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BiomX Announces Positive Results from Part 1 of the Phase 1b/2a Study Evaluating BX004 for Treatment of Chronic Pulmonary Infections in Patients with Cystic Fibrosis

BX004 therapy safe and well-tolerated across all patients and dose levels

Preliminary signals of efficacy also observed, with notable reductions in bacterial burden

Dosing in patients in Part 2 initiated, results expected in Q3 23

Company to host webcast/cc to discuss Part1 data today at 9:00 am ET

CAMBRIDGE, Mass. and NESS ZIONA, Israel, Feb. 22, 2023 (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 positive results from Part 1 of the Phase 1b/2a trial evaluating the Company's novel phage cocktail, BX004, for the treatment of chronic pulmonary infections caused by *Pseudomonas aeruginosa* (or *P. aeruginosa*) in patients with cystic fibrosis ("CF").

"We are very excited to share these positive results from Part 1 of our Phase 1b/2a CF study," said Jonathan Solomon, Chief Executive Officer of BiomX. "Although Part 1 of the study was designed primarily to assess safety and tolerability of BX004, a goal that was achieved, we are highly encouraged to see preliminary evidence of efficacy in patients treated with BX004 despite the small sample size and short duration of treatment. At Day 15, mean *P. aeruginosa* burden was reduced by 1.42 $\log_{10}$ CFU/g compared to 0.28 $\log_{10}$ CFU/g in those receiving placebo. The BiomX Phase 1b/2a clinical trial is the first reported double blind placebo-controlled study evaluating a cocktail-based phage product to demonstrate notable reductions in bacterial burden in cystic fibrosis. Based on the favorable safety profile in Part 1, as confirmed by the Data Monitoring Committee, we have already dosed patients in Part 2 of the Phase 1b/2a study and expect to report results in the third quarter of 2023."

"We would like to thank all of the patients, physicians and healthcare providers who participated in Part 1 of the study and our dedicated team and collaborators for all their work. We also appreciate the continued support from the Cystic Fibrosis Foundation, which, through its Therapeutics Development Award program, provides significant resources to help advance new therapeutics for CF."

"Despite the available new CFTR directed therapies, CF patients continue to suffer from

intractable, persistent infections, such as those caused by *P. aeruginosa*, and new treatment approaches are clearly needed," 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. "BiomX's study results, in addition to previous data gathered through compassionate use, strongly endorse the potential of phage-based treatments in effectively targeting pathogenic bacteria within infected tissue. I look forward to the results from Part 2 of this study later this year."

"Given the ability of antibiotics to reduce susceptible bacteria and concurrently improve lung function, we are hopeful that we will observe similar findings with BX004 following the extended treatment course planned in Part 2 of the study," said Merav Bassan, Ph.D.Chief Development Officer of BiomX.

Summary of Part 1 Results

Part 1 of the Phase 1b/2a study of BX004 evaluated the safety, tolerability, pharmacokinetics (PK), and 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 in a single ascending dose and multiple dose design.

Highlights Included:

- No safety events related to treatment with BX004
- Mean *P. aeruginosa* colony forming units (CFU) at Day 15 (compared to baseline): -1.42 $\log_{10}$ CFU/g (BX004) vs. -0.28 $\log_{10}$ CFU/g (placebo). This reduction was seen on top of standard of care inhaled antibiotics
- 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); no phages were detected in patients receiving placebo
- There was no emerging resistance to BX004 during or after treatment with BX004
- As expected, likely due to short course of therapy, there was no detectable effect on % predicted FEV1

BiomX is developing BX004, utilizing its proprietary BOLT platform, 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 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 pulmonary infections caused by *P. aeruginosa*. Part 2 of the Phase 1b/2a study of BX004 will evaluate the safety and efficacy of BX004 in 24 CF patients with chronic pulmonary infection caused by *P. aeruginosa* randomized to treatment or placebo in a 2:1 ratio. Results from Part 2 are expected in the third quarter of 2023.

Conference Call and Webcast Information

BiomX management will host a conference call and webcast today at 9:00 am to review the results of the Phase 1b/2a trial results. To participate in the conference, please dial 1-877-407-0724 (U.S.), or 1-201-389-0898 (International). A live and archived webcast of the call will be available on the Investors section of the Company's website at www.biomx.com.

About BiomX

BiomX is a clinical-stage company developing both natural and engineered phage cocktails designed to target and destroy bacteria that target and destroy bacteria in the treatment of chronic diseases. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets. For more information, please visit www.biomx.com

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 the potential safety or efficacy of BX004, the expected timing of Part 2 of the Phase 1b/2a study and the potential of targeted phage therapy to treat infections in CF patients, 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's 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. 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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