Biomea Fusion Reports First Quarter 2023 Financial Results and Corporate Highlights

May 2, 2023

- Reported initial positive clinical data from first two cohorts of Phase II of ongoing Phase I/II study (COVALENT-111) of BMF-219, Biomea's lead investigational, orally administered covalent menin inhibitor, as a novel, potentially disease-modifying treatment for patients with type 2 diabetes
- Continued enrolling four liquid tumor cohorts in ongoing Phase I study of BMF-219 (COVALENT-101), each focused on distinct patient subsets of acute lymphocytic and myeloid leukemias (ALL/AML), including patients with MLL rearrangements (MLLr) and NPM1 mutations, diffuse large B-cell lymphoma (DLBCL), multiple myeloma (MM) and chronic lymphocytic leukemia (CLL)
- Continued enrolling patients with KRAS-mutated solid tumors, including non-small cell lung cancer (NSCLC), colorectal cancer (CRC) and pancreatic ductal adenocarcinoma (PDAC), in ongoing Phase I/Ib study of BMF-219 (COVALENT-102)
- Advanced second product candidate, BMF-500, a novel third generation covalent inhibitor of fms-like tyrosine kinase 3 (FLT3), toward the clinic, with IND cleared to begin a Phase I study of BMF-500 (COVALENT-103)
- Closed public offering of common stock with gross proceeds of $172.5 million, together with final cash balance of $86.7 million at end of first quarter of 2023, Biomea had approximately $250 million in cash, cash equivalents, restricted cash and investments after the raise in early April 2023

REDWOOD CITY, Calif., May 02, 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, reported first quarter 2023 financial results and business highlights.

"In 2023, we expect to continue to advance our clinical programs in diabetes and oncology and plan to report multiple data readouts throughout the remainder of the year, including late-breaking clinical data from COVALENT-111 at the upcoming American Diabetes Association, or ADA, Scientific Sessions," said Thomas Butler, CEO and Chairman of Biomea. "Loss of mass and function of beta cells is an underlying cause of type 2 diabetes. There is biological precedent, reinforced by our extensive preclinical data for BMF-219, that suggests inhibiting menin may enable the proliferation, preservation, and reactivation of healthy, functional beta cells capable of producing insulin, thereby leading to long-term glycemic control in patients with type 2 diabetes. We believe that none of the currently approved therapies for diabetes adequately addresses the beta cell mass and function loss. With its intended disease-modifying mechanism of action, BMF-219 could potentially represent a monumental shift for the treatment of patients with diabetes. The initial data we reported from COVALENT-111 in the first quarter of 2023 demonstrated that after just four weeks of treatment with BMF-219, the majority of patients in our lowest dose cohorts showed HbA1c improvements, with indications of potential longer-term disease modification and control. We are excited to report additional data from COVALENT-111 to the diabetes-focused scientific community at ADA in June."

First Quarter 2023 Clinical and Regulatory Highlights

DIABETES

- **COVALENT-111 (BMF-219 for Type 2 Diabetes)**
  - BMF-219 is the first investigational menin inhibitor in clinical development for the treatment of type 2 diabetes patients.
  - Reported initial clinical data in March 2023 from the first two cohorts of the Phase II portion of COVALENT-111. As reported, 89% of patients enrolled in Cohort 3 (n=10 patients at 100 mg without food) achieved a reduction in HbA1c, 78% achieved ≥ 0.5% reduction in HbA1c and 56% achieved ≥ 1% reduction in HbA1c (median and mean reduction over the cohort: -1.0% and -0.81%, respectively). BMF-219 was well tolerated and demonstrated a favorable safety profile with no dose discontinuations.
  - **Anticipated Upcoming Milestones:**
    - Report further clinical updates from COVALENT-111 at ADA in June 2023.

