



## **Biomea Fusion Highlights Recent Updates and Anticipated 2024 Corporate Milestones at 42nd Annual J.P. Morgan Healthcare Conference**

January 9, 2024

- Expansion portion of Phase II COVALENT-111 study readout in 216 patients with type 2 diabetes expected in 2024.
- Open label portion of Phase II COVALENT-112 study readout in 40 patients with type 1 diabetes expected in 2024.

REDWOOD CITY, Calif., Jan. 09, 2024 (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, today announced that Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board, will present recent clinical progress and 2024 corporate milestones at the 42<sup>nd</sup> Annual J.P. Morgan Healthcare Conference on Tuesday, January 9, 2024 from 8:15 am – 8:55 am PST.

A live webcast of the presentation will be available on the Investors & Media page of Biomea's website at: <https://investors.biomeafusion.com/news-events/events>.

"2023 was a truly remarkable year for Biomea as we had several positive data readouts in both type 2 diabetes and AML. Meanwhile, we initiated the expansion portion of the type 2 diabetes trial and received IND and CTA clearance for type 1 diabetes and have just now dosed our first patient in that study. Our second pipeline asset BMF-500 was also advanced into the clinic and is enrolling steadily," stated Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board. "We believe BMF-219 has the potential to address the root cause of diabetes and modify its progression in patients. Our goal is to develop a short-term treatment that will reconstitute insulin producing beta cells and thereby allow a patient with diabetes to normalize blood sugar levels in a natural way. Over the past months, we have built out our team and the necessary study sites to fully explore the potential utility of BMF-219 across the different subtypes of diabetes patients. In 2024, we are planning to complete the dosing and follow-up of over 200 expansion cohort patients. This data is expected to provide the foundation for registrational studies in type 2 diabetes, which we plan to start in 2025. We are also set up to explore BMF-219's potential in type 1 diabetes with our Phase 2 study, COVALENT-112, and will share data from the 40 patient open label portion within this year. And finally, we will continue the patient enrollment in our liquid and solid tumor studies and anticipate completing the dose escalation steps in each of the cohorts within this year. 2024 will be an exciting year for Biomea and we are looking forward to providing you continued updates throughout as we further define a registrational path forward for each of our diabetes and oncology assets."

### **RECENT UPDATES & ANTICIPATED 2024 MILESTONES**

#### **DIABETES**

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

- Presented proof-of-concept clinical data in a Phase II study with only 4 weeks of dosing:
  - Compared to baseline, 84% of all type 2 diabetes patients dosed for 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 achieved a controlled HbA1c of 7% or below at the end of Week 12, two months after the last dose of BMF-219, and 36% of type 2 diabetes patients in the 200 mg cohorts showed a durable HbA1c reduction of 1% or more at Week 26, five months after the last dose of BMF-219.
- FDA and Health Canada cleared the initiation of the expansion portion of the Phase II 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 escalation portion of COVALENT-111 and present 26-week data, five months after last dose of BMF-219, from cohorts (50 mg, 100 mg, and 200 mg) that were dosed with BMF-219 for 28 days, at the Advanced Technologies and Treatments for Diabetes Meeting in March 2024.
- On track to finish enrolling three expansion cohorts of COVALENT-111 and provide initial data in 2024

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

- FDA and Health Canada cleared the IND / CTA for Phase II study COVALENT-112 of BMF-219 in type 1 diabetes. 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 type 1 diabetes patient in COVALENT-112.

**Anticipated 2024 Milestones:**

- Complete enrollment of the open label portion (n=40).
- On track to 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 I topline data in AML with first complete responder achieving Minimal Residual Disease negativity.
- 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 II dose.

### **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 recommended Phase II dose.

### **COVALENT-103 (BMF-500 for Acute Leukemias)**

- Announced FDA clearance of IND for BMF-500 and started enrollment of leukemia patients with FLT3 mutations.

**Anticipated 2024 Milestones:**

- On track to complete dose escalation portion of COVALENT-103 and establish recommended Phase II dose.

## **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.

## **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](https://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 I/II COVALENT-111 study of BMF-219 in type 2 diabetes, our Phase II COVALENT-112 study of BMF-219 in type 1 diabetes, our Phase I COVALENT-101 study of BMF-219 in relapsed or refractory acute myeloid leukemia, our Phase I/Ib COVALENT-102 study of BMF-219 in KRAS mutant solid tumors and our Phase I 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 Fusion discovery 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.

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