

June 27, 2022



# BiomX Announces Dosing of the First Two Patients in Phase 1b/2a Study of BX004 for Treatment of Chronic Respiratory Infections in Patients with Cystic Fibrosis

*Data Readout from Part I of the Study Expected in 3Q 2022*

BRANFORD, Conn. and NESS ZIONA, Israel--(BUSINESS WIRE)-- BiomX Inc. (NYSE American: PHGE) ("BiomX" or the "Company"), a clinical-stage microbiome company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today announced the dosing of the first two patients in the Company's Phase 1b/2a study evaluating BX004 for the treatment of chronic respiratory infections in patients with cystic fibrosis ("CF").

"We are pleased to reach this important clinical milestone in our cystic fibrosis program," said Jonathan Solomon, Chief Executive Officer of BiomX. "In prior *in vitro* studies, BX004, a novel phage cocktail targeting *P. aeruginosa*, demonstrated activity against antibiotic resistant strains of *P. aeruginosa*, as well as enhanced biofilm penetration compared to antibiotic therapies. In the first part of this study, we will assess the safety, pharmacokinetics, and clinical activity of BX004 in eight CF patients, and we look forward to discussing these data in the third quarter of 2022."

"Despite the significant advancements made in the treatment of cystic fibrosis, *P. aeruginosa* remains a leading cause of patients' morbidity and mortality. The treatment options for patients suffering from antibiotic resistant strains are limited," said Eitan Kerem, M.D., Professor of Pediatrics and former Chairman of the Department of Pediatrics and the Pediatric Pulmonology Unit of the Hadassah University Medical Center in Jerusalem. "New and innovative treatment approaches such as the one potentially provided by BX004 are therefore urgently needed to address this significant unmet medical need. Furthermore, under a prior compassionate use program in the U.S., phage therapy has already demonstrated the ability to reduce bacterial burden and improve pulmonary (FEV<sub>1</sub>) function in people with CF, thereby providing further rationale for pursuing this approach. I look forward to seeing the results from this important study in the near future."

BiomX is developing BX004 for the treatment of CF patients with chronic respiratory infections caused by *Pseudomonas aeruginosa*, a main contributor to morbidity and mortality in patients with CF. In September 2021, BX004 was cleared by the U.S. Food and Drug Administration to initiate a Phase 1b/2a study in CF patients with chronic respiratory infections caused by *Pseudomonas aeruginosa*.

The Phase 1b/2a study of BX004 is composed of two parts. Part 1 of the study will evaluate the safety, pharmacokinetics, and microbiologic/clinical activity of BX004 in eight CF patients

in a single ascending dose and multiple dose design, with results expected in the third quarter of 2022. Part 2 of the study will evaluate the safety and efficacy of BX004 in 24 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio. Results from Part 2 are expected in the first quarter of 2023.

In January 2022, BiomX received a Therapeutics Development Award of up to \$5 million from the Cystic Fibrosis Foundation (“CF Foundation”). The award is structured as an equity investment in which the CF Foundation has agreed to purchase up to \$5M million of BiomX common stock across two separate tranches. The first tranche was received on December 21, 2021, with the CF Foundation making an initial equity investment of \$3 million.

## **About BiomX**

BiomX is a clinical-stage microbiome company developing both natural and engineered phage cocktails designed to target and destroy bacteria in the treatment of chronic diseases. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.

Additional information is available at [www.biomx.com](http://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 discusses its expectations regarding the timing and design of its Phase 1a/2b study, and reporting the results thereof, and the potential to receive an additional \$2 million investment from the CF Foundation, BiomX is making 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 control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. 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 30, 2022 and additional disclosures BiomX makes in its other filings with the SEC, which are available on the SEC’s website at [www.sec.gov](http://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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