Biomea Fusion Announces First Patient Dosed with Chronic Lymphocytic Leukemia (CLL) in COVALENT-101 Trial

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- COVALENT-101 now includes patients with relapsed/refractory (R/R) CLL
- BMF-219 is the first menin inhibitor in the clinic for CLL
- Preclinical data presented at ASCO 2022 demonstrated the potency of BMF-219, a covalent menin inhibitor, across varying cytogenetic risk profiles and Rai stages, indicating broad activity with over 98% cell lethality in these CLL models at clinically achievable concentrations
- R/R CLL patient population represents an area of high unmet need

REDWOOD CITY, Calif., Oct. 27, 2022 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea”)(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 the dosing of the first patient in the CLL cohort of COVALENT-101, the company’s ongoing Phase I clinical trial evaluating BMF-219, Biomea’s investigational covalent menin inhibitor, in patients with R/R AML, ALL, DLBCL, MM, and now CLL.

“Despite the advances in the treatment of CLL, we know that the majority of patients relapse and are in need of a new, novel therapy,” stated Thomas Butler, Biomea’s Chief Executive Officer and Chairman of the Board. “Based on the remarkable preclinical data we presented at ASCO of BMF-219’s effect in CLL models, including comparisons to currently available treatments, we believe BMF-219 could represent a transformative treatment option for CLL patients. With many of the Biomea Fusion team members having a long history and involvement with the successful development of CLL agents, and ibrutinib in particular, it’s quite special to be able to now evaluate the clinical potential of BMF-219 for those CLL patients that are still in need of a therapy.”

At ASCO, Biomea presented data demonstrating BMF-219’s powerful cell-killing activity as a novel, first-in-class single agent against CLL patient samples, representing a broad spectrum of mutational profiles, including those with poor prognostic mutations, such as TP53 and NOTCH1, chromosomal aberrations such as del(13q), trisomy 12 and complex karyotype. BMF-219 demonstrated near 100% response even in samples resistant to multiple standard-of-care agents.

“I am very proud of our research and translational team’s ability to further elucidate the central role of the scaffold protein menin and identify a host of specific subsets across various cancers where BMF-219 is achieving robust preclinical results. We are very excited to continue to advance this new therapeutic approach for patients with multiple liquid and solid tumors, many of whom have very little remaining alternatives,” concluded Thomas Butler.

Biomea’s preclinical presentations on CLL can be accessed at the following link: https://biomeafusion.com/publications/.

About COVALENT-101

COVALENT-101 is a Phase I, open-label, multi-center, dose escalation and dose expansion study originally designed to assess the safety, tolerability, and pharmacokinetics/pharmacodynamics of oral dosing of BMF-219 in patients with R/R acute leukemias —including subpopulations where menin inhibition is expected to provide maximal therapeutic benefit (e.g., patients with MLL1/KMT2A gene rearrangements or NPM1 mutations), multiple myeloma (MM) and diffuse large B-cell lymphoma (DLBCL). The study design has now been expanded to include a cohort for patients with R/R CLL. Additional information about the Phase I clinical trial of BMF-219 can be found at ClinicalTrials.gov using the identifier NCT05153330.

About Chronic Lymphocytic Leukemia (CLL)

CLL is a chronic leukemia that progresses relatively slowly and typically impacts older adults. In the United States, approximately 20,000 patients are diagnosed with CLL each year. While the existing treatment options produce 5-year survival outcomes greater than 87%, there is an unmet need for patients that have high- or medium-risk cytogenetic profiles and those who have relapsed or were refractory to existing treatments.

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. 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-219, the potential of BMF-219 as a treatment for various types of cancer and diabetes, our research, development and regulatory plans, including the progress of our ongoing COVALENT-101 clinical trial of BMF-219, the availability of data from the 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 or unforeseen results in preclinical development, patient enrollment and in the initiation, conduct and completion of our ongoing and planned clinical trials and other research, development and regulatory 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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