Biomea Fusion Announces First Patient Dosed in OPAL Study Evaluating Icovamenib in Combination with Semaglutide in Obesity

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• *Initiated Study to Assess the Potential Impact of the Combination of Icovamenib and Low-Dose Semaglutide on Physical Function, Body Weight, Body Composition, Muscle Health, and Metabolic Outcomes*

SAN CARLOS, Calif., Aug. 13, 2026 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea," "Biomea Fusion" or "the Company") (Nasdaq: BMEA), a clinical-stage diabetes and obesity company, today announced that the first participant has been dosed in a new arm of the ongoing platform research study, *Investigating and Optimizing Physical Function with Weight Loss: A Multi-Arm Open Label Adaptive Platform Trial ("OPAL")*. The study is being conducted in collaboration with the University of Leicester and is led by Professor Dame Melanie Davies and Professor Thomas Yates at the University of Leicester and Leicester Diabetes Centre ("LDC") and the NIHR Biomedical Research Centre Leicester.

The newly activated experimental OPAL study arm will evaluate the effects of Biomea's investigational small molecule, icovamenib (100mg, QD for 12 weeks) in combination with low-dose semaglutide (for 24 weeks) versus low dose semaglutide alone (for 24 weeks) in individuals without type 2 diabetes that are either overweight (with one or more weight-related complications) or obese. This randomized double-blind study-arm, is designed to enroll 64 participants randomized 1:1 to assess whether adding icovamenib to semaglutide can enhance weight loss while evaluating its potential effects on physical function, body composition, muscle health, and metabolic outcomes. The primary endpoint assessment will be performed at Week 24.

"We are pleased to have dosed the first participant in this OPAL study arm evaluating icovamenib in combination with semaglutide," said Professor Dame Melanie Davies, DBE, Professor of Diabetes Medicine, University of Leicester, and Co-Founder of the LDC. "This marks an important step in translating the encouraging preclinical findings with this combination into the clinical setting. As the treatment of obesity continues to evolve, we believe it is increasingly important to look beyond weight loss alone and understand how therapies may impact physical function, body composition, muscle health, and broader metabolic outcomes. Through OPAL, we look forward to evaluating whether the addition of icovamenib to semaglutide can enhance weight loss while supporting these important measures of health."

"Dosing the first participant marks an important milestone in our effort to better understand how we can optimize the quality, and not just the magnitude, of weight loss," said Professor Thomas Yates, Professor of Physical Activity, Sedentary Behaviour and Health, University of Leicester, and LDC. "As GLP-1–based therapies become an important part of obesity treatment, improving the effects of weight loss in particular on lean mass, bone integrity and functional capacity is increasingly important. We are excited to now explore within OPAL if the combination of icovamenib with a standard GLP-1 based therapy may provide improvements of these very critical markers of metabolic health."

"This study is expected to help us further support icovamenib's differentiated pharmacology and will provide valuable insights into its potential as a therapeutic approach for obesity in addition to diabetes," said Thorsten Kirschberg, PhD, Executive Vice President of Research at Biomea Fusion. "In preclinical studies, icovamenib enhanced key efficacy outcomes of semaglutide, which resulted in improved weight reduction driven by fat loss while preserving lean mass. These findings, together with icovamenib's observed effects on GLP-1 receptor expression, myogenesis, and adipose tissue metabolism, provide a strong scientific rationale for evaluating whether adding icovamenib to semaglutide can not only increase weight loss but also support improved body composition, muscle health, and physical function."

The clinical evaluation of icovamenib in combination with semaglutide is supported by preclinical studies in which icovamenib enhanced the efficacy of semaglutide, with improved weight reduction driven by fat loss and observed preservation of lean mass. Additional preclinical studies have demonstrated that icovamenib upregulates GLP-1 expression, supports myogenesis, and shifts adipose tissue metabolism toward energy expenditure. Together, these findings support the evaluation of icovamenib in combination with GLP-1 receptor agonist-based therapy as a potential approach to improve weight loss while supporting broader metabolic health.

About the OPAL Study
The OPAL study (ISRCTN10203365) is an adaptive platform trial designed to investigate whether newer generations of weight loss therapies, as well as equivalent diet-induced weight loss, can improve overall physical function, as measured by walking performance and other validated assessments of muscle health. The study will also evaluate whether combining pharmacologic weight loss therapies with structured exercise programs can further enhance these benefits. Additional endpoints include changes in muscle and fat mass, blood-based markers of metabolic health, and patient-reported quality of life measures.

About The Leicester Diabetes Center
The Leicester Diabetes Centre (LDC) constitutes one of Europe's largest and preeminent facility for diabetes translational research, education, and clinical training. As a premier institution for diabetes and metabolic studies, it integrates world-class clinical care with an expansive, internationally recognized research infrastructure.

