Biomea Fusion Reports Second Quarter 2021 Financial Results and Business Highlights

August 11, 2021

- Completed investigational new drug (“IND”) enabling studies for lead program, BMF-219, an irreversibly binding menin inhibitor. On track to complete IND submission for Phase I/II study of BMF-219 as treatment for patients with menin-dependent acute myeloid leukemia (“AML”) and acute lymphocytic leukemia (“ALL”) during the second half of this year
- Continued to advance ongoing preclinical studies of BMF-219 in a number of menin-dependent liquid and solid tumors, including Diffuse Large B Cell Lymphoma (“DLBCL”), to expand potential impact of novel drug
- Initiated pathway validation studies in type 2 diabetes
- Continued to expand team and laboratory facilities to support long-term growth and clinical and preclinical development plans
- Strengthened Board of Directors with appointment of Sumita Ray, J.D., Chief Legal and Administrative Officer at Calithera Biosciences, Inc.

REDWOOD CITY, Calif., Aug. 11, 2021 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea”) (Nasdaq: BMEA), a preclinical-stage biopharmaceutical company focused on the discovery and development of irreversible small molecules to treat patients with genetically defined cancers, reported financial results for the second quarter of 2021.

“We continue to make notable progress as we rapidly advance BMF-219 toward a planned entry into the clinic and continue to grow our company and pipeline,” said Thomas Butler, Biomea’s CEO and Chairman of the Board. “In the second quarter, we successfully completed IND-enabling studies for BMF-219 and are now in the final stages of completing our IND submission to the FDA to advance BMF-219 to a Phase I study for the treatment of patients with menin-dependent AML and ALL. We also continued to make important progress pursuing our broad, ambitious, preclinical strategy focused on exploring the potential of this novel irreversible small molecule across a number of menin-dependent liquid and solid tumors, including DLBCL.”

Mr. Butler continued, “While our primary focus is oncology drug development, there are multiple diseases where the menin pathway is implicated and where an irreversibly binding small molecule approach may have an important impact, including for patients with type 2 diabetes. At our core, we feel a profound responsibility to help patients with our novel chemistry. To that end, we look forward to seeing the results of our exploratory pathway validation in type 2 diabetes next year.”

Business Highlights

- **Completed IND-enabling studies with irreversibly binding menin inhibitor BMF-219.** Biomea successfully conducted IND-enabling studies with BMF-219, an irreversible menin inhibitor for the treatment of patients with menin-dependent AML and ALL. Biomea anticipates submitting the IND during the second half of 2021.

- **Continued preclinical studies of BMF-219 in DLBCL.** Biomea continues to explore the potential of BMF-219 for a number of menin-dependent liquid and solid tumor cancers, including a subset of DLBCL, with a number of preclinical studies currently underway. The Company plans to report its findings in DLBCL in the first quarter of 2022. Despite the high dependency of several cancers on menin, Biomea Fusion is not aware of any menin inhibitors currently in clinical development for these cancer types.

- **Initiated pathway validation studies in diabetes.** Based on a growing body of internal and external scientific evidence, Biomea has initiated key preclinical studies to explore the potential of its irreversible menin inhibitors as a treatment for type 2 diabetes. The Company plans to report its findings in the first quarter of 2022. Biomea Fusion is not aware of any menin inhibitors currently in clinical development for diabetes.

- **Expanded team and in-house research capabilities to support long-term growth and clinical and preclinical development plans.** Biomea strengthened its executive team with the appointments of Franco Valle as Chief Financial Officer, Alex Cacovean, M.D. as Executive Medical Director and Sasha Blaug Ph.D. as Senior VP of Corporate Development. Biomea has successfully grown its headcount this year to date by 29 for a total of 41 current team members. The Company has also completed the buildout of its own laboratory facilities to further support the research and preclinical pipeline development of its irreversible platform.

- **Strengthened the Company's Board of Directors.** In the second quarter Biomea appointed Sumita Ray J.D., Chief Legal and Administrative Officer at Calithera Biosciences, Inc., to its Board. Ms. Ray is an industry veteran with over 20 years of expertise in FDA regulatory law, global health care law and compliance, brand support, product launches, collaborations and alliances.

Financial Highlights

Second Quarter 2021 Year to Date Financial Results

- Biomea reported a net loss attributable to common stockholders of $14.3 million for the first six months of 2021, compared to a net loss of $0.7 million for the same period in 2020.

