Biomea Fusion Reports Second Quarter 2022 Financial Results and Business Highlights

August 1, 2022

- Continued to make significant progress advancing BMF-219, the company's lead investigational orally administered covalent menin inhibitor, in multiple oncology indications
  - COVALENT-101 (Phase I) study is enrolling for patients with Acute Lymphoblastic Leukemia (ALL), Acute Myeloid Leukemia (AML), Diffuse Large B-cell Lymphoma (DLBCL), and Multiple Myeloma (MM)
  - On track to submit IND for BMF-219 in solid tumors, including non-small cell lung cancer, colorectal cancer and pancreatic cancer in the fourth quarter of 2022
  - New preclinical ex vivo and validation data for BMF-219 underlying the company's oncology clinical development strategy presented at the 2022 annual meetings of the American Society of Clinical Oncology (ASCO) and the American Association for Cancer Research (AACR), respectively
- Expanded clinical development strategy for BMF-219 to include type 2 diabetes
  - New preclinical in vivo data for BMF-219 underlying the company's innovative approach to treat type 2 diabetes with covalent menin inhibition presented at the American Diabetes Association (ADA) Scientific Sessions 2022
  - On track to submit IND for BMF-219 in type 2 diabetes in the second half of 2022
  - Upcoming two oral presentations at the 2022 annual meeting of the European Association for the Study of Diabetes (EASD) in September
- Announced selection of second IND candidate, BMF-500, a potential best-in-class, oral, covalent inhibitor of FLT3 with picomolar potency against aggressive leukemia cell models
- Cash position of $150.2 million at the end of the second quarter of 2022

REDWOOD CITY, Calif., Aug. 01, 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 second quarter 2022 financial results and business highlights.

"The team continues to deliver against critical corporate goals as we look to build tremendous value potential for the company in the near and long-term. During the second quarter, we focused specifically on key clinical operations and clinical science activities to support COVALENT-101. Additionally, we continued to design and execute key experiments to support our diabetes effort as we march towards the clinic," said Thomas Butler, Biomea's Chief Executive Officer and Chairman of the Board. "The scaffold protein menin has many more functional responsibilities than was previously characterized and, thus, is central to multiple disease settings. Moreover, we believe our approach of covalent menin inhibition with BMF-219 offers potential safety, tolerability, efficacy and durability benefits to patients. We are now well positioned to execute a robust clinical development plan for BMF-219, which includes many liquid and solid tumor indications, as well as type 2 diabetes. Beyond menin inhibition, we are advancing toward the clinic with our second IND candidate, BMF-500, a covalent FLT3 inhibitor with best-in-class potential."

Second Quarter 2022 Pipeline Highlights

Cancer

- Enrolled first patient with MM in the ongoing first-in-human Phase I clinical trial (COVALENT-101) evaluating BMF-219 in patients with relapsed or refractory acute leukemias, DLBCL, and MM
- Presented Trial in Progress posters for COVALENT-101 at multiple prominent oncology conferences in the United States and in Europe
- Presented preclinical data in two posters at AACR 2022 highlighting the 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
- On track to submit IND for BMF-219 in KRAS mutant NSCLC, CRC, and pancreatic ductal adenocarcinoma (PDAC) in the fourth quarter of 2022
- Presented preclinical data at ASCO 2022 demonstrating BMF-219's potency in multiple ex vivo tumor models of Chronic Lymphocytic Leukemia (CLL) with varying cytogenetic risk profiles, Rai stages, and resistance to standard-of-care agents indicating broad activity across these models
- Announced IND candidate selection, BMF-500, a potential best-in-class oral covalent inhibitor of FLT3, one of the most frequently altered genes in AML and associated with poor prognosis

Diabetes

- Presented new preclinical data in two posters at the ADA Scientific Sessions 2022, demonstrating BMF-219's strong, prolonged glycemic control, insulin sensitization, and hemoglobin A1C (HbA1c) reduction in two preclinical rat models of diabetes while on drug and after washout, outperforming standard-of-care agents
- Announced upcoming oral presentations of BMF-219 preclinical data from two animal models of diabetes at the EASD 2022 annual meeting which will include additional data not previously presented at the ADA Scientific Sessions 2022
- On track to submit IND for BMF-219 in type 2 diabetes in the second half of 2022

Second Quarter 2022 Financial Results

- **Net Income/Loss:** Biomea reported a net loss attributable to common stockholders of $33.6 million for the six months ended June 30, 2022, compared to a net loss of $14.3 million for the same period in 2021.
- **R&D Expenses:** Research and development expenses were $23.9 million for the six months ended June 30, 2022, compared to $9.0 million for the same period in 2021. The increase of $14.9 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 product candidates, BMF-219 and BMF-500.
- **G&A Expenses:** General and administrative expenses were $9.9 million for the six months ended June 30, 2022, compared to $5.3 million for the same period in 2021. The increase of $4.7 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 June 30, 2022, the Company had cash, cash equivalents, restricted cash, and investments of $150.2 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-500 and BMF-219, 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 COVALENT-101 Phase I clinical trial, including ongoing enrollment in the trial, our pursuit of BMF-219 in metabolic diseases, our plans to submit an IND application for BMF-219 in KRAS mutant NSCLC, CRC and PDAC, our plans to submit an IND application for BMF-219 in type 2 diabetes, our plans to continue IND-enabling studies for BMF-500 and file an IND, 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.

- See attached for financial tables -

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

	Three Months Ended June 30,	Six Months Ended June 30,

	2022	2021	2022	2021
Operating expenses:				
Research and development [1]	$ 12,582	$ 5,224	$ 23,932	$ 9,022
General and administrative [1]	4,892	3,211	9,942	5,270
Total operating expenses	17,474	8,435	33,874	14,292
Loss from operations	(17,474)	(8,435)	(33,874)	(14,292)
Interest and other income, net	216	36	250	41
Net loss	$ (17,258)	$ (8,399)	$ (33,624)	$ (14,251)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	6	17	(7)	2
Comprehensive loss	$ (17,252)	$ (8,382)	$ (33,631)	$ (14,249)
Net loss per common share, basic and diluted	(0.59)	(0.33)	(1.15)	(0.77)
Weighted-average number of shares used to compute basic and diluted net loss per common share	29,196,398	25,161,038	29,161,437	18,598,521

[1] Includes stock-based compensation as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ 1,253	$ 611	$ 2,265	$ 924
General and administrative	1,306	852	2,624	1,458
Total stock-based compensation expense	$ 2,559	$ 1,463	$ 4,889	$ 2,382

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents, investments, and restricted cash	$ 150,170	$ 175,743
Working capital	144,776	171,924
Total assets	161,736	185,705
Stockholders' equity	150,390	178,783