# MBX Biosciences Announces Successful End-of-Phase 2 FDA Meeting and Provides Phase 3 Development Plan for Once-Weekly Canvuparatide for Hypoparathyroidism

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**Following End-of-Phase 2 meeting, MBX remains on track to initiate Phase 3 in Q3 2026**

CARMEL, Ind., March 09, 2026 (GLOBE NEWSWIRE) -- MBX Biosciences, Inc. (Nasdaq: MBX), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel precision peptide therapies for the treatment of endocrine and metabolic disorders, today announced the successful completion of an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) to discuss the overall Phase 3 trial design for once-weekly canvuparatide for the treatment of chronic hypoparathyroidism (HP).

“We are very encouraged by the outcome of our End-of-Phase 2 meeting and the constructive feedback supporting our planned Phase 3 trial for canvuparatide,” said Sam Azoulay, M.D., Chief Medical Officer of MBX Biosciences. “We believe canvuparatide has the potential to establish a new standard of care in hypoparathyroidism by restoring physiologic PTH activity and maintaining normocalcemia with the convenience of a patient-centric once-weekly dosing regimen. Feedback from physicians and patients has reinforced strong interest in a less burdensome treatment option, which we believe should translate into enthusiastic enrollment in the Phase 3 trial, and we look forward to enrolling the first patient in Q3 2026 now that we have confirmed the regulatory path toward an NDA submission.”

Based on feedback from the FDA, MBX plans to advance once-weekly canvuparatide into a Phase 3 trial in the third quarter of 2026. Phase 3 trial design elements have now been selected, including the number of patients, primary endpoint (including proportion of participants who achieve normal serum calcium and independence from conventional therapy) and key secondary endpoints (including normalization of urinary calcium), as well as dose selection, titration schedule and duration of the study.

The Phase 3 double-blind placebo-controlled trial will enroll approximately 160 patients, randomized in a 3:1 ratio to receive canvuparatide or placebo. Following randomization, there will be a 4-week fixed dose period of 600 micrograms of canvuparatide (or placebo), followed by an 18-week dose-titration period, and a 4-week maintenance period.

The Company also announced today that once-weekly canvuparatide has been granted orphan drug designation by the European Medicines Agency for the treatment of chronic hypoparathyroidism, supporting its continued clinical development in Europe.

**About Canvuparatide**
Canvuparatide is a parathyroid hormone peptide prodrug that is designed as a potential long-acting hormone replacement therapy for the treatment of HP. Leveraging the company’s proprietary Precision Endocrine Peptide™ (PEP™) platform technology, canvuparatide was designed to provide convenient, once-weekly administration and a continuous, infusion-like PTH exposure with lower daily peak-to-trough ratios than observed with daily PTH dosing regimens. Canvuparatide received orphan drug designation from the U.S. Food and Drug Administration for the treatment of HP.

**About Hypoparathyroidism (HP)**
HP is a rare endocrine disease caused by a deficiency of parathyroid hormone (PTH) released by the parathyroid glands that results in decreased calcium levels in the blood, leading to hypocalcemia. Hypocalcemia can cause a variety of symptoms, such as muscle cramping or spasm, tingling, and neurological symptoms such as depression, confusion, and cognitive impairment. More serious complications can occur, including seizures and cardiac arrhythmia. HP can interfere with daily activities, negatively impacting the quality of life for patients. We estimate that HP affects more than 250,000 individuals in the U.S. and Europe. The current standard of care for HP does not address the underlying cause of the disease, PTH deficiency, and consists primarily of high doses of oral calcium and active vitamin D supplements.

**About MBX Biosciences**
MBX Biosciences is a biopharmaceutical company focused on the discovery, development and commercialization 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 canvuparatide (MBX 2109) for the treatment of chronic hypoparathyroidism (HP) preparing for Phase 3 development; an obesity portfolio that includes MBX 4291 in Phase 1 development, as well as multiple discovery and pre-clinical obesity candidates; and imapextide (MBX 1416) for the treatment of post-bariatric hypoglycemia (PBH) in Phase 2 development. The Company is based in Carmel, Indiana. To learn more, please visit the Company website at www.mbxbio.com and follow it on LinkedIn.

**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 design of a Phase 3 trial; expectations regarding timing, including plans to initiate a Phase 3 clinical trial in Q3 2026; the potential for canvuparatide to be a new standard of care for HP; the potential market opportunity in HP; orphan drug designation and the intended benefits of such designation; and the unmet need for a new treatment option.

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; MBX Biosciences’ ability to execute on its strategy including obtaining the requisite regulatory approvals on the expected timeline, if at all; uncertainties relating to preclinical and clinical development activities; the Company’s dependence on third parties to conduct clinical trials, manufacture its product candidates and develop and commercialize its product candidates, if approved; MBX Biosciences’ ability to attract, integrate and retain key personnel; risks related to the Company’s financial condition and need for substantial additional funds in order to complete development activities and commercialize a product candidate, if approved; risks related to regulatory developments and approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities; risks related to establishing and maintaining MBX Biosciences’ intellectual property protections; risks related to the

competitive landscape for MBX Biosciences' product candidates; and final audit adjustments and other developments that may arise that would cause MBX Biosciences' expectations with respect to the estimate of cash, cash equivalents and marketable securities as of December 31, 2025 to differ, perhaps materially, from the financial results that will be reflected in MBX Biosciences' audited consolidated financial statements for the fiscal year ended December 31, 2025; as well as other risks described in "Risk Factors," in MBX Biosciences' Quarterly Report on Form 10-Q for the three months ended September 30, 2025, Annual Report on Form 10-K for the year ended December 31, 2024 filed with the Securities and Exchange Commission (SEC), 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 Biosciences 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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