Established through a strategic partnership between the University Hospitals of Leicester National Health Service (NHS) Trust and the University of Leicester, the LDC facilitates a unique synergy between NHS clinicians, clinical researchers, and academic investigators within the University of Leicester Diabetes Research Centre.

About the University of Leicester
The University of Leicester is a leading global university, home to more than 21,000 students and 4,000 staff, with an outstanding reputation for world class research, innovative teaching and widening access to higher education.

It holds an overall Gold rating in TEF 2023 and is ranked among the UK's Top 30 for research quality, with 89% of research rated world leading or internationally excellent (REF 2021).

Leicester ranks 25th in the UK in the 2026 Times Higher Education World University Rankings and 33rd in the Complete University Guide 2026, and is top 10 in the UK for student experience and top 15 for student satisfaction in the 2025 National Student Survey.

Named the Daily Mail University of the Year 2025 and shortlisted for the Times Higher Education University of the Year 2024 and The Times and The Sunday Times University of the Year 2025, Leicester is driven by a commitment to excellence, inclusion and meaningful global impact.

Leicester is also taking a sector-leading approach to responsible AI adoption in higher education and providing students and staff with access to Microsoft 365 Copilot, helping them build the digital confidence, critical AI literacy and future skills needed to learn, work and lead in an AI-enabled world. This sits alongside Leicester's commitment to embedding work-related learning across the student experience.

The NIHR Biomedical Research Centre Leicester
The National Institute for Health and Care Research (NIHR) Biomedical Research Centre (BRC) Leicester is part of the NIHR and hosted by the University Hospitals of Leicester NHS Trust in partnership with the University of Leicester, Loughborough University and the University Hospitals of Northamptonshire NHS Group.

The NIHR BRC Leicester undertakes translational clinical research in priority areas of high disease burden and clinical need. These are:

- Respiratory and infectious diseases
- Personalised cancer prevention and treatment
- Lifestyle (including diabetes)
- Environment and health
- Data innovation for multiple long term health conditions and ethnic health
- Cardiovascular disease

The BRC harnesses the power of experimental science to explore and develop ways to help prevent and treat chronic disease. It brings together 120 highly skilled researchers, 45 academic 'rising stars', more than 90 support staff and students and over 450 public contributors. By having scientists working closely with clinicians and the public, the BRC can deliver research that is relevant to both patients and the professionals who treat them. www.leicesterbrc.nihr.ac.uk

The mission of the National Institute for Health and Care Research (NIHR) is to improve the health and wealth of the nation through research. We do this by:

- Funding high quality, timely research that benefits the NHS, public health and social care;
- Investing in world-class expertise, facilities and a skilled delivery workforce to translate discoveries into improved treatments and services;
- Partnering with patients, service users, carers and communities, improving the relevance, quality and impact of our research;
- Attracting, training and supporting the best researchers to tackle complex health and social care challenges;
- Collaborating with other public funders, charities and industry to help shape a cohesive and globally competitive research system;
- Funding applied global health research and training to meet the needs of the poorest people in low and middle income countries.

NIHR is funded by the Department of Health and Social Care. Its work in low and middle income countries is principally funded through UK international development funding from the UK government.

About Icovamenib
Icovamenib is an orally administered investigational small molecule currently in Phase 2 clinical development for the treatment of type 1 and type 2 diabetes. Preclinical evidence shows that icovamenib promotes reversible downmodulation of menin, a transcriptional regulator implicated in beta cell biology. Preclinical data also has shown that icovamenib induced glucose-dependent beta cell proliferation and enhances insulin production and secretion. Through these proposed mechanisms, icovamenib has the potential to restore beta cell mass and function and thereby improve glycemic control. As a potential beta cell restorative therapy, icovamenib represents a novel treatment approach for individuals living with diabetes.

About Biomea Fusion
Biomea Fusion is a clinical-stage biopharmaceutical company advancing oral small molecule therapies, icovamenib and BMF-650, for diabetes and obesity. These programs target metabolic disorders, a global health challenge affecting nearly half of Americans and one-fifth of the world's population. Biomea's mission is to deliver transformative treatments that restore health for patients living with diabetes, obesity, and related conditions. 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, including icovamenib and BMF-650, the potential of icovamenib as a treatment for type 2 diabetes and as a combination therapy with semaglutide to enhance metabolic health, the potential of BMF-650 as a treatment for obesity; our research, development and regulatory plans, the timing of initiation, patient enrollment and dosing, progress and availability of data from our clinical trials and the LDC's OPAL platform study; the mechanism of action of our product candidates and development programs; our engagement with regulatory authorities and collaboration with clinical and scientific experts; and the results and 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 future clinical trials and the risk that we may encounter delays or adverse outcomes in regulatory interactions, 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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