients with genetically defined cancers and metabolic diseases. An irreversible small molecule is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional reversible 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 irreversible-binding therapeutic agents against key oncogenic drivers of cancer and metabolic diseases. Biomea Fusion’s goal is to utilize its capabilities and system to become a leader in developing irreversible 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 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 the number of clinical sites expected to be involved in the ongoing Phase I clinical trial of BMF-219 and the anticipated scope of the trial, our plans to prepare for and initiate additional clinical trials of BMF-219 in other types of cancer and in diabetes, our plans to announce our next pipeline candidate, 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 patient enrollment and in the initiation, conduct and completion of our 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 SEC, including its most recent period 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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