MBX Biosciences Announces One-Year Data Demonstrating Sustained Benefit of Once-Weekly Canvuparatide as a Potential PTH Replacement Therapy in Chronic Hypoparathyroidism

June 12, 2026

Responder rate of 57% at one year in open-label extension (OLE) comparable to 63% at 12 weeks in Phase 2 Avail™ trial

Results consistent with restoration of systemic PTH activity through serum calcium normalization, reduction of urine calcium excretion, restoration of bone metabolism and increase of eGFR (a measure of kidney function)

High retention rate with 90% of patients entering the OLE remaining in the study at one year

Canvuparatide was generally well tolerated with no new safety signals during the OLE

PK supports once-weekly dosing, with low peak-to-trough ratio and stable exposure

Phase 3 pivotal trial remains on track to initiate in Q3 2026

Company to host conference call today at 8:00 a.m. ET

CARMEL, Ind. and BURLINGTON, Mass., June 12, 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 full results from the 12-week Avail™ Phase 2 trial and new one-year data from the ongoing open-label extension (OLE) study of once-weekly canvuparatide in adult patients with chronic hypoparathyroidism.

“These results continue to support the potential of once-weekly canvuparatide to address important unmet needs for patients with hypoparathyroidism,” said Michael T. Collins, M.D. Endocrinologist, Special Volunteer and Senior Clinical Advisor at the National Institutes of Health. “The maintenance of calcium homeostasis, increased eGFR, decreased urine calcium and bone remodeling observed through one year are encouraging and consistent with the physiologic effects of restored PTH action. A therapy that can provide sustained control of multiple disease markers with once-weekly administration could represent a meaningful advance for patients and supports moving into Phase 3 study for canvuparatide.”

“The full Phase 2 and one-year OLE results underscore the potential for once-weekly canvuparatide to become a best-in-class treatment option for patients with chronic hypoparathyroidism,” said Kent Hawryluk, President and Chief Executive Officer of MBX Biosciences. “The totality of the clinical data we announced today – including the impact of canvuparatide on calcium, kidney function and bone – support a convenient once-weekly approach to physiologic PTH replacement, which may reduce the treatment burden for patients living with this chronic disease. We remain on track to begin the Phase 3 trial in Q3 2026 and we are excited to be one step closer to delivering a new potential treatment option for patients with hypoparathyroidism.”

Key Findings from the 12-Week Avail™ Phase 2 Trial and One-Year OLE

Responder Rate

- **At 12 Weeks**: As previously reported, 63% of canvuparatide-treated patients (30/48) achieved the primary composite endpoint compared with 31% of placebo-treated patients (5/16) (p=0.042). The primary endpoint was defined as maintaining albumin-adjusted serum calcium levels in the normal range and independence from conventional therapy (active vitamin D and >600 mg/day of calcium supplements).
- **At One Year**: 57% of evaluable patients (31/54) achieved responder status; zero contribution from rescue therapy (PRN) in the last week of the one-year treatment period.

Pharmacokinetic Profile

- **Pharmacokinetics (PK):** PK data from the Phase 2 trial continued to support the potential for once-weekly dosing. PK demonstrated consistent concentration of canvuparatide active drug with a T_{max} of 2-3 days, minimal fluctuation and a peak-to-trough ratio of approximately 1.3 over a week, ensuring consistent systemic drug exposure over the entire weekly dosing interval.

Evidence of Physiologic PTH Replacement

- **Calcium Homeostasis:** Mean serum calcium levels were maintained within the normal range through one year of treatment, while mean 24-hour urine calcium levels decreased from baseline and remained within the normal range, with continued reductions observed over time in both canvuparatide-treated patients and those who switched from placebo.
- **Kidney Function:** Mean estimated glomerular filtration rate (eGFR) increased from baseline at Week 12 in canvuparatide-treated patients and remained improved through one year of treatment.
- **Bone Activity:** Markers of bone resorption (C-terminal peptide; CTx) and formation (procollagen type 1 N-terminal propeptide; P1NP) demonstrated the expected pattern of bone turnover associated with PTH replacement therapy through one year. Changes in bone mineral density (BMD) T-scores and Z-scores were consistent with restoration of physiologic bone remodeling.

