Biomea Fusion Reports First Quarter 2022 Financial Results and Business Highlights

May 16, 2022

- COVALENT-101 study continues to enroll relapsed/refractory (R/R) acute myeloid leukemia (AML) and acute lymphocytic leukemia (ALL) patients and has included R/R diffuse large B-cell lymphoma (DLBCL) and R/R multiple myeloma (MM) patients to the study. Company continues to explore indication expansion with the announced upcoming presentation of preclinical *ex vivo* data of BMF-219 in Chronic Lymphocytic Leukemia (CLL) at the American Society of Clinical Oncology (ASCO)
- Presented preclinical validation data for BMF-219 in multiple solid and liquid tumor types at AACR 2022, with BMF-219 showing strong cytotoxic activity as a single agent at similar concentrations across multiple preclinical patient-derived (PDX) models *ex vivo* including DLBCL, MM, colorectal cancer (CRC), non-small cell lung cancer (NSCLC), and pancreatic cancer
- Announced upcoming presentation of preclinical *in vivo* data of BMF-219 in diabetes at the American Diabetes Association (ADA) Scientific Sessions 2022 and plans to initiate a Phase I/II trial in the second half of 2022 using BMF-219 as a first-in-class covalent menin inhibitor in type 2 diabetes patients
- Cash position of $165.6 million at the end of the first quarter of 2022

REDWOOD CITY, Calif., May 16, 2022 (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, reported first quarter 2022 financial results and business highlights.

“We had a very exciting start to the year as we initiated our first Phase I study of BMF-219, COVALENT-101, in AML and ALL patients. We have now expanded enrollment to include also DLBCL and MM patients. Targeting menin with our covalent inhibitor is an innovative approach with potential safety, tolerability, efficacy, and durability advantages. Our COVALENT-101 investigators are enthusiastic to use BMF-219 for many of their patients who currently have relapsed from or not responded to traditional approaches,” said Thomas Butler, Biomea’s Chief Executive Officer and Chairman of the Board.

Mr. Butler continued, “We believe covalent inhibitors afford the optimal profile for a therapeutic. The aim is to maximize depth and durability of response, to support improved survival, while minimizing exposure, which is the source for unwanted toxicity. We have now provided preclinical evidence highlighting BMF-219’s profound anti-tumor effects in MYC-driven cancers and pan-KRAS mutant solid tumors. By indirectly targeting MYC and KRAS via the scaffold protein menin, our preclinical data demonstrates that BMF-219 can affect these oncoproteins in a very meaningful way. We are managing our expenses and will continue to execute on the clinical development of this first-in-human and first-in-class covalent menin inhibitor not only in the various tumor types, but also in type 2 diabetic patients.”

Clinical and Regulatory Highlights

- Enrolled first patient in first-in-human Phase I clinical trial evaluating BMF-219 in patients with relapsed or refractory acute leukemias, including those with MLL1/KMT2A gene rearrangements or NPM1 mutations.
- Presented preclinical data at AACR 2022 highlighting impact of BMF-219 on MYC- and KRAS-driven solid tumors. Building on prior data, BMF-219 exhibited robust anti-tumor effect in cell lines and PDX models in DLBCL and MM cell lines.
- Announced upcoming presentation of preclinical BMF-219 data from multiple *in vivo* models of diabetes at ADA Scientific Sessions 2022.
- Announced upcoming presentation of preclinical BMF-219 data from multiple *ex vivo* models of CLL at ASCO 2022.

Corporate Highlights

- Appointed Steve Morris, M.D. as Chief Medical Officer. Dr. Morris led a basic and translational research laboratory at St. Jude Children’s Research Hospital, where he served for 25 years. Among his lab’s pioneering work at St. Jude was the discovery and characterization of anaplastic lymphoma kinase, or ALK.

First Quarter 2022 Financial Results

- **Net Income/Loss:** Biomea reported a net loss attributable to common stockholders of $16.4 million for quarter ended March 31, 2022, compared to a net loss of $5.9 million for the same period in 2021.
- **R&D Expenses:** Research and development expenses were $11.4 million for the quarter ended March 31, 2022, compared to $3.8 million for the same period in 2021. The increase of $7.6 million was primarily due to an increase in personnel-related expenses, as well as an increase in preclinical and clinical development costs, including manufacturing and external consulting, related to the Company's lead product candidate, BMF-219.
- **G&A Expenses:** General and administrative expenses were $5.1 million for the quarter ended March 31, 2022, compared to $2.1 million for the same period in 2021. The increase of $3.0 million was primarily due to higher personnel-related expenses and other corporate costs to support the Company's expanding operations as well as additional costs incurred as a public company.
- **Cash, Cash Equivalents, Restricted Cash, and Investments:** As of March 31, 2022, the Company had cash, cash equivalents, restricted cash, and investments of $165.6 million, compared to $175.7 million as of December 31, 2021.

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 our cash runway, the clinical and therapeutic potential of our product candidates and development programs, including BMF-219, 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 COVALENT-101 Phase I clinical trial, including ongoing enrollment in the trial, its expansion to include patients with DLBCL and MM, 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 patient enrollment and in the initiation, conduct and completion of our 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:

Van Sandwick
Director, Investor Relations & Corporate Development
vsandwick@biomeafusion.com
(650) 460-7759

- 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,	
	2022	**2021**
Operating expenses:		
Research and development [1]	$ 11,350	$ 3,798
General and administrative [1]	5,050	2,059
Total operating expenses	16,400	5,857

Loss from operations	(16,400)	(5,857)
Interest and other income, net	34	5
Net loss	$ (16,366)	$ (5,852)
Other comprehensive loss:		
Unrealized gain (loss) on investments, net	(13)	(15)
Comprehensive loss	$ (16,379)	$ (5,867)
Net loss per common share, basic and diluted	(0.56)	(0.49)
Weighted-average number of shares used to compute basic and diluted net loss per common share	29,126,088	11,964,205

(1) Includes stock-based compensation as follows:

	Three Months Ended March 31,	
	2022	**2021**
Research and development	$ 1,012	$ 313
General and administrative	1,318	606
Total stock-based compensation expense	$ 2,330	$ 919

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

	March 31, 2022	**December 31, 2021**
Cash, cash equivalents, investments, and restricted cash	$ 165,572	$ 175,743
Working capital	159,061	171,924
Total assets	174,864	185,705
Stockholders' equity	164,765	178,783