Biomea Fusion Reports Fourth Quarter and Full Year 2023 Financial Results and Corporate Highlights

April 1, 2024

- In 2023, reported Phase 2 data (COVALENT-111) in type 2 diabetes patients supporting the disease-modifying potential of BMF-219 to address a root cause of diabetes: a loss of healthy, insulin-producing beta cells.
    - After just a 4-week treatment period in type 2 diabetes patients, who had previously failed standard of care (HbA1c > 7.0% and < 10%), BMF-219 demonstrated continued glycemic control at 26 weeks, or five months, after cessation of dosing.
    - Enrollment underway in COVALENT-111 expansion cohort (n=216) to evaluate dosing duration up to 12 weeks; initial readout after 26 weeks of follow up expected in 2024.
- In 2023, initiated a Phase 2 study of BMF-219 in type 1 diabetes patients (COVALENT-112); initial readout anticipated in 2024.
- Biomea aims to deliver short-term, non-chronic treatment that will reconstitute insulin-producing beta cells, allowing diabetes patients' own bodies to durably normalize blood sugar levels.
- Data readouts of COVALENT-111 and COVALENT-112 in 2024 will inform the design of potentially pivotal Phase 3 studies in type 2 and type 1 diabetes, targeting 2025 initiation.
- In 2023, reported initial topline data from Phase 1 study of BMF-219 in acute myeloid leukemia (AML); continuing to progress COVALENT-101 in liquid tumors, COVALENT-102 in solid tumors and COVALENT-103 (BMF-500) in AML.
- Cash position of $177.2 million at the end of the fourth quarter of 2023.

REDWOOD CITY, Calif., April 01, 2024 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea" or "the Company") (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing oral covalent small molecules to treat and improve the lives of patients with metabolic diseases and genetically defined cancers, reported fourth quarter and full year 2023 financial results and corporate highlights.

"2023 was a pivotal year for Biomea as we reported first positive data in type 2 diabetes and initiated our first clinical study in type 1 diabetes. We also announced initial positive data in AML in 2023. It has been gratifying to see the ongoing and continued improvement in HbA1c after only a 4-week dosing period with BMF-219 in type 2 diabetes patients with poorly controlled diabetes. Critically, we have now evaluated BMF-219 out to 26 weeks, or 5 months, after the last dose of BMF-219, and reported promising longer-term data. Based on these clinical and our preclinical findings we have observed with confidence, that the inhibition of menin is correlated with beta cell proliferation and function, and is providing durable effects for patients," stated Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board. "Our preclinical data showed also that longer inhibition of menin at higher doses increased beta cell mass and function, as well as promoted controlled proliferation and enhanced insulin content in beta cells. We have now initiated expansion cohorts to evaluate the translation of these preclinical findings in the clinical setting. We believe BMF-219 has the potential to address the root cause of diabetes and modify disease progression in patients across a broad spectrum of clinical profiles, from early to later stage treatment. Our goal is to deliver a short-term, non-chronic treatment that will reconstitute insulin-producing beta cells, allowing the patients' own bodies to normalize blood sugar levels. Importantly, we continued to build a first-class pipeline of covalent inhibitors. In 2023 BMF-500 entered the clinic as the only covalent FLT3 inhibitor in clinical development."

Mr. Butler continued, "We anticipate 2024 will be an even more momentous year for Biomea, as we steadily march toward late-stage clinical development in both type 2 and type 1 diabetes. This year, we plan to complete and report the results of dosing and follow-up of over 200 type 2 diabetes patients enrolled in our Phase 2 expansion cohorts. We expect these data will inform potentially registrational studies, which we plan to start in 2025, pending discussions with regulatory authorities. In 2024, we also expect to report data from 40 patients enrolled in the open label portion of our Phase 2 study in type 1 diabetes patients. On the oncology front, we will continue patient enrollment in our liquid and solid tumor studies of BMF-219 and BMF-500 and anticipate completing the dose escalation steps in each of the cohorts as well this year. Since our launch as a public company just over three years ago, we have consistently demonstrated the ability to accelerate innovative science and execute against aggressive development timelines. In 2024, we'll continue to work methodically yet quickly to deliver the patient data required for potentially registrational studies we are planning to begin in the following year."

