BiomX Provides a Program Update and Announces New FDA Feedback Potentially Expanding BX004 Development Pathways

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BiomX believes that it has fully addressed the FDA's queries related to the third-party nebulizer used to deliver BX004, which are narrow in scope; an additional FDA request for limited technical clarifications on the nebulizer has also been addressed

In parallel, new written FDA feedback underscores the significant unmet need BiomX is addressing and outlines new potential development approaches

European enrollment and dosing remain strong; Phase 2b study remains on track to report topline results in the first quarter of 2026

NESS ZIONA, Israel, Oct. 17, 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 provided an update on progress relating to the previously disclosed U.S. Food and Drug Administration (FDA) clinical hold placed on the U.S. portion of the BX004 Phase 2b trial in cystic fibrosis (CF). The Company also announced that it has received new encouraging written feedback provided by the FDA outlining potential development strategies for BX004, including approaches to enrich study populations in Phase 3 development.

BX004 Phase 2b Trial Update

In responding to the initial clinical hold of the U.S. portion of the Phase 2b trial, BiomX, together with the third-party nebulizer manufacturer, promptly provided a comprehensive package of data and analyses to address the FDA's feedback and queries related to the third-party nebulizer device used to deliver BX004. Following its review of this package, the FDA issued an additional request for limited technical clarifications related to the nebulizer's performance. BiomX believes that it has fully addressed the FDA's queries, which are narrow in scope and pertain solely to the nebulizer device. The FDA has not raised any concern regarding the BX004 drug product itself.

Importantly, patient recruitment and dosing in Europe have continued ahead of plan throughout the U.S. clinical hold. The BX004 Phase 2b trial remains on track to report topline results in the first quarter of 2026. All third-party nebulizer components used in the European trial are CE marked and approved for use in the EU.

"Patient enrollment and dosing in Europe have progressed faster than expected, and the BX004 Phase 2b trial remains on track to report topline results in the first quarter of 2026," said Jonathan Solomon, Chief Executive Officer of BiomX. "In parallel, we have responded to the FDA's additional, limited queries regarding the data on the third-party nebulizer used to deliver BX004. We believe the information provided appropriately addresses the FDA's questions and look forward to continuing our dialog with the FDA to support a potential lifting of the clinical hold in the U.S. in the near term," stated Mr. Solomon.

New FDA Feedback on BX004 Development Pathways

BiomX has also received new written feedback from the FDA recognizing that, even in the era of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) modulators, there remains a significant unmet need for therapies addressing chronic *Pseudomonas aeruginosa* infection in individuals with CF. The FDA outlined several potential development pathways, including opportunities to refine inclusion criteria and enrich patient populations in a Phase 3 program, with the aim of enhancing the ability to demonstrate therapeutic benefits.

"We are encouraged by the FDA's perspective recognizing persistent unmet need in this patient population and by the constructive guidance on potential development pathways," added Mr. Solomon. "We believe this feedback can help us optimize study design and potentially broaden the clinical relevance of BX004, subject to future data from the Phase 2b trial, regulatory alignment, and resources."

BiomX plans to incorporate the FDA's recommendations, as appropriate, into ongoing development plans and anticipates further discussion with the FDA at an End-of-Phase 2 meeting following completion and review of the Phase 2b trial results.

About BX004

BiomX is developing BX004, a fixed multi-phage cocktail, for the treatment of CF patients with chronic pulmonary infections caused by *Pseudomonas aeruginosa* (*P. aeruginosa*), a main contributor to morbidity and mortality in patients with CF. In February 2023, BiomX announced positive results from Part 1 of the Phase 1b/2a study, showing safety, tolerability, and microbiologic activity. In November 2023, BiomX announced positive topline results from Part 2 of the Phase 1b/2a trial, in which BX004 demonstrated improvement in pulmonary function associated with a reduction in *P. aeruginosa* burden compared to placebo in a predefined subgroup of patients with reduced lung function (baseline FEV1<70%). Pending resolution of the clinical hold imposed by the FDA, BiomX is expects to enroll up to approximately 60 patients in a randomized, double blind, placebo-controlled, multicenter Phase 2b trial of BX004 in CF patients with chronic *P. aeruginosa* lung infections. The 8-week study will assess lung function, bacterial load, and quality of life metrics. BX004 has received FDA Fast Track and Orphan Drug Designations.

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 clinical hold imposed by the FDA, the possibility that the data BiomX provided will allow the FDA to lift such clinical hold, that such clinical hold will be lifted in the near term, if at all, the timing of reporting of topline results, resumption of patient enrollment in the U.S. and timing thereof, the impact of the FDA clinical hold on the BX004 Phase 2b trial, potential development pathways and potential opportunities to refine inclusion criteria and enrich patient populations, and enhance the ability to demonstrate clinical benefit, 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; possible impacts of the government shut down in the U.S.; 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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