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BiomX Announces Publication in Nature Communications of Phage Cocktail BX004 Phase 1b/2a Part 1 Data Demonstrating Strong Activity in Cystic Fibrosis

Premier research journal article provides validation for BiomX's phage therapy platform, showcasing first-in-human Phase 1b/2a trial results for antibiotic-resistant P. aeruginosa infections

New, updated data demonstrates a further bacteria reduction of 2.7 log_{10} (approximately 500-fold) compared to placebo, with no emergent resistance and preservation of a healthy microbiome

BiomX is advancing its Phase 2b trial of BX004 with topline results expected Q1 2026

NESS ZIONA, Israel, July 08, 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 publication of a peer-reviewed article in *Nature Communications* titled, "Phage therapy with nebulized cocktail BX004-A for chronic *Pseudomonas aeruginosa* infections in cystic fibrosis: a randomized first-in-human trial". The article notably features previously unreported antimicrobial efficacy data from the Phase 1b/2a clinical trial and reinforces the strength of BiomX's innovative approach to developing bacteriophage therapies for chronic disease with substantial unmet needs. The publication is available at: Link.

"The publication of our peer-reviewed results in a preeminent research journal, including new data showing antimicrobial activity of BX004, provides significant third-party validation of our phage therapy platform to treat patients with chronic *P. aeruginosa* cystic fibrosis (CF) infections," said Jonathan Solomon, BiomX's Chief Executive Officer. "Building upon the strong scientific rigor of our clinical program and our findings in patients showing meaningful bacterial reduction where antibiotics have failed, we have initiated our Phase 2b trial of BX004, with topline results expected in the first quarter of 2026."

The peer-reviewed results of Part 1 of BiomX's BX004 Phase 1b/2a study include new analyses showing that BX004 achieved a substantially greater improvement of approximately 500-fold (additional improvement of 2.7 log_{10}) in bacterial reduction compared with placebo in CF patients. Notably, the data highlights that no bacterial resistance to BX004 emerged during the trial, addressing a critical limitation of traditional antibiotics. Findings from Part 1 of the Phase 1b/2a study were consistent with the results observed in Part 2.

"Drawing on decades of experience in large-scale genomic analysis and bacterial defense mechanisms, the study demonstrates how large-scale data analysis can be used to optimize

bacteriophage cocktails for treating chronic infection associated with cystic fibrosis," said Rotem Sorek, Ph.D., Professor of Genetics, Weizmann Institute of Science. "By combining experimental and computational methods, we've developed a design approach that broadens bacterial strain coverage, lowers the likelihood of resistance, and enhances activity against bacterial biofilms, establishing an effective framework for designing next-generation bacteriophage therapeutics."

Key Highlights from the Study

Part 1 of BiomX's Phase 1b/2a study evaluated the safety, tolerability, pharmacokinetics, and anti-microbiologic activity of BX004 over a 7-day treatment period in nine CF patients (seven on BX004, two on placebo) with chronic *P. aeruginosa* pulmonary infection. The Part 1 data demonstrated:

- **Strong Safety Profile:** BX004 was safe and well-tolerated with no treatment-related safety events across all patients and dose levels tested.
- **Successful bacterial reduction achieved:** At day 15, BX004-treated patients showed a negative 1.42 $\log_{10}$ reduction in *P. aeruginosa* bacteria from baseline, while patients receiving placebo worsened by +1.26 $\log_{10}$ CFU/g. This 2.7 $\log_{10}$ CFU/g treatment effect (which represents approximately a 500-fold, or 99.8%[1], greater bacterial reduction with BX004 versus placebo) was achieved on top of standard of care inhaled antibiotics. These findings resulted from an additional *post hoc* analysis and are being reported for the first time. Results at day 4 during BX004 treatment showed *P. aeruginosa* burden reduction (1.9 $\log_{10}$ CFU per gram of sputum difference between groups).
- **Therapeutic phages successfully reached and persisted at infection site:** Phages were detected in all patients treated with BX004 during the dosing period, including in several patients up to day 15 (one week after end of therapy). As expected, no phages were detected in patients receiving placebo.
- **No bacterial resistance to treatment:** There was no emerging treatment-related resistance to BX004 during or after treatment with BX004, addressing efficacy of phage against bacteria where resistance is common amongst traditional antibiotics.
- **Favorable shifts in microbiome composition post treatment:** Microbiological signals included a reduction in *P. aeruginosa* relative abundance and an increase in microbiome alpha diversity in the phage-treated group, in contrast to the placebo group.

The *Nature Communications* publication describes the full translational path from laboratory discovery to clinical testing. Environmental phages were isolated and screened using *P. aeruginosa* grown under conditions mimicking the CF lung environment.*In silico* screening confirmed the absence of known genes associated with antibiotic resistance or virulence.

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 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 U.S. Food and Drug Administration 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 plans to initiate and enroll patients in the Phase 2b trial and timing of topline results thereof, enrollment of patients in a Phase 2b trial of BX004, the Company's leadership in developing natural and engineered phage cocktails and personalized phage treatments for chronic diseases, the potential safety, efficacy and toleration of BX004, the potential benefits of BX004, future clinical development of BX004, and the potential of its candidates to address the substantial unmet needs of patients with intractable 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] A 2.7 $\log_{10}$ reduction represents a 10^2.7 = ~500-fold reduction in bacterial load, which equates to approximately 99.8% reduction.

Source: BiomX Inc