RECENT UPDATES & ANTICIPATED 2024 MILESTONES

DIABETES

COVALENT-111 (BMF-219 for Type 2 Diabetes)

- Presented proof-of-concept data supporting the proposed mechanism of action of BMF-219 with clinical data in a Phase 2 study after 4 weeks of dosing:
  - Compared to baseline, 84% of all type 2 diabetes patients failing standard of care with poorly controlled diabetes (HbA1c > 7.0% and < 10%) dosed for only four weeks with BMF-219 showed a reduction in HbA1c at week 4 and 74% at week 12 (n=32), two months after the final dose of BMF-219. 60% of type 2 diabetes patients dosed with 100 mg without food achieved a controlled HbA1c of 7% or below at the end of week 12, two months after the last dose of BMF-219. Across 100 mg QD, 200 mg QD, and 100 mg BID cohorts (N=40), 38% of patients had ≥0.5% HbA1c reduction (with a mean HbA1c reduction of 1.2%), and 23% of patients had ≥1.0% HbA1c reduction (with a mean HbA1c reduction of 1.5%) at Week 26, 5 months after the last dose of BMF-219.
  - Patients in COVALENT-111 are displaying improved glycemic control while off therapy, supporting improved pancreatic function following BMF-219 treatment. Patients who demonstrated the greatest HbA1c reduction at Week 26 (22 weeks off treatment), had the greatest improvement in beta cell function as measured by HOMA-B and C-peptide.
  - BMF-219 was generally well tolerated with no serious adverse events and no adverse event-related study discontinuations, and no symptomatic or clinically significant hypoglycemia.
- FDA and Health Canada cleared the initiation of the expansion portion of this Phase 2 study, which will evaluate BMF-219 administered at 100 mg and 200 mg, with dosing durations up to 12 weeks in a minimum of 216 type 2 diabetes patients.

Anticipated 2024 Milestones:

- On track to complete 400 mg cohort to inform the Escalation Phase Arm D design.
- On track to complete enrollment of the three expansion cohorts of COVALENT-111 (n=216) in type 2 diabetes patients with poorly controlled diabetes and provide 26 week follow up data.

COVALENT-112 (BMF-219 for Type 1 Diabetes)

- FDA and Health Canada cleared the IND / CTA for Phase 2 study COVALENT-112 of BMF-219 in type 1 diabetes patients. The study is designed to enroll 150 adults with type 1 diabetes and examine the safety and efficacy of BMF-219 at two oral dose levels, 100 mg and 200 mg, for 12 weeks of treatment followed by a 40 week off-treatment period. The trial will also include an open label portion (n=40), enrolling participants with type 1 diabetes up to 15 years since diagnosis.
- Dosed the first 2 type 1 diabetes patients in COVALENT-112.

Anticipated 2024 Milestones:

- On track to complete enrollment of the open label portion (n=40) and establish the initial proof of concept based on clinical data in type 1 diabetes patients treated in COVALENT-112 with BMF-219.

ONCOLOGY

COVALENT-101 (BMF-219 for Liquid Tumors)

- Presented initial Phase 1 topline data in AML with first complete responder achieving minimal residual disease negativity, with no dose-limiting toxicities observed and no adverse event related treatment discontinuations.
- Continued patient enrollment exploring BMF-219's utility in liquid tumors (AML/ALL, MM, CLL, DLBCL).

Anticipated 2024 Milestones:

- On track to complete dose escalation portion of COVALENT-101 in liquid tumors and establish recommended Phase 2 dose (RP2D).

COVALENT-102 (BMF-219 for KRAS-Mutant Solid Tumors)

- Continued patient enrollment exploring BMF-219's utility in KRAS-driven solid tumors (PDAC, NSCLC, CRC).

Anticipated 2024 Milestones:

- On track to complete dose escalation portion of COVALENT-102 in solid tumors and establish RP2D.

COVALENT-103 (BMF-500 for Acute Leukemias)

- Announced FDA clearance of IND for BMF-500 in COVALENT-103, a Phase 1 study, and started enrollment of Biomea's novel third generation investigational oral covalent inhibitor of FMS-like tyrosine kinase 3 (FLT3).

Anticipated 2024 Milestones:

- On track to complete dose escalation portion of COVALENT-103 and establish RP2D.

FUSION™ SYSTEM DISCOVERY PLATFORM

- Built out and opened new lab facilities to validate and progress in-house research efforts.
- Continued the development of the Biomea FUSION™ Platform technology.

Anticipated 2024 Milestones:

- On track to announce a third development candidate from the Biomea FUSION™ Platform technology.

