Biomea Fusion to Present at 41st Annual J.P. Morgan Healthcare Conference and Highlight 2023 Corporate Milestones

January 9, 2023

REDWOOD CITY, Calif., Jan. 09, 2023 (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, today announced that Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board, will present recent progress and 2023 corporate milestones at the 41st Annual J.P. Morgan Healthcare Conference on Wednesday, January 11, 2023 from 11:15 – 11:55 am ET, and that Biomea management will hold 1x1 meetings during the conference January 9 – 11.

A live webcast of the presentation will be available on the Investors & Media page of Biomea's website at: https://investors.biomeafusion.com/news-events/events.

"2022 was a year of strong execution and fundamental infrastructure build as we transitioned to a clinical-stage company and expanded our pipeline. We enter 2023 with three clinical trials studying BMF-219 across 8 cancer indications covering both blood cancers and solid tumors as well as in Type 2 diabetes, the 7th leading cause of death in the United States," stated Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board. "We anticipate advancing BMF-500 into the clinic during the first half of 2023, subsequent to FDA clearance of an IND, which will increase our clinical pipeline to 4 clinical trials covering 10 indications. COVALENT-111, our Phase I/II study in Type 2 diabetes is now due to report initial safety and efficacy from the first two cohorts of the Phase II portion by the end of Q1."

Mr. Butler further commented, "we continue to activate sites and enroll patients in our Phase I/Ib (COVALENT-101) study of BMF-219 in patients with several liquid tumor types, and plan to report initial clinical data from this study in the first half of 2023. In addition, we anticipate initiating dosing imminently in our Phase I/Ib (COVALENT-102) study of BMF-219 in patients with KRAS-mutated solid tumors. In 2023, we will continue the patient-centric urgency and disciplined execution that are now well-established hallmarks of Team Fusion."

RECENT & ANTICIPATED MILESTONES

ONCOLOGY

- **COVALENT-101 (BMF-219)**
  - Presented robust anti-tumor activity of covalent menin small molecule inhibitor, BMF-219, as a single agent and mechanistic evidence for novel inhibition of the menin protein in preclinical models of diffuse large B-cell lymphoma (DLBCL), multiple myeloma (MM), and chronic lymphocytic leukemia (CLL). BMF-219 displayed single agent potency, surpassing greater than 90% cell killing at clinically relevant exposures in DLBCL, MM and CLL cell lines and patient-derived samples.
  - BMF-219 is the first investigational menin inhibitor in clinical development to show potential as a therapeutic agent in hematologic malignancies outside of MLLr and NPM1 mutated acute myeloid leukemia/acute lymphoblastic leukemia (AML/ALL) patients, specifically in subsets of DLBCL, MM and CLL patients.
  - Biomea continued site activation and patient enrollment for the dosing of BMF-219 across four liquid tumor cohorts in the COVALENT-101 study, including patients with AML/ALL, DLBCL, MM and CLL.
  - **Next Anticipated Milestone:**
    On track to present initial clinical data of AML/ALL patients (including those with MLL rearrangement and NPM1 mutation) dosed in the COVALENT-101 study in the first half of 2023.
- **COVALENT-102 (BMF-219)**
  - Presented strong and highly specific pan-KRAS anti-cancer activity of BMF-219 as a single agent across KRAS G12C, G12D, G12V and G13D mutant cell lines including in non-small cell lung cancer (NSCLC), colorectal cancer (CRC) and the most prevalent type of pancreatic cancer, PDAC.
  - BMF-219 is the first investigational menin inhibitor in development to enter clinical trials for the treatment of solid tumors. A targeted pan-KRAS inhibitor could have the potential to treat 25-35% of NSCLC, 35-45% of CRC, and approximately 90% of PDAC patients.

- Biomea received FDA clearance of its IND in the fourth quarter of 2022 and has since initiated a Phase I/Ib clinical trial of BMF-219 as a monotherapy in patients who have unresectable, locally advanced, or metastatic NSCLC, CRC or PDAC with an activating KRAS mutation.
- **Next Anticipated Milestone:**
  On track to dose first patient in COVALENT-102 study in January 2023.

- **COVALENT-103 (BMF-500)**
  - Presented data showing multi-fold higher potency and increased cytotoxicity of Biomea's covalent FLT3 small-molecule inhibitor BMF-500 compared to the commercially available reversible, non-covalent FLT3 inhibitor gilteritinib, and complete, sustained tumor regression in mouse models of FLT3-ITD AML with maintenance of effect after cessation of therapy.
  - **Next Anticipated Milestone:**
    On track to file IND for BMF-500 in the first half of 2023 to initiate COVALENT-103 study of the covalent FLT3 inhibitor in patients with acute leukemia.

DIABETES

- **COVALENT-111 (BMF-219)**
  - Presented preclinical data highlighting the ability of BMF-219 in a Type 2 diabetes rat model to restore normal HOMA-B, a measure of pancreatic beta cell function, following only 4-weeks of treatment and to significantly lower HbA1c compared to active control, liraglutide, -3.5% vs -1.7%, respectively.
  - BMF-219 is the first investigational menin inhibitor in development to enter clinical trials for the improvement of glycemic control and insulin sensitivity in Type 2 diabetes patients.
  - Biomea completed the healthy volunteer portion of the Phase I/II COVALENT-111 study of BMF-219 in Canada. BMF-219 was well tolerated with an encouraging pharmacokinetic and pharmacodynamic profile in healthy volunteers and with no safety signals detected.
  - Biomea received FDA clearance in December 2022 to expand the Phase II portion of COVALENT-111 to sites in the U.S. and in January 2023 announced dosing of the first U.S. patient with Type 2 diabetes. The company continues to enroll Type 2 diabetes patients in the Phase II portion of the study in Canada as well.
  - **Next Anticipated Milestones:**
    On track to present initial clinical data from the first two cohorts of the Phase II portion of the study by the end of Q1 2023, and to present details of the healthy volunteer (Phase I) portion of the study at a scientific medical meeting in 2023.

FUSION™ SYSTEM DISCOVERY PLATFORM

- Developed two covalently binding small molecules (BMF-219 and BMF-500), each within 18 months from target identification to IND candidate, leveraging the proprietary FUSION™ System Discovery Platform and showing excellent preclinical profiles.
- **Next Anticipated Milestone:**
  On track to announce a third development candidate from the FUSION platform in the first half of 2023.

About Biomea Fusion

Biomea Fusion is a 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's goal is to utilize its capabilities and platform to become a leader in developing covalent small molecules in order to maximize the clinical benefit when treating 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 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, 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 clinical trials, including COVALENT-101, COVALENT-102 and our Phase I/II clinical COVALENT-111 study of BMF-219 in Type 2 diabetes, our plans to present clinical data from our COVALENT-101 study and the first two cohorts of the Phase II portion of our COVALENT-111 study, our plans to dose the first patient in our COVALENT-102 study, our plans to submit an IND application for BMF-500 in patients with FLT3 mutations, our plans to provide clinical updates on the healthy volunteer section of our Phase I/II Type 2 diabetes study of BMF-219, our plans to announce a third development candidate from the FUSION platform, 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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