MBX Biosciences Announces Last Subject Last Visit in Phase 1 Trial of MBX 1416 for the Treatment of Post-Bariatric Hypoglycemia

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Topline results expected in early January 2025

CARMEL, Ind., Nov. 18, 2024 (GLOBE NEWSWIRE) -- MBX Biosciences, Inc. (Nasdaq: MBX), a clinical-stage biopharmaceutical company focused on the discovery and development of novel precision peptide therapies for the treatment of endocrine and metabolic disorders, today announced the completion of the last subject's last visit in its Phase 1 single and multiple ascending dose trial of MBX 1416, the Company's long-acting glucagon-like peptide 1 (GLP-1) receptor antagonist in development for the treatment of post-bariatric hypoglycemia (PBH).

"We are pleased to complete the last subject visit in our Phase 1 trial of MBX 1416 in healthy adults and extend our sincere appreciation to the participants, investigators and clinical team for their support," said Kent Hawryluk, President and Chief Executive Officer of MBX Biosciences. "This achievement is a significant milestone in our MBX 1416 program, bringing us closer to treating patients with PBH, for which there are no approved therapies. We look forward to sharing full-topline results in early January 2025."

The Phase 1 clinical trial is a randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple ascending doses of MBX 1416 in healthy adult participants. The trial is being conducted in the United States and enrolled a total of 69 participants. The primary endpoint is safety and tolerability, and secondary endpoints include pharmacokinetics and pharmacodynamics. More information on the Phase 1 study can be found at www.clinicaltrials.gov, identifier NCT06036784.

About MBX 1416
MBX 1416 is an investigational long-acting glucagon-like peptide-1 (GLP-1) receptor antagonist in development as a potential treatment for PBH. It was designed using the Company's novel, proprietary PEP™ platform to prevent the occurrence of severe hypoglycemia in individuals with PBH so they can lead healthier and more independent lives.

About Post-Bariatric Hypoglycemia
Post-bariatric hypoglycemia (PBH) is a rare and serious complication of bariatric surgery. PBH is characterized by repeated episodes of symptomatic hypoglycemia, triggered by exaggerated secretion of GLP-1 levels following a meal, and can present as early as six months after Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy. Hypoglycemic episodes can occur multiple times per day and can periodically manifest with severe symptoms, such as dizziness, confusion, loss of consciousness or seizure. The unpredictability of hypoglycemic episodes and their associated risks may meaningfully hinder daily activities. As a result, the patient burden can be substantial, and many individuals cannot drive, work or live alone. To date, there are no approved pharmacotherapies to treat PBH. As the use of surgery to address metabolic conditions continues to rise, the incidence of PBH is expected to increase, reinforcing the need for safe and effective therapies.

About MBX Biosciences
MBX Biosciences is a biopharmaceutical company focused on the discovery and development of novel precision peptide therapies based on its proprietary PEP™ platform, for the treatment of endocrine and metabolic disorders. The Company is advancing a pipeline of novel candidates for endocrine and metabolic disorders with clinically validated targets, established endpoints for regulatory approval, significant unmet medical needs and large potential market opportunities. The Company's pipeline includes its lead product candidate MBX 2109, in Phase 2 development for the treatment of chronic hypoparathyroidism (HP); MBX 1416, in Phase 1 development for the treatment of post-bariatric hypoglycemia (PBH); and an obesity portfolio that includes MBX 4291, as well as multiple discovery and pre-clinical candidates in development for the treatment of obesity. The Company is based in Carmel, Indiana. To learn more, please visit the Company website at www.mbxbio.com and follow it on LinkedIn.

About MBX's Proprietary Precision Endocrine Peptide (PEP™) Platform
MBX was founded by global leaders with a transformative approach to peptide drug design and development. Leveraging this expertise, the Company designed its proprietary Precision Endocrine Peptide™ (PEP™) platform to overcome the key limitations of unmodified and modified peptide therapies and to improve clinical outcomes and simplify disease management for patients. PEPs are selectively engineered to have optimized pharmaceutical properties, including extended time-action profiles and consistent drug concentrations with low peak-to-trough concentration ratios, consistent exposure to target tissues, and less frequent dosing.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding: MBX Biosciences' expectations regarding the Phase 1 trial of MBX 1416, including the timing of topline results and statements relating to the ability of MBX 1416 to treat patients with PBH.

Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect MBX Biosciences' business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to the Company's research and development activities; uncertainties relating to preclinical and clinical development activities; the risk that preliminary results may not be indicative of later results; the Company's dependence on third parties to conduct clinical trials; MBX Biosciences' ability to attract, integrate and retain key personnel; risks related to regulatory developments and approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities; as well as other risks described in "Risk Factors," in MBX Biosciences' Registration Statement on Form S-1 filed with the Securities and Exchange Commission (SEC), most recent Quarterly Report on Form 10-Q, as well as subsequent filings with the SEC. MBX Biosciences expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law, and claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

MBX uses and intends to continue to use its Investor Relations website as a means of disclosing material nonpublic information and for complying with

its disclosure obligations under Regulation FD. Accordingly, investors should monitor the Company's Investor Relations website, in addition to following the Company's press releases, SEC filings, public conference calls, presentations, and webcasts.

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