FOURTH QUARTER AND FULL YEAR 2023 FINANCIAL RESULTS

- **Cash, Cash Equivalents, Restricted Cash, and Investments:** As of December 31, 2023, the Company had cash, cash equivalents and restricted cash of $177.2 million, compared to $113.4 million as of December 31, 2022.
- **Net Income/Loss:** The Company reported a net loss attributable to common stockholders of $34.9 million for the three months ended December 31, 2023, compared to a net loss of $25.3 million for the same period in 2022. Net loss attributable to common stockholders was $117.3 million for the year ended December 31, 2023, compared to a net loss of $81.8 million for the same period in 2022.
- **Research and Development (R&D) Expenses:** R&D expenses were $30.9 million for the three months ended December 31, 2023, compared to $20.5 million for the same period in 2022. The increase of $10.3 million was primarily due to an increase in clinical development cost and external consulting related to the Company's product candidates, BMF-219 and BMF-500, as well as an increase in personnel-related costs and facilities cost due to new lease agreements for additional office and laboratory space. R&D expenses were $102.5 million for the year ended December 31, 2023 compared to $62.7 million for the same period in 2022. The increase of $39.8 million was primarily due to an increase in clinical development and manufacturing costs related to the Company's product candidates, BMF-219 and BMF-500, an increase in personnel-related costs as well as an increase in facilities cost due to new lease agreements for additional office and laboratory space.
- **General and Administrative (G&A) Expenses:** G&A expenses were $6.5 million for the three months ended December 31, 2023, compared to $5.7 million for the same period in 2022. The increase of $0.7 million in was primarily due to increased personnel-related expenses, including stock-based compensation. G&A expenses were $23.6 million for the year ended December 31, 2023 compared to $20.9 million for the same period in 2022. The increase of $2.7 million was primarily due to increased personnel-related expenses, including stock-based compensation, due to an increase in headcount, as well as an increase in professional and consulting services to support the growth of the Company.

About Biomea Fusion

Biomea Fusion is a clinical stage biopharmaceutical company focused on the discovery and development of oral covalent small molecules to treat patients with metabolic diseases and genetically defined cancers. 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. 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 the clinical and therapeutic potential of our product candidates and development programs, including BMF-219 and BMF-500, the potential of BMF-219 as a treatment for type 1 and type 2 diabetes, various types of liquid tumors and leukemia, and KRAS mutant solid tumors, the potential of BMF-500 as a treatment for cancers with a FLT3 mutation, our research, development and regulatory plans, the progress of our

ongoing and upcoming clinical trials, including our Phase 1/2 COVALENT-111 study of BMF-219 in type 2 diabetes, our Phase 2 COVALENT-112 study of BMF-219 in type 1 diabetes, our Phase 1 COVALENT-101 study of BMF-219 in relapsed or refractory acute myeloid leukemia, our Phase 1/1b COVALENT-102 study of BMF-219 in KRAS mutant solid tumors and our Phase 1 COVALENT-103 study of BMF-500 in leukemia, the anticipated enrollment of patients and availability of data from our clinical trials and the timing of such events, and our expectations regarding the Biomea FUSION™ Platform and our plans to announce a third development candidate, 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, 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 and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development [1]	$ 30,866	$ 20,539	$ 102,546	$ 62,713
General and administrative [1]	6,462	5,737	23,589	20,921
Total operating expenses	37,328	26,276	126,135	83,634
Loss from operations	(37,328)	(26,276)	(126,135)	(83,634)
Interest and other income, net	2,444	962	8,880	1,806
Net loss	$ (34,884)	$ (25,314)	$ (117,255)	$ (81,828)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	—	12	1	9
Comprehensive loss	$ (34,884)	$ (25,302)	$ (117,254)	$ (81,819)
Net loss per common share, basic and diluted	$ (0.98)	$ (0.86)	$ (3.44)	$ (2.80)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	35,754,165	29,441,596	34,106,923	29,271,777

[1] Includes stock-based compensation as follows (non-cash operating expenses):

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Research and development	$ 2,031	$ 1,227	$ 6,933	$ 4,678
General and administrative	1,833	1,489	7,198	5,658
Total stock-based compensation expense	$ 3,864	$ 2,716	$ 14,131	$ 10,336

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents, investments, and restricted cash	$ 177,236	$ 113,400

Working capital	156,321	98,718
Total assets	199,927	129,307
Stockholders' equity	169,237	108,539

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