July 14, 2025

BiomX Announces Successful Initiation of Phase 2b Trial with First Patient Dosed in BX004 Program in Patients with Cystic Fibrosis

First patient dosing in Company's Phase 2b trial marks pivotal milestone in phage therapy development program targeting antibiotic-resistant lung infections in Cystic Fibrosis patients; topline results are expected in Q1 2026

Prior Phase 1b/2a efficacy findings demonstrated complete bacterial clearance in 14.3% of patients after just 10 days of treatment

Feedback from U.S. Food and Drug Administration (FDA) anticipated in H2 2025, regarding plans to evaluate investigation and use of real-world evidence linking bacterial reduction to clinical outcomes; successful alignment could potentially streamline approval pathway for this urgently needed treatment option

NESS ZIONA, Israel, July 14, 2025 (GLOBE NEWSWIRE) -- BiomX Inc. (NYSE American: PHGE) ("BiomX" or the "Company"), a clinical-stage company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today announced the successful initiation of patient dosing in the Company's Phase 2b trial with first patient dosed. The trial is evaluating BX004 for the treatment of cystic fibrosis (CF) patients with chronic pulmonary infections caused by *Pseudomonas aeruginosa* (*P. aeruginosa*) infections, which remain a leading cause of death in this patient population despite modern treatments. Pending topline results expected in the first quarter of 2026, BX004 could potentially be positioned as the leading phage-based therapy for CF patients with these deadly infections.

"This first patient dosing marks a significant milestone for our BX004 program and for CF patients with chronic *P. aeruginosa* infections who desperately need new options," said Jonathan Solomon, Chief Executive Officer of BiomX. "We're seeing tremendous enthusiasm from both patients and investigators based on our encouraging Phase 1b/2a results, in which 14.3% of patients cleared infections completely after 10 days of treatment. Notably, this included individuals who had been living with chronic infections for over a decade, making these outcomes particularly meaningful and rarely seen in this population. In the second half of 2025, we anticipate feedback from the FDA regarding our plans on the analyses of real-world evidence to link bacterial reduction to clinical outcomes. Regulatory alignment on a microbiological endpoint would streamline the approval pathway and provide a means of addressing these patients with urgent unmet needs. With both Fast Track and Orphan Drug designations already secured, we believe we are well-positioned to further develop our phage-based therapy for these life-threatening infections, pending positive topline trial readout, which readout is expected in the first quarter of 2026."

The Phase 2b trial is a randomized, double-blind, placebo-controlled study evaluating BX004 in approximately 60 CF patients with chronic *P. aeruginosa* infections. Patients are randomized 2:1 to receive either BX004 or placebo via inhalation twice daily for 8 weeks. The trial is designed to measure multiple efficacy endpoints, including reduction in bacterial burden, improvements in lung function[1], and enhanced quality of life as measured by CFQ-R[2] and CRISS[3]. The trial builds on the successful Phase 1b/2a results, which showed BX004's potential ability to target and destroy *P. aeruginosa* that conventional treatments failed to eradicate.

About BX004

BiomX is developing BX004, a fixed multi-phage cocktail, for the treatment of CF patients with chronic pulmonary infections caused by *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%). BiomX is now enrolling up to approximately 60 patients in a randomized, placebo-controlled 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 its anticipated timing for reporting results for its clinical assets and whether the results will be positive, as well as the design of clinical trials thereof, potential timing of expected feedback from the FDA, potential approval for BX004, and the potential of its candidates to address the substantial unmet needs of patients with intractable infections and become the leading phage-therapy for CF patients with deadly infections, 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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[1] Lung function measured as FEV1 (Forced Expiratory Volume in 1 second)
[2] Cystic Fibrosis Questionnaire-Revised (CFQ-R)
[3] Chronic Respiratory Infection Symptom Score (CRISS)

Source: BiomX Inc