Biomea Fusion Presents Updated Preliminary Clinical Data for Covalent FLT3 Inhibitor BMF-500 in Relapsed or Refractory Acute Leukemia at EHA 2025

June 13, 2025

New clinical results show sustained CRi, deep bone marrow responses, and encouraging survival in FLT3-mutant AML patients, including those previously treated with gilteritinib

REDWOOD CITY, Calif., June 13, 2025 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea” or the “Company”) (Nasdaq: BMEA), a clinical-stage diabetes and obesity medicines company, today announced updated preliminary clinical data from the ongoing Phase I COVALENT-103 trial of BMF-500 in adults with relapsed or refractory (“R/R”) acute leukemia (“AL”). The results will be presented in a poster presentation at the European Hematology Association (“EHA”) 2025 Congress in Milan, Italy.

The presentation by Dr. Farhad Ravandi of The University of Texas MD Anderson Cancer Center will highlight emerging safety, pharmacokinetics/pharmacodynamics, and early clinical activity data for BMF-500, a highly selective covalent FMS-like tyrosine kinase 3 (“FLT3”) inhibitor, in heavily pretreated patients with R/R AL.

Key Results from the EHA 2025 Poster Presentation
27 patients were enrolled across two study arms, Arm A (no CYP3A4 inhibitor; n=10) and Arm B (CYP3A4 inhibitor; n=17). All patients had R/R AL, with a median of 4 prior lines of therapy. 18 of the 27 patients were FLT3 mutations (“FLT3m”) while the other 9 patients had FLT3 wild-type AL. Frequent co-mutations included WT1, TP53, IDH1/2, and NRAS. All 18 FLT3m patients had failed gilteritinib in the R/R setting and 9 of the 18 had received at least two FLT3 inhibitors prior to study entry. 26 of 27 (96%) enrolled patients had also received and failed the BCL2 inhibitor venetoclax. Key findings include:

Clinical Activity Observed:

- 9 of 11 efficacy-evaluable FLT3m patients, defined as all patients enrolled who received at least one dose and had at least one disease assessment, showed bone marrow (BM) blast reduction; 5 of 11 achieved >50% BM blast reduction.
- 1 FLT3m patient achieved complete remission with incomplete hematologic recovery (CRi), sustained for 6 cycles.
- 1 FLT3m patient achieved morphologic leukemia-free state (MLFS); response is ongoing.
- 1 FLT3m patient met all criteria for partial response (PR) except platelet recovery; categorized as near PR.
- 2 of 4 efficacy-evaluable FLT3 wild-type patients achieved durable disease control ≥120 days, with treatment ongoing for one patient.
- Additional clinical improvements include reductions in peripheral blasts, transfusion dependency, and frequency of hydroxyurea use.

Pharmacokinetics/Pharmacodynamics:

- FLT3 inhibition correlated with BMF-500 systemic exposures.
- Bone marrow and plasma concentrations of BMF-500 and its metabolites were comparable, suggesting good compartmental penetration.

Survival:

- Median overall survival (mOS) among all treated FLT3m patients (n=18) was 3.8 months (Arm A) and 3.5 months (Arm B) during dose escalation.
- For the efficacy-evaluable FLT3m patients (n=12), the mOS for Arms A and B was 3.8 and 3.6 months, respectively during dose escalation.
- These survival durations compare favorably to historical mOS of 2.1 months in patients with R/R FLT3m acute myeloid leukemia (“AML”) post-failure with both gilteritinib and venetoclax. [1]

Ongoing Dose Escalation:

- Dose escalation continues at 200 mg BID (Arm A) and 75 mg BID (Arm B).
- Based on observed activity and tolerability, further evaluation is underway to determine optimal biologic dose (“OBD”) and recommended Phase II dose (“RP2D”).

Safety and Tolerability

- BMF-500 was generally well-tolerated across dose levels.
- No dose-limiting toxicities (DLTs), QT prolongation, or discontinuations due to treatment-related adverse events were reported.
- Escalation is ongoing without safety restrictions.

“The updated COVALENT-103 results continue to support the potential of BMF-500 as a selective, covalent FLT3 inhibitor,” said Mick Hitchcock, Ph.D., Interim Chief Executive Officer of Biomea Fusion. “We are encouraged by the depth of bone marrow responses, the achievement of MLFS and CRi, and the early survival benefit in heavily pretreated patients with FLT3 mutations who had progressed following prior FLT3 inhibitor therapy. These data speak to BMF-500’s potential to meaningfully improve outcomes in a high-risk AML population with no currently available treatment options.”

Following completion of the COVALENT-103 dose escalation phase in R/R AL patients with FLT3m, Biomea plans to conclude its internal development of BMF-500 in oncology and is actively exploring strategic partnerships to advance the program.

Poster Presentation Details

- **Date/Time:** Saturday, June 14 (18:30-19:30 CEST)
- **Title:** Covalent FLT3 Inhibitor BMF-500 in Relapsed or Refractory (R/R) Acute Leukemia (AL): Preliminary Phase 1 Data from the COVALENT-103 Study (NCT05918692)
- **Poster Number:** PS1520
- **Presenter:** Farhad Ravandi, M.D., University of Texas MD Anderson Cancer Center

A**bout 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 R/R AL with FLT3 wild-type or FLT3m. The Phase I COVALENT-103 study aims to evaluate the safety and tolerability of BMF-500, determine the optimal biologic dose and recommended Phase II dose, and identify initial efficacy signals. 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 is an investigational, orally bioavailable, covalent small molecule inhibitor of FLT3, discovered in-house using Biomea’s proprietary FUSION™ System. Designed to be highly potent and selective, BMF-500 has demonstrated encouraging potential in extensive preclinical studies. Its kinase inhibitory profile indicates strong target selectivity, which may translate to a reduced risk of off-target effects.

About Biomea Fusion
Biomea Fusion is a clinical-stage diabetes and obesity medicines company focused on the development of its oral small molecules, icovamenib and BMF-650, both designed to significantly improve the lives of patients with diabetes, obesity, and other metabolic diseases. 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, including BMF-500, the potential of BMF-500 as a treatment for patients with FLT3m R/R AL, our research, development, partnership and regulatory plans, 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 preliminary or interim results of preclinical studies or clinical trials may not be predictive of future or final results in connection with future clinical trials and 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’s business and operations are described in additional detail in its periodic filings with the U.S. Securities and Exchange Commission (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.

Reference:
1. Corley et al. (P1798) HemaSphere 2024;8(S1), 3339-3340.

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