Biomea Fusion Announces FDA Clearance of Investigational New Drug (IND) Application for Covalent FLT3 Inhibitor BMF-500 in Relapsed or Refractory Acute Leukemia

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- BMF-500, a novel 3rd generation covalent inhibitor of fms-like tyrosine kinase 3 (FLT3), is the second investigational compound, discovered and developed by Biomea's FUSION™ System, to advance to the clinic.
- Phase I study (COVALENT-103) of BMF-500 will examine its safety and efficacy in patients with relapsed or refractory acute leukemia with FLT3 wild-type and FLT3 mutations, including those with MLLr / NPM1 mutations.
- BMF-500 has demonstrated approximately 20-fold greater potency compared to Gilteritinib in acute myeloid leukemia (AML) cell lines, MV-4-11 and MOLM-13.
- BMF-500 has demonstrated more than 50-fold greater potency compared to the clinically investigated reversible menin/MLL inhibitors in acute myeloid leukemia (AML) cell lines, MV-4-11 and MOLM-13.
- BMF-219 and BMF-500 preclinical combination shows greater than additive cell killing in acute leukemia cell lines and patient samples.

REDWOOD CITY, Calif., May 01, 2023 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea" or "the company") (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, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application to begin a Phase I trial (COVALENT-103) of BMF-500, an investigational covalent FLT3 inhibitor, in adult patients with relapsed or refractory acute leukemia.

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 6,000 incident patients in the U.S. each year. In addition, academic literature suggests that >50% of AML patients with an NMP1 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.

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 best-of-class potential based on extensive preclinical studies. The kinase profile of BMF-500 showed high target selectivity, suggesting the potential for minimal 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 BMF-219, Biomea's investigational covalent menin inhibitor currently in clinical development across solid and liquid tumor types.

"BMF-500 is an exceptionally potent molecule and the second covalent inhibitor we have developed in-house and advanced to the clinic showing high target selectivity and inhibition. We are planning single agent studies of BMF-500 as well as combination studies with BMF-219 to explore the potential of this powerful dual-mechanistic approach to amplify and sustain patient treatment responses," said Thomas Butler, Biomea's CEO and Chairman of the Board. "I would like to thank the FDA, our contract research organizations partners, our consultants, our investors, and of course TEAM FUSION for the commitment, guidance, support, and tireless effort in getting BMF-500 from bench to the clinic. It has been a true community effort, and we are humbled by the opportunity to potentially help patients fight and win against these aggressive cancers."

Previous data presented at the 2022 American Society of Hematology (ASH) Annual Meeting showed BMF-500's picomolar affinity to activating FLT3 mutations, including FLT3-ITD and various tyrosine kinase domain (TKD) mutations. BMF-500 demonstrated multi-fold higher potency and increased cytotoxicity than commercially available non-covalent FLT3 inhibitor gilteritinib. These data also showed complete tumor regression in mouse models of FLT3-ITD AML and maintenance of effect without continued exposure.

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 BMF-219. Additionally, Biomea has shown the potential of combinatorial approaches of BMF-500 and BMF-219 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 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.

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 with various cancers and metabolic diseases, including diabetes. 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 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 an FLT3 inhibitor and as a treatment for various types of cancers, the potential of BMF-219 as a treatment for various types of cancer and diabetes, our research, development and regulatory plans, the progress of our ongoing and upcoming clinical trials, including COVALENT-101, COVALENT-102, COVALENT-103 and our Phase I/II COVALENT-111 study of BMF-219 in type 2 diabetes, , 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, the preparation, filing and clearance of INDs, 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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