One-Year OLE Safety Summary

- Once-weekly canvuparatide was generally well tolerated through one year of treatment, with no new safety signals observed during the OLE.
- Most treatment emergent adverse events were mild or moderate in severity.
- No treatment-related serious adverse events were reported.
- Injection site reactions were reported in 10% of patients in the OLE.

Exploratory Assessments

- **Patient-Reported Outcomes**: Trends toward improvement were observed across multiple SF-36v2 domains; however, interpretation was limited by incomplete baseline data.

Upcoming Presentations

One-year OLE data from the Phase 2 trial will be presented at the 3rd Parathyroid Summit during ENDO 2026 on June 12, 2026, and full results from the 12-week Avail™ Phase 2 trial will be presented at ENDO 2026 at 3:00 pm CT on June 13, 2026, in Chicago. These presentations will be available on MBX's website at https://investors.mbxbio.com/news-events/presentations following each presentation.

Conference Call Details

The Company will host a conference call and webcast today at 8:00 a.m. ET to discuss full results from the 12-week Avail ™ Phase 2 trial and one-year OLE data for once-weekly canvuparatide. Company management will be joined by Richard DiMarchi, Ph.D., Distinguished Professor of Chemistry at Indiana University and MBX scientific co-founder, and Michael T. Collins, M.D., endocrinologist and Senior Clinical Advisor at the National Institutes of Health. Those who would like to participate may access the live webcast here or dial 1-877-407-0779 (US) or 1-201-389-0914 (international). The live and archived webcast of the call and slide presentation will be available in the Investors section of the Company's website at https://investors.mbxbio.com/news-events/events.

About the Avail™ Trial

The Avail™ Phase 2 trial (NCT06465108) is a multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety, pharmacokinetics, and efficacy of canvuparatide in patients with hypoparathyroidism. The study randomized 64 patients into four treatment arms: canvuparatide 400ug, 600ug, 800ug administered by subcutaneous once-weekly injection, and a placebo arm. The 12-week treatment period includes a four-week fixed dose period followed by an 8-week titration period during which canvuparatide dosing may be adjusted every two weeks in 200ug increments. The primary endpoint for efficacy is normalization of albumin adjusted serum calcium while independent from active vitamin D and calcium supplements (<600 mg/day) at Week 12. Secondary endpoints include safety and tolerability; pharmacokinetic profile; urine calcium, serum phosphorus, 1,25 dihydroxyvitamin D, and bone biomarkers. Following the 12-week treatment period, 60 patients (94%) elected to receive once-weekly canvuparatide in the two-year open-label extension study with 90% of patients who entered the OLE continuing treatment in the ongoing study.

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 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 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 preparing for Phase 3 development; and an obesity portfolio that includes MBX 4291 in Phase 1 development and MBX 5765 in preclinical development, as well as additional discovery candidates. The Company is based in Carmel, Indiana and Burlington, Massachusetts. 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," "will," "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: the potential for canvuparatide to be a once-weekly PTH replacement therapy; the potential for canvuparatide to become a best-in-class treatment option for chronic HP; expectations regarding future clinical evaluation of canvuparatide, including timing of the Phase 3 confirmatory trial; and statements relating to canvuparatide having a favorable safety profile.

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, including the risk for differences between interim data and final data from the Company's ongoing clinical trials; 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; and risks related to the competitive landscape for MBX Biosciences' product candidates; as well as other risks described in "Risk Factors," in MBX Biosciences' Annual Report on Form 10-K for the year ended December 31, 2025, Quarterly Report on Form 10-Q for the three months ended March 31, 2026, as well as subsequent filings filed with the Securities and Exchange Commission (SEC) , including the matters described in this press release. 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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