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

CAMBRIDGE, Mass. and NESS ZIONA, Israel, Oct. 04, 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 the completion of patient dosing in Part 2 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”). The Company remains on track to report results from Part 2 of the study in November 2023.

“BX004 has been designed to address a significant unmet need facing thousands of CF patients who require new treatments to combat persistent and deadly lung infections,” said Jonathan Solomon, Chief Executive Officer of BiomX. “With patient dosing now complete in Part 2 of our Phase 1b/2a study, we remain on track to announce results next month. I am also pleased to note that our two late-breaker, oral presentations highlighting our Part 1 results were well received by the CF community at the recent European Cystic Fibrosis Society (ECFS) conference and European Respiratory Society (ERS) Congress, further underscoring clinician and patient interest in the BX004 program. The Part 1 data has also been accepted as a late-breaker, oral presentation at the upcoming IDWeek 2023 meeting, which should provide another important venue for building awareness of the BX004 program.”

Details of the oral presentation of the Part 1 data are as follows:

**Conference:** IDWeek 2023  
**Session Title:** Late Breaking Abstracts: Clinical Trials  
**Session Type:** Oral Abstract  
**Session Date:** Saturday October 14, 2023  
**Session Time:** 1:45 PM - 3:00 PM ET  
**Location:** 254 AB  
**Presentation Title:** (2891) Nebulized Phage Therapy for Patients with Cystic Fibrosis with
Chronic *Pseudomonas aeruginosa* Pulmonary Infection: A Phase 1b/2a Randomized, Double-Blind, Placebo-Controlled, Multicenter Study

**Presenter:** Urania Rappo, MD, BiomX Inc., Cambridge, United States

**Presentation Time:** 2:21 PM - 2:33 PM ET

**About BX004**

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 ("FDA") to initiate a Phase 1b/2a study in CF patients with chronic pulmonary infections caused by *P. aeruginosa*. The Phase 1b/2a trial is composed of two parts. In February 2023, the Company reported positive results from Part 1 of the study which evaluated the safety, pharmacokinetics, and microbiologic/clinical activity of BX004 in nine CF patients in a single ascending dose and multiple dose design. Part 2 of the study will evaluate the safety and efficacy of BX004 in at least 24 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio. Results from Part 2 of the trial are expected in November 2023. In August 2023, the FDA granted BX004 Fast Track designation for the treatment of chronic respiratory infections caused by *Pseudomonas aeruginosa* (PsA) bacterial strains in patients with CF.

**About BiomX**

BiomX is a clinical-stage 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. For more information, please visit [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 the potential safety or efficacy of BX004, the expected timing, of announcement of results of Part 2 of the Phase 1b/2a study and potential clinician and patient interest in the BX004 program, 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 29, 2023, 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.

**BiomX Contacts:**

Investor Relations:
LifeSci Advisors, LLC
John Mullaly
(617)-698-9253
jmullaly@lifesciadvisors.com

BiomX, Inc.
Anat Primovich
Corporate Project Manager
+972 (50) 697-7228
anatp@biomx.com

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