- Research and development expenses were $9.0 million for the first six months of 2021, compared to $0.6 million for the same period in 2020. The increase of $8.4 million was primarily due to an increase in personnel-related expenses, as well as an increase in pre-clinical development costs, including manufacturing and external consulting, related to the IND-enabling studies for BMF-219.

- General and administrative expenses were $5.3 million for the first six months of 2021, compared to $0.1 million for the same period in 2020. The increase of $5.2 million was primarily due to higher personnel-related expenses and other corporate costs to support the Company's expanding operations, including legal and accounting.

- As of June 30, 2021, the Company had cash, cash equivalents, restricted cash, and investments of $203.0 million.

About Biomea Fusion

Biomea Fusion is a preclinical-stage biopharmaceutical company focused on the discovery and development of irreversible small molecules to treat patients with genetically defined cancers. An irreversible small molecule drug is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional reversible drugs, including greater target selectivity, lower drug exposure and the ability to drive a deeper, more durable response. Leveraging its extensive expertise in irreversible binding chemistry and development, the Company built its proprietary FUSION System discovery platform to advance a pipeline of novel irreversible, small molecule therapies. The lead product candidate, BMF-219, is an orally bioavailable, potent and selective irreversible inhibitor of menin, an important transcriptional regulator known to play a direct role in oncogenic signaling in multiple cancers. In preclinical studies, administration of BMF-219 has resulted in robust anti-tumor responses across a range of liquid and solid tumor models and has been well-tolerated in animal studies. Biomea Fusion is developing BMF-219 for the treatment of liquid and solid tumors that are highly dependent on menin, including leukemias containing the mixed lineage leukemia ("MLL") fusion protein. The Company is currently completing investigational new drug enabling studies and expects to file an IND application with the U.S. Food and Drug Administration in the second half of 2021. Additionally, literature has implicated menin inhibition as a potential therapeutic strategy for the treatment of various forms of diabetes, including type 2 diabetes. Biomea Fusion has initiated preclinical work to assess the potential of the menin pathway in type 2 diabetes and will report findings in the first quarter of 2022. Beyond BMF-219, the Company is utilizing its novel platform to develop irreversible treatments against other high-value oncogenic drivers of cancer and expects to nominate its second development candidate in the first half of 2022. Biomea Fusion's goal is to utilize its capabilities and platform to become a leader in developing irreversible small molecules in order to maximize the depth and durability of clinical benefit when treating various cancers.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the potential safety, efficacy, and continued development of BMF-219, the timing for completing the IND filing or starting the clinical development, the building out our proprietary irreversible platform and progress made in early-stage small pipeline molecules through their preclinical development, including the timing for nominating development candidates in each program. These statements often include words such as "believe," "expect," "anticipate," "intend," "plan," "estimate," "seek," "will," "may," or similar expressions. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond the Company's control. Any forward-looking statements in this statement are based on management's current expectations of future events 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. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of the Company's product candidate development activities and planned IND-enabling and clinical trials, the Company's ability to execute on its strategy, regulatory developments in the United States, the Company's ability to fund operations, and the impact that the current COVID-19 pandemic will have on the Company's clinical trials and pre-clinical studies, supply chain, and operations, as well as those risks and uncertainties set forth in the Company's Quarterly Report on Form Q for the quarter ended June 30, 2021, filed with the Securities and Exchange Commission on August 11, 2021, and its other filings filed with the United States Securities and Exchange Commission filed from time. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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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,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 5,224	$ 216	$ 9,022	$ 550
General and administrative	3,211	79	5,270	143
Total operating expenses	8,435	295	14,292	693
Loss from operations	(8,435)	(295)	(14,292)	(693)
Interest and other income, net	36	2	41	2
Net loss	$ (8,399)	$ (293)	$ (14,251)	$ (691)
Other comprehensive loss:				
Changes in unrealized gain on short term investments, net	17	—	2	—
Comprehensive loss	$ (8,382)	$ (293)	$ (14,249)	$ (691)
Net loss per common share, basic and diluted	(0.33)	(0.03)	(0.77)	(0.07)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	25,161,038	9,746,868	18,598,521	9,252,931

Includes stock-based compensation as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Research and development	$ 611	$ -	$ 924	$ -
General and administrative	852	-	1,458	-
Total stock-based compensation expense	$ 1,463	$ -	$ 2,382	$ -

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

	June 30, 2021	**December 31, 2020**
Cash, cash equivalents, investments, and restricted cash	$ 203,044	$ 61,695
Working capital	195,579	60,604
Total assets	209,533	62,526
Stockholders' equity	202,016	5,169