

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): May 1, 2023

Biomea Fusion, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40335
(Commission
File Number)

82-2520134
(IRS Employer
Identification No.)

900 Middlefield Road, 4th Floor
Redwood City, CA
(Address of Principal Executive Offices)

94063
(Zip Code)

Registrant's Telephone Number, Including Area Code: (650) 980-9099

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value	BMEA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On May 1, 2023, Biomea Fusion, Inc. (the “Company”) issued a press release titled, “Biomea Fusion Announces FDA Clearance of Investigational New Drug (IND) Application for Covalent FLT3 Inhibitor BMF-500 in Relapsed or Refractory Acute Leukemia.” A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated herein by reference.

Forward-Looking Statements

Statements made or incorporated by reference in this Current Report on Form 8-K 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 Company’s cash runway, the clinical and therapeutic potential of the Company’s 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, the Company’s research, development and regulatory plans, the progress of the Company’s ongoing and upcoming clinical trials, including COVALENT-101, COVALENT-102, COVALENT-103 and the Company’s 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. The Company intends 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 is making this statement for purposes of complying with those safe harbor provisions.

Any forward-looking statements made or incorporated by reference in this Current Report on Form 8-K are based on the Company’s current expectations, estimates and projections only as of the date of this Current Report on Form 8-K 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 the Company 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 its ongoing and planned clinical trials and other research, and development activities. These risks concerning the Company’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. The Company explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits**

Exhibit Number	Description
99.1	Press release titled “Biomea Fusion Announces FDA Clearance of Investigational New Drug (IND) Application for Covalent FLT3 Inhibitor BMF-500 in Relapsed or Refractory Acute Leukemia.”
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOMEA FUSION, INC.

Date: May 2, 2023

By: _____ /s/ Thomas Butler
Thomas Butler
Principal Executive Officer

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

- 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 1, 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.

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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.

Contact:

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