MBX Biosciences Presents Positive Results from Phase 1 Study of MBX 2109 in Late-Breaking Oral Presentation at the American Society for Bone and Mineral Research Annual Meeting

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MBX 2109 increased albumin adjusted serum calcium and suppressed endogenous PTH(1-84)

CARMEL, Ind., October 16, 2023 — MBX Biosciences, Inc., a clinical stage biopharmaceutical company developing Precision Endocrine Peptide™ (PEP™) therapeutics to treat an array of endocrine disorders, today announced the presentation of positive results from its Phase 1 single and multiple ascending dose trial of MBX 2109 in healthy adults, as a late-breaking oral presentation at the American Society for Bone and Mineral Research (ASBMR) Annual Meeting, held in Vancouver, Canada from October 13-16, 2023. MBX 2109 is the company's long-acting parathyroid hormone (PTH) peptide prodrug in development for the treatment of hypoparathyroidism (HP).

"The positive safety and PK/PD results support the potential of MBX 2109 as the first once-weekly PTH prodrug for the treatment of HP and will inform dose selection in our planned Phase 2 trial in patients with HP, which is expected to begin this quarter," said Kent Hawryluk, President and Chief Executive Officer of MBX Biosciences. "The current standard of care for HP does not target the underlying pathophysiology of the disease, and the success of the Phase 1 trial brings our development plan closer to delivering a potential best-in-class PTH therapy that may address this significant unmet need."

The randomized, double blind, placebo-controlled Phase 1 trial enrolled 76 healthy adult volunteers and was designed to evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of single ascending doses (SAD) and multiple ascending doses (MAD) of MBX 2109. The primary endpoint was safety and tolerability, and secondary endpoints included PK and PD parameters. In the SAD portion of the study, healthy adult volunteers were randomized to receive either placebo or a single subcutaneous (SC) dose of MBX 2109 at 50 µg, 150 µg, 300 µg, 460 µg, or 600 µg. In the MAD portion of the study, healthy adult volunteers were randomized to receive four once-weekly SC doses of either placebo or MBX 2109 at 200 µg, 400 µg, 600 µg, or 900 µg.

Participant demographics across the cohorts were well-balanced. Single and repeat doses of MBX 2109 were generally well-tolerated, and the majority of treatment emergent adverse events were mild in severity. No MBX 2109 dose-related serious or severe adverse events, or deaths were observed.

The observed PK parameters following single and repeat doses of MBX 2109 reflected the intended prodrug design and support once-weekly dosing. Following multiple doses of MBX 2109, there was a dose-related increase in mean albumin-adjusted serum calcium concentrations and dose-dependent suppression in endogenous PTH(1-84), consistent with the expected PTH pharmacology.

MBX Biosciences is preparing for an End-of-Phase 1 meeting with the U.S. Food and Drug Administration this quarter, and the company anticipates initiating its Phase 2 trial of MBX 2109 in patients with HP thereafter.

About Hypoparathyroidism

Hypoparathyroidism (HP) is a rare endocrine disorder caused by a deficiency of parathyroid hormone that results in decreased calcium and increased phosphorus levels in the blood. HP affects approximately 200,000 individuals worldwide, most of whom develop the condition following damage to or removal of the parathyroid glands during thyroid surgery. HP is associated with a wide range of symptoms such as paresthesias, muscle cramps, seizures, an impaired quality of life, and an increased risk of comorbidities including kidney stones and impaired renal function. The goal of treatment is to maintain blood calcium levels in the low-normal range while preventing symptoms of hypocalcemia. Current standard of care consists of high doses of calcium supplements and active vitamin D, which may contribute to the risk of renal disease and do not address the underlying pathophysiology caused by a lack of parathyroid hormone.

About MBX 2109

MBX 2109 is an investigational long-acting parathyroid hormone peptide prodrug in development as a PTH replacement therapy for hypoparathyroidism. It was designed with the company's novel, proprietary Precision Endocrine Peptide™ (PEP™) platform technology to provide sustained PTH activity with a convenient once-weekly dosing regimen. In July 2022, MBX 2109 received orphan drug designation from the U.S. Food and Drug Administration for the treatment of hypoparathyroidism. MBX aims to simplify and improve an individual's disease management, while relieving both the symptoms of the disorder and long-term complications.

About MBX Biosciences

MBX Biosciences, Inc. is a clinical-stage biopharmaceutical company pioneering Precision Endocrine Peptide™ (PEP™) therapeutic candidates tc help people with endocrine disorders live fuller and healthier lives. MBX is advancing a pipeline of PEPs for clinically validated targets designed to deliver superior pharmaceutical properties and overcome key limitations of native peptide therapeutics. MBX's pipeline includes its lead product candidate MBX 2109, which has completed Phase 1 development for the treatment of hypoparathyroidism, and MBX 1416, in Phase 1 development for the treatment of post-bariatric hypoglycemia. The company is supported by leading life science investors including Frazier Life Sciences, New Enterprise Associates, Norwest Venture Partners, OrbiMed, RA Capital Management 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 and Twitter.

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