Biomea Fusion Presents at the 2022 ASH Annual Meeting Preclinical Data on BMF-500 Supporting its Potential as the Most Potent and Selective FLT3 Inhibitor to Date

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- BMF-500, an investigational third generation covalent FLT3 inhibitor, demonstrated preclinically:
  - Picomolar affinity to activating FLT3 mutations including FLT3-ITD and various tyrosine kinase domain (TKD) mutations
  - Multi-fold higher potency and increased cytotoxicity than commercially available non-covalent FLT3 inhibitor gilteritinib
  - Complete tumor regression in mouse models of FLT3-ITD acute myeloid leukemia (AML) and maintenance of effect without continued exposure
- Biomea Fusion remains on track to file an IND for BMF-500 in the first half of 2023

REDWOOD CITY, Calif., Dec. 12, 2022 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (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, presented preclinical data today for BMF-500, an investigational covalent FLT3 inhibitor, at the 64th American Society of Hematology (ASH) Annual Meeting. The preclinical poster can be viewed at Biomea's website at https://biomeafusion.com/publications.

BMF-500, a 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 designed to have a therapeutic profile to allow for combinations with standard of care and/or novel targeted agents like BMF-219, Biomea's investigational covalent menin inhibitor. The company is on track to submit an investigational new drug (IND) application for BMF-500 in the first half of 2023 and, subject to successful IND clearance, plans to initiate clinical trials evaluating BMF-500 as a single agent and in novel combinations shortly thereafter.

"The majority of late-stage and approved FLT3 inhibitors fall short of providing sufficient and sustained inhibition of FLT3 signaling required for maximal benefit. We believe the exquisite potency, selectivity and durability of BMF-500, all of which are possible through the design of this novel covalent molecule with our proprietary FUSION system, have the potential to translate to deep and durable remissions in patients with FLT3-mutant AML, representing nearly a third of all AML patients," said Steve Morris, M.D., Biomea's Chief Medical Officer. "We look forward to advancing BMF-500 toward the clinic in 2023, which will mark our second clinical-stage novel covalent small molecule program for cancer and further solidify our position as a leader in next-generation covalent medicines."

"The impressive profile of BMF-500 speaks to the bench strength of our Discovery Team and to our ability to design and deliver novel therapeutics. We believe that targeting FLT3 with a covalent inhibitor, as we did with menin, represents another significant opportunity to improve the outcomes that reversible inhibition provide. BMF-500 has the potential to be an effective option as a monotherapy as well as in combination," said Thomas Butler, Biomea's Chief Executive Officer and Chairman of the Board.

The data presented at the ASH conference today showed that in FLT3-driven AML cell lines, three-hour exposure to BMF-500 produced complete phospho-FLT3 inhibition, which was maintained following washout of the compound. The commercially available reversible (i.e., non-covalent) FLT3 inhibitor gilteritinib required 16 times higher concentration than BMF-500 and continuous exposure for 96 hours to produce the same effect. The covalent small molecule inhibitor BMF-500 exhibited potent inhibition of FLT3 receptor kinase and marked cell killing in FLT3-ITD AML cell lines, as demonstrated by IC90s at physiologically relevant doses. In addition, the kinase profile of BMF-500 revealed high target selectivity and selective cytotoxicity profile against a panel of non-target cancer cell lines suggesting the potential for minimal off-target liabilities. As part of the poster presentation, Biomea also presented the results of two preclinical animal xenograft models in which BMF-500 demonstrated antitumor activity with sustained tumor regression and improved survival while being well tolerated, with body weight maintenance across treatment groups.

About BMF-500

BMF-500 is a novel orally bioavailable, highly potent and selective covalent small molecule inhibitor of FLT3 in preclinical development, which has been shown to exhibit favorable durability, selectivity and tolerability in preclinical studies in comparison to commercially available FLT3 inhibitor gilteritinib. BMF-500 was discovered and developed in-house by Biomea using its proprietary FUSION™ System and designed to have a therapeutic profile to allow for combinations with standard of care and novel targeted agents like BMF-219, Biomea's investigational covalent menin inhibitor. The kinase profile of BMF-500 showed high target selectivity, suggesting the potential for minimal off-target liabilities.

About FLT3 (fms-like tyrosine kinase 3)

FLT3 is a receptor tyrosine kinase (RTK) that plays a central role in the survival, proliferation, and differentiation of immature blood cells. Notably, 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 6,000 incident patients in the United States each year. 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 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 is a leader in advancing next-generation covalent small molecule medicines designed to maximize clinical benefit to treat 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 and BMF-500, the potential of BMF-500 as a treatment for various types of cancer, our research, development and regulatory plans, including our plans to submit an IND for BMF-500 and to initiate clinical trials of BMF-500 as a single agent and in novel combinations, 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 the initiation, conduct and completion of preclinical studies, including IND-enabling studies, the submission and clearance of IND applications, and 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 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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