BiomX Provides Update on BX004 Phase 2b Trial in Cystic Fibrosis

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The Company continues working with the third-party manufacturer to address recent FDA follow-up information requests which are required to lift the clinical hold concerning the nebulizer device used in the Phase 2b trial

An independent Data Monitoring Committee (DMC) completed a safety review following adverse events identified in the BX004 Phase 2b trial and recommended that the study continue with revised dosing

Following the DMC review, the study protocol will be updated, and topline results are now expected in Q2 2026

NESS ZIONA, Israel, Nov. 25, 2025 (GLOBE NEWSWIRE) -- BiomX Inc. (NYSE American: PHGE) ("BiomX" or the "Company"), a clinical-stage company advancing novel natural and engineered phage therapies targeting specific pathogenic bacteria, today announced that the U.S. Food and Drug Administration (FDA) is continuing its evaluation of the nebulizer device used for drug administration in the Company's Phase 2b trial of BX004 in patients with cystic fibrosis. The Company is working with the third-party manufacturer to address recent FDA follow up information requests in order to lift the FDA's clinical hold with respect to the trial. In parallel, an independent DMC has completed a safety review of the BX004 Phase 2b clinical trial.

BiomX recently received additional follow-up questions from the FDA related to the third-party nebulizer device used for BX004 administration. The Company is working closely with the device manufacturer to assemble the remaining additional information requested by the Agency. BiomX considers the outstanding items readily addressable to resolve the outstanding questions raised by the FDA while maintaining a productive and ongoing dialogue with the Agency. The Company expects enrollment in the U.S. to resume once this process is complete.

Separately, an independent DMC has conducted a safety review of the BX004 Phase 2b clinical trial. The review included participants who experienced adverse events, and following its evaluation, the DMC recommended that the study continue with an adjusted dosing regimen. In accordance with the recommendations, BiomX is updating the trial protocol, and pending availability of financial resources and other factors, topline results are now expected in the second quarter of 2026.

"We are encouraged by the DMC's conclusion that the BX004 study may continue once the adjusted dosing regimen has been implemented. We remain committed to advancing a potential treatment for the unmet need of *Pseudomonas aeruginosa* (*P. aeruginosa*) infections in patients with cystic fibrosis," said Jonathan Solomon, Chief Executive Officer of BiomX. "We are working closely with our device manufacturer to provide the FDA with the remaining clarifications and remain confident in the path forward for BX004. We look forward to reporting topline results in the second quarter of 2026."

About BX004
BX004 is a fixed multi-phage cocktail designed to target *P. aeruginosa*, a major contributor to morbidity and mortality in people with cystic fibrosis. In February 2023, BiomX announced positive Part 1 Phase 1b/2a results demonstrating safety, tolerability, and microbiologic activity. In November 2023, BiomX announced positive topline results from Part 2, in which BX004 demonstrated improvement in pulmonary function associated with a reduction in *P. aeruginosa* burden versus placebo in a predefined subgroup of patients with reduced lung function (baseline FEV1<70%). Pending resolution of the FDA clinical hold on U.S. enrollment, and availability of funding resources, BiomX is expects to enroll up to approximately 60 patients in a randomized, double blind, placebo-controlled, multi-center Phase 2b trial evaluating lung function, bacterial load, and quality-of-life measures over an 8-week treatment period. BX004 has received Fast Track and Orphan Drug Designations from the U.S. FDA.

About BiomX
BiomX is a clinical-stage company leading the development of natural and engineered phage cocktails and personalized phage treatments designed to target and destroy harmful bacteria for the treatment of chronic diseases with substantial unmet needs. BiomX discovers and validates proprietary bacterial targets and applies its BOLT ("BacteriOphage Lead to Treatment") platform to customize phage compositions against these targets. For more information, please visit www.biomx.com, the content of which does not form a part of this press release.

Safe Harbor
This press release contains express or implied "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. For example, when BiomX refers to the possibility that the data BiomX provides will allow the FDA to lift the clinical hold, sufficiency of financial resources, resumption of patient enrollment and timing thereof, the expected timing for topline results and the potential impact of the adjustment to the dosing regimen on the BX004 Phase 2b trial, it is using forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on BiomX management's current beliefs, expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of BiomX's control. These risks and

uncertainties include, but are not limited to, changes in applicable laws or regulations; the possibility that BiomX may be adversely affected by other economic, business, and/or competitive factors, including risks inherent in pharmaceutical research and development, such as: adverse results in BiomX's drug discovery, preclinical and clinical development activities, the risk that the results of preclinical studies and early clinical trials may not be replicated in later clinical trials, BiomX's ability to enroll patients in its clinical trials, and the risk that any of its clinical trials may not commence, continue or be completed on time, or at all; decisions made by the FDA, and other regulatory authorities; decisions made by investigational review boards at clinical trial sites and publication review bodies with respect to our development candidates; BiomX's ability to obtain, maintain and enforce intellectual property rights for its platform and development candidates; its potential dependence on collaboration partners; competition; uncertainties as to the sufficiency of BiomX's cash resources to fund its planned activities for the periods anticipated and BiomX's ability to manage unplanned cash requirements; and general economic and market conditions. Therefore, investors should not rely on any of these forward-looking statements and should review the risks and uncertainties described under the caption "Risk Factors" in BiomX's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 25, 2025, and additional disclosures BiomX makes in its other filings with the SEC, which are available on the SEC's website at www.sec.gov. Forward-looking statements are made as of the date of this press release, and except as provided by law BiomX expressly disclaims any obligation or undertaking to update forward-looking statements.

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