MBX Biosciences Doses First Patient in Phase 2 Avail™ Trial of MBX 2109 for the Treatment of Hypoparathyroidism

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Topline results expected in Q3 2025

CARMEL, Ind., Aug. 12, 2024 (GLOBE NEWSWIRE) -- MBX Biosciences, Inc., 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 that it has dosed the first patient in its Phase 2 Avail™ trial of MBX 2109, the Company's parathyroid hormone (PTH) peptide prodrug that is designed to be long-acting and is in development for the treatment of chronic hypoparathyroidism (HP).

"We are pleased to advance our innovative Precision Endocrine Peptide™ (PEP™) candidate, MBX 2109, by dosing our first patient with HP," said Kent Hawryluk, President and Chief Executive Officer of MBX Biosciences. "The Phase 1 findings for safety, pharmacokinetics and pharmacodynamics support the potential of MBX 2109 as the first once-weekly PTH prodrug for HP, and initiation of patient dosing brings us closer to launching our potential PTH therapy. We look forward to continued enrollment and dosing of patients, with topline results anticipated in the third quarter of 2025."

The Phase 2 Avail trial is a randomized double-blind, placebo-controlled clinical trial in adult patients with HP. The Avail trial evaluates the safety, tolerability and efficacy of MBX 2109 over a 12-week period in approximately 48 patients. The primary endpoint of the Phase 2 clinical trial is the proportion of patients who can discontinue active vitamin D and reduce calcium supplements to less than or equal to 600 mg per day after 12 weeks of treatment while maintaining normal serum calcium levels. Secondary endpoints include safety and tolerability of MBX 2109 and characterization of the pharmacokinetics and pharmacodynamic activity (including urine calcium, serum phosphorus, 1,25 dihydroxyvitamin D and bone biomarkers) and the impact on quality of life using patient-reported outcome tools.

In the Avail trial, patients are randomized (1:1:1:1) to weekly subcutaneous injections of placebo or 400 µg, 600 µg, and 800 µg of MBX 2109. The 12-week treatment period is comprised of a 4-week fixed dose period and an 8-week titration period. During the titration period, patients who have not been able to discontinue active vitamin D and/or reduce calcium supplements may up-titrate the study drug using a protocol-specified algorithm. Patients completing the 12-week treatment period will be eligible to participate in a 104-week long-term extension study in which all patients will receive MBX 2109.

The Avail trial began in 2024 and topline results are expected in the third quarter of 2025. More information on the Phase 2 Avail™ trial can be found at www.clinicaltrials.gov, identifier NCT06465108.

About Hypoparathyroidism

HP is a rare endocrine disease caused by a deficiency of PTH released by the parathyroid glands that results in decreased calcium levels in the blood leading to hypocalcemia. Hypocalcemia can result in a variety of acute 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 arrhythmias. As a result, HP can interfere with daily activities, negatively impacting the quality of life for patients and we estimate that HP affects approximately 120,000 people in the United States and more than 250,000 in the United States and Europe. The most common cause for HP, in approximately 75% of cases, is the inadvertent removal or damage to the parathyroid glands during neck surgery. It can also be caused by certain autoimmune processes and genetic conditions. The current standard of care for HP does not address the PTH deficiency, which is the underlying cause of the disease. To avoid hypocalcemia and its symptoms due to PTH deficiency, the current standard of care consists primarily of high doses of oral calcium supplements and active vitamin D.

About MBX 2109

MBX 2109 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, MBX 2109 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. MBX 2109 received orphan drug designation from the U.S. Food and Drug Administration for the treatment of HP.

About MBX Biosciences

MBX Biosciences, Inc. is a biopharmaceutical company focused on the discovery and development of novel precision peptide therapies for the treatment of endocrine and metabolic disorders. The company 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™, or 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. 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 supported by leading life science investors including Deep Track Capital, Driehaus Capital Management, Frazier Life Sciences, New Enterprise Associates (NEA), Norwest Venture Partners, OrbiMed, RA Capital Management, funds and accounts advised by T. Rowe Price Associates, Inc. and Wellington Management. MBX is based in Carmel, Indiana. To learn more, please visit the company website at www.mbxbio.com and follow us on LinkedIn.

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