# Biomea Fusion to Host Conference Call to Present initial Clinical Data from Phase I COVALENT-103 Study of BMF-500, a Covalent FLT3 Inhibitor, in Relapsed or Refractory Acute Leukemia

December 6, 2024

REDWOOD CITY, Calif., Dec. 06, 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 diabetes, obesity, and genetically defined cancers, today announced that it will host a conference call and webcast on Monday, December 9, 2024 at 4:30 pm EST to present data from COVALENT-103, the company’s Phase I trial of BMF-500, an investigational covalent FLT3 inhibitor developed using the proprietary FUSION™ System, in adult patients with relapsed or refractory acute leukemia.

**Conference Call and Webcast Details**
Webcast of Biomea’s investor update on Monday, December 9, 2024 at 4:30 pm EST will be available to registered attendees under the Investors and Media section of the company’s website at https://investors.biomeafusion.com/news-events/events. A replay of the presentation will be archived on Biomea’s site following the event.

**About COVALENT-103**
COVALENT-103 is a multicenter, open-label, non-randomized trial seeking to evaluate the safety and efficacy of BMF-500, a twice daily oral treatment, in adult patients with relapsed or refractory acute leukemia with FMS-like tyrosine kinase 3 (FLT3) wild-type and FLT3 mutations. Additional information about the Phase I clinical trial of BMF-500 can be found at ClinicalTrials.gov using the identifier, NCT05918692.

**About BMF-500**
BMF-500, an investigational, novel, orally bioavailable, highly potent and selective covalent small molecule inhibitor of FLT3, was discovered and developed in-house at Biomea using the company’s proprietary FUSION™ System and has demonstrated encouraging potential based on extensive preclinical studies. The kinase inhibitory profile of BMF-500 showed high target selectivity, suggesting the potential for reduced off-target liabilities. BMF-500 was designed to have a therapeutic profile to allow for combinations with standard of care and/or novel targeted agents like icovamenib, Biomea’s investigational covalent menin inhibitor currently in clinical development for solid and liquid tumors as well as diabetes.

Previous data presented at the 2022 American Society of Hematology Annual Meeting showed BMF-500’s picomolar affinity for inhibition of activating FLT3 mutations, including FLT3-ITD and various tyrosine kinase domain (TKD) mutations. BMF-500 demonstrated multi-fold higher potency and increased cytotoxicity than the commercially available non-covalent FLT3 inhibitor gilteritinib. These data also showed complete tumor regression in mouse models of FLT3-ITD acute myeloid leukemia (AML), with no tumor regrowth even after treatment cessation.

Data presented at the 2023 American Association for Cancer Research (AACR) Annual Meeting exhibited the potential utility of combination strategies to achieve higher antileukemic cell killing with reduced concentrations of BMF-500 and icovamenib. Additionally, Biomea has shown the potential of combinatorial approaches of BMF-500 and icovamenib with MEK and BCL2 blockade in other preclinical studies. These data provide preclinical evidence for combining pathway-specific inhibitors as a promising therapeutic strategy for further investigation in acute leukemia.

**About FLT3 in AML**
FLT3 is a receptor tyrosine kinase (RTK) that plays a central role in the survival, proliferation, and differentiation of immature blood cells. FLT3 gene mutations are common in patients with AML and are associated with a poor prognosis. Nearly 30% of AML patients have a FLT3 mutation, representing more than 7,000 incident patients in the U.S. each year. In addition, academic literature suggests that more than 50% of AML patients with an NPM1 mutation also harbor a FLT3 mutation. While FLT3-specific and pan-tyrosine kinase inhibitors are approved by the FDA across various lines of therapy in AML, these agents have produced relatively low rates of durable responses and overall survival remains an unmet need.

**About Biomea Fusion**
Biomea Fusion is a clinical-stage biopharmaceutical company focused on the discovery and development of oral covalent small molecules to improve the lives of patients with diabetes, obesity, 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, X, 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, 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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