November 29, 2023

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

BX004 showed clinically meaningful improvement in pulmonary function as measured in FEV1[1] and Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain in a predefined subgroup of patients with reduced lung function[2]

Treatment with BX004 also achieved P. aeruginosa culture conversion to negative at end of 10 days of treatment in 3 patients (14%) versus none for placebo[3]

In a prespecified subgroup of patients on background use of continuous inhaled antibiotics, BX004 showed a 2.8 log_{10} CFU/g[1] reduction in P. aeruginosa burden at end of treatment versus placebo, exceeding Part 1 results

BX004 therapy was safe and well-tolerated

Plans to advance BX004 program into pivotal Phase 2b/3 trial

Company to host webcast/cc to discuss Part 2 data today at 9:00 am ET; Key Opinion Leader (KOL) event scheduled for December 4, 2023, at 12:00 pm ET

CAMBRIDGE, Mass. and NESS ZIONA, Israel, Nov. 29, 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 safety and efficacy results from 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").

"These study results are highly encouraging especially given the short treatment duration of 10 days with BX004," said Jonathan Solomon, Chief Executive Officer of BiomX. "In Part 2 of the study, BX004 showed clinically meaningful improvement in pulmonary function compared to placebo, as measured by relative FEV1[1] improvement (5.67% at Day 17, 1 week after end of treatment) and Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain (8.87 points at Day 17) in a predefined subgroup of patients with reduced lung function[2]."

“Reduction in *P. aeruginosa* bacterial burden was also observed. 3 of 21 (14%) BX004-treated patients converting to a negative *P. aeruginosa* sputum culture at end of treatment (Day 10) versus 0 of 10 (0%) in the placebo arm[3] – an impressive result considering that these three patients had *P. aeruginosa* lung infections for 10 years or longer and the short treatment duration,” 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 and former board member of the European Cystic Fibrosis Society. “Although there was variability in the mean *P. aeruginosa* levels in the entire study population, in a prespecified subgroup of patients on standard of care inhaled antibiotics on continuous regimen, at end of treatment (Day 10), the mean *P. aeruginosa* burden was reduced by 2.91 $\log_{10}$ CFU/g in the treatment group compared to 0.11 $\log_{10}$ CFU/g in those receiving placebo. This exceeded the reduction observed in Part 1 of the trial.”

Considering these results, the Company plans to advance the BX004 program to a larger, pivotal Phase 2b/3 trial, subject to regulatory feedback and availability of sufficient funding.

“This is truly a watershed moment, not only in the clinical development of phage therapy, but also for the entire CF community,” said Robert T. “Chip” Schooley, M.D., Distinguished Professor of Medicine, Division of Infectious Diseases and Global Public Health and Co-Director, Center for Innovative Phage Applications and Therapeutics at the University of California, San Diego. “This study provides compelling clinical evidence from a controlled, double blind, randomized clinical trial that administration of a phage-based therapy can potentially, in a short