Biomea Fusion Reports Preclinical Data on BMF-219 and Trial in Progress Presentations at AACR 2022 Annual Meeting

April 8, 2022

- Covalent menin inhibitor BMF-219 showed strong cytotoxic activity as a single agent at similar concentrations across multiple preclinical patient derived (PDX) models *ex vivo*, including diffuse large B-cell lymphoma (DLBCL), multiple myeloma (MM), colorectal cancer (CRC), non-small cell lung cancer (NSCLC), and pancreatic cancer
- Single agent BMF-219 demonstrated pronounced anti-cancer activity *in vitro* across KRAS G12C, G12D, G13D, and G12V mutant cell lines, including higher cell killing in comparison to commercially available KRAS G12C inhibitors and other clinical menin reversible inhibitors
- BMF-219 was multi-fold more potent and exerted greater cytotoxicity compared to clinical reversible menin inhibitors in DLBCL patient-derived *ex vivo* samples and over 99% cell lethality in MM cell lines with RAS mutations as a single agent
- A Phase I study (COVALENT-101) of BMF-219 is currently enrolling patients with relapsed / refractory acute leukemias, DLBCL, and MM

REDWOOD CITY, Calif., April 08, 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, today presented new data at the American Association of Cancer Research (AACR) Annual Meeting demonstrating BMF-219's potent and highly effective activity in multiple preclinical models of DLBCL, MM, and KRAS human *ex vivo* tumor models and cell lines in poster presentations. In addition, the company presented a Trial In Progress (TIP) poster presentation detailing the design of Biomea's ongoing Phase I clinical trial (COVALENT-101).

The preclinical and TIP presentations can be viewed on Biomea's website at https://biomeafusion.com/publications.

"Today, we unveiled a dataset in which single agent BMF-219 demonstrated pronounced cytotoxic activity across multiple liquid and solid tumor types that we will be pursuing in the clinic. These data clearly show BMF-219's powerful cell-killing activity in a broad spectrum of tumor types, including a very robust pan-KRAS effect," said Steve Morris, MD, Biomea's Chief Medical Officer. "In liquid and solid tumor preclinical studies, BMF-219 has demonstrated a highly differentiated profile from both non-covalent menin inhibitors as well as clinical-stage and FDA-approved covalent KRAS G12C inhibitors. We are very excited to see how this differentiated profile translates in the clinical setting across multiple liquid and solid tumors."

In comparison to two highly specific KRAS G12C inhibitors, BMF-219 exhibited broader potency across KRAS-mutated cell lines (G12C, G12D, G13D, and G12V) and *ex vivo* PDX tumor models indicating pan-KRAS activity with over 90% growth inhibition in most of these models. Additionally, BMF-219 showed the potential to increase the depth of response across G12C cell lines, notably achieving a higher percentage of cell killing in G12C colorectal cancer cells compared to the commercially available KRAS inhibitor sotorasib and another clinical-stage KRAS inhibitor. Additionally, BMF-219 exhibited robust growth inhibition as a single agent against high-grade B-cell lymphoma cell lines that are known to have low response to standard of care, as well as in multiple MM cells with TP53 and RAS mutations at similar drug concentrations.

A targeted pan-KRAS inhibitor has the potential to treat the 25-35% of NSCLC, 40-45% of CRC, and ~90% of pancreatic cancer patients who have KRAS-mutant tumors. If approved, BMF-219 could be an effective treatment for relapsed/refractory DLBCL and MM, where patients have a significant unmet need despite a large armamentarium of therapeutic options. Additionally, we believe BMF-219 has the potential to be an effective therapeutic option for menin-dependent acute leukemias, including the >45% of AML patients that are believed to have menin-dependent disease.

Poster Presentation Details

Details for the upcoming presentations are as follows:

Anti-tumor activity of irreversible menin inhibitor, BMF-219, in high-grade B-cell lymphoma and multiple myeloma preclinical models (Abstract #1205)

Session Category: Experimental and Molecular Therapeutics
Session Title: Novel Targets and Pathways
Session Date and Time: Tuesday, April 12, 2022 9:00 AM - 12:30 PM
Location: New Orleans Convention Center, Exhibit Halls D-H, Poster Section 24
Poster Board Number: 23
Permanent Abstract Number: 2654

Irreversible menin inhibitor, BMF-219, inhibits the growth of KRAS-mutated solid tumors (Abstract #1202)

Session Category: Experimental and Molecular Therapeutics
Session Title: Signaling Pathway Inhibitors
Session Date and Time: Tuesday, April 12, 2022 9:00 AM - 12:30 PM
Location: New Orleans Convention Center, Exhibit Halls D-H, Poster Section 25
Poster Board Number: 8
Permanent Abstract Number: 2665

COVALENT-101: A Phase 1 study of BMF-219, a novel oral irreversible menin inhibitor, as a single agent in patients with relapsed/refractory (R/R) acute lymphocytic/acute myeloid leukemia (ALL/AML), diffuse large B-cell lymphoma (DLBCL), and multiple myeloma (MM) (NCT05153330) (Abstract #7613)

Session Category: Clinical Trials
Session Title: Phase I Trials in Progress 1
Session Date and Time: Tuesday, April 12, 2022 9:00 AM - 12:30 PM
Location: New Orleans Convention Center, Exhibit Halls D-H, Poster Section 34
Poster Board Number: 10
Permanent Abstract Number: CT210

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 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, 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.

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