Biomea Fusion to Become a Diabetes & Obesity Medicines Company

January 13, 2025

Icovamenib & BMF-650 (oral small molecule GLP-1) are the cornerstones of the metabolic franchise
Biomea preparing icovamenib for late-stage clinical development
2025 corporate update to be presented at the 43rd Annual J.P. Morgan Healthcare Conference

REDWOOD CITY, Calif., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea” or “Biomea Fusion” or “the Company”) (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing oral covalent small molecules to improve the lives of patients announced today that the company will become a diabetes and obesity medicines company. Based on the most recent clinical trial results, the strategic focus for icovamenib will be in metabolic disorders. The company will prioritize insulin deficient patients and combination strategies with GLP-1-based therapies for obesity and diabetes. Biomea plans to conclude its studies exploring icovamenib’s potential in oncology and explore partnerships to further advance its oncology assets, while concentrating internal resources on metabolic disorders.

Icovamenib, a potential first-in-class menin inhibitor for the treatment of diabetes, demonstrated the strongest activity in patients with the lowest insulin production
Placebo adjusted 1.5% mean reduction in HbA1c (a measure of blood glucose control) in severe insulin deficient patients uncontrolled on one or more antidiabetic agents at baseline.

Icovamenib showed strong activity in patients uncontrolled on GLP-1-based therapies
Placebo adjusted mean HbA1c reduction of 1.0% in patients suboptimally controlled at baseline with GLP-1-based therapies, consistent with preclinical findings demonstrating enhanced GLP-1 receptor expression and increased glucose-stimulated insulin secretion with the combination of icovamenib and a GLP-1-based therapy such as semaglutide.

Icovamenib demonstrated statistically significant and clinically meaningful benefits validating the mechanism of action
Greater clinical benefits were achieved in patients who were most insulin deficient.

Icovamenib achieved these results while patients were off treatment for 14 weeks
Patients received icovamenib for only 12 weeks, with a primary follow up at Week 26.

Icovamenib was well tolerated and demonstrated a favorable safety profile
No adverse-event related discontinuations, hypoglycemic events, or serious adverse events were reported.

In the prespecified subgroup of severely insulin deficient patients, all patients (100%) responded to 100mg of icovamenib for 12 weeks, displaying a durable reduction in HbA1c 14 weeks after treatment completion, with a continued decline in mean HbA1c while off therapy. In the United States and Europe, these patients represent approximately 20% of the type 2 diabetes patient population. They typically have the lowest insulin production, highest unmet medical need, highest all-cause mortality and worst cardiovascular outcomes. These patients can be easily identified using their HbA1c and body mass index (BMI). These results give us great hope to have identified a pathway with the potential to address diabetes at the root cause level, the depleted pool and function of beta cells. We plan to present further results of the COVALENT-111 trial at an upcoming medical conference.

In preclinical *in vivo* studies of icovamenib in combination with GLP-1-based therapies, icovamenib demonstrated encouraging metabolic benefits, including superior glycemic control, enhanced beta cell function, significant body weight reduction and improved lean muscle mass. We believe these findings not only underscore the potential for icovamenib to enhance GLP-1-based therapies but also highlight its promise as a disease-modifying agent. Further clinical evaluation will follow, with additional insights anticipated during the J.P. Morgan Conference. Biomea will discuss its clinical plan with FDA to support these two patient groups and move into late-stage development. The current plan includes the following two clinical trials:

- **Phase 2/3 (adaptive design): icovamenib in patients with insulin deficient type 2 diabetes (HbA1c ≥8.5% and BMI <32 kg/m^2), uncontrolled at baseline on current antidiabetic medication**
- **Phase 2b: icovamenib in combination with a GLP-1- based therapy in patients uncontrolled on a GLP-1-based therapy at baseline and in patients initiating a GLP-1-based therapy**

“We are excited to focus our efforts on metabolic disorders and to accelerate the development of icovamenib in 2025,” said Thomas Butler, Chief Executive Officer of Biomea Fusion. “Our decision reflects the significant potential we see in addressing the insulin deficient patients and those initiating or failing on a GLP-1-based therapy. Today we have a clear understanding of where our menin inhibitor icovamenib has the most impact and which patient population has the most potential benefit. We can easily identify those patients using HbA1c and BMI alone. Icovamenib was only dosed for 12 weeks in our study COVALENT-111, yet we saw continued reductions in HbA1c 3 months thereafter. We look forward to seeing the 52-week data as we expect the responses to further deepen beyond Week 26.”

JP Morgan Presentation Information

Thomas Butler, Chief Executive Officer and Chairman of the Board, will present on the company and its plans for 2025 at the 43rd Annual J.P. Morgan Healthcare Conference on Wednesday, January 15, 2025, at 1:30 PM Pacific Time / 4:30 PM Eastern Time. Additionally, Biomea's management team will be hosting one-on-one meetings throughout the conference, taking place from January 13 to January 16.

A live audio webcast of the presentation can be accessed here or by visiting the Investors & Media section of Biomea's website at https://investors.biomeafusion.com/news-events/events. A replay of the webcast will be available following the live presentation.

About Icovamenib
Icovamenib is an investigational, orally bioavailable, potent, and selective covalent inhibitor of menin. The molecule was built using Biomea Fusion's FUSION™ System and is designed to regenerate insulin-producing beta cells with the aim to cure diabetes. Icovamenib's proposed mechanism of action in diabetes is to enable the proliferation, preservation, and reactivation of a patient's own healthy, functional, insulin-producing beta cells. As the potentially first disease-modifying therapy for type 1 diabetes and type 2 diabetes, icovamenib could become an important addition and complement to the diabetes treatment landscape once it has successfully completed its ongoing clinical studies.

About Biomea Fusion
Biomea Fusion is a clinical-stage biopharmaceutical company focused on the discovery and development of oral covalent small molecules to improve the lives of patients with diabetes, obesity, 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, X 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, their mechanism of action, and their potential relative to approved products marketed by third parties; the potential benefits to future trial design and program development of subtyping diabetes patients and their potential to be used in combination with approved products marketed by third parties; our research, development and regulatory plans, the including our plans to engage with the U.S. Food and Drug Administration, progress of our ongoing and planned clinical trials, including anticipated data readouts from such trials, 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 preliminary or interim results of preclinical studies or clinical trials may not be predictive of future or final results in connection with ongoing or future clinical trials and 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 (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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