ONCOLOGY

- **COVALENT-101 (BMF-219 for Genetically Defined Liquid Tumors)**
    - BMF-219 is the first investigational menin inhibitor in clinical development to be evaluated as a therapeutic agent in hematologic malignancies outside of MLLr and NPM1 mutated AML/ALL patients, specifically in subsets of DLBCL, MM and CLL patients.
    - Continued site activation and patient enrollment across four liquid tumor cohorts including patients with AML/ALL, DLBCL, MM and CLL.
    - **Anticipated Upcoming Milestones:**
        - Report initial clinical data of AML/ALL patients (including those with MLLr rearrangement and NPM1 mutations) dosed in the COVALENT-101 study in the second quarter of 2023.
- **COVALENT-102 (BMF-219 for KRAS-Mutant Solid Tumors)**
    - BMF-219 is the first investigational menin inhibitor in clinical development 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.
    - Dosed first patient in January 2023 in COVALENT-102, a study of BMF-219 as a monotherapy in patients with unresectable, locally advanced, or metastatic NSCLC, CRC or PDAC with an activating KRAS mutation.
    - Continued site activation and patient enrollment across all three solid tumor indications (NSCLC, CRC and PDAC with an activating KRAS mutation).
- **COVALENT-103 (BMF-500 for Acute Leukemias)**
    - BMF-500 is a potential best-in-class oral covalent inhibitor of FLT3, designed and developed in-house, and the second investigational compound, discovered by Biomea's FUSION™ System.
    - Demonstrated approximately 20-fold greater potency compared to Gilteritinib and 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.
    - **Anticipated Upcoming Milestones:**
        - Initiate enrollment of BMF-500 in Phase I study (COVALENT-103) examining safety and efficacy in patients with relapsed or refractory acute leukemia with FLT3 wild-type and FLT3 mutations, including those with MLLr / NPM1 mutations.

FUSION™ SYSTEM DISCOVERY PLATFORM

- Continued to advance third development candidate derived from Biomea's proprietary FUSION System platform to discover novel covalently binding small molecules. Both BMF-219 and BMF-500 were discovered via the FUSION System, each within 18 months from target identification to IND candidate selection.
    - **Anticipated Upcoming Milestones:**
        - Provide update on third development candidate in the second quarter of 2023.

FIRST QUARTER 2023 FINANCIAL RESULTS

- **Cash, Cash Equivalents, Restricted Cash, and Investments:** As of March 31, 2023, the Company had cash, cash equivalents, restricted cash, and investments of $86.7 million, compared to $113.4 million as of December 31, 2022, excluding gross proceeds of $172.5 million from a public offering of common stock in early April 2023.
- **Net Income/Loss:** Biomea reported a net loss attributable to common stockholders of $29.1 million for the three months ended March 31, 2023, compared to a net loss of $16.4 million for the same period in 2022.
- **Research and Development (R&D) Expenses:** R&D expenses were $24.4 million for the three months ended March 31, 2023, compared to $11.4 million for the same period in 2022. The increase of $13.0 million was primarily due to an increase personnel-related costs as well as an increase in clinical and preclinical development costs, including manufacturing and external consulting, related to the Company's product candidates, BMF-219 and BMF-500.
- **General and Administrative (G&A) Expenses:** G&A expenses were $5.6 million for the three months ended March 31, 2023, compared to $5.1 million for the same period in 2022. The increase of $0.6 million was primarily due to higher

personnel-related costs and other corporate costs to support the Company's expanding operations as well as additional costs incurred as a public company.

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 planned clinical trials, including COVALENT-101, COVALENT-102, COVALENT-103 and our Phase I/II COVALENT-111 study of BMF-219 in type 2 diabetes, our plans to provide clinical updates, including additional data from the initial dosing cohorts in COVALENT-111 and initial clinical data from patients in the COVALENT-101 study, 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.

- See attached for financial tables -

BIOMEA FUSION, INC.
Condensed Statement of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development [1]	$ 24,395	$ 11,350
General and administrative [1]	5,636	5,050
Total operating expenses	30,031	16,400
Loss from operations	(30,031)	(16,400)
Interest and other income, net	980	34
Net loss	$ (29,051)	$ (16,366)
Other comprehensive loss:		
Unrealized gain (loss) on investments, net	1	(13)
Comprehensive loss	$ (29,050)	$ (16,379)
Net loss per common share, basic and diluted	(0.98)	(0.56)
Weighted-average number of shares used to compute basic and diluted net loss per common share	29,586,468	29,126,088

[1] Includes stock-based compensation as follows:

	Three Months Ended

	March 31,	
	2023	2022
Research and development	$ 1,474	$ 1,012
General and administrative	1,759	1,318
Total stock-based compensation expense	$ 3,233	$ 2,330

BIOMEA FUSION, INC.
Condensed Balance Sheet Data
(Unaudited)
(in thousands)

	March 31, 2023	December 31, 2022
Cash, cash equivalents, investments, and restricted cash	$ 86,651	$ 113,400
Working capital	70,157	98,718
Total assets	112,638	129,307
Stockholders' equity	83,129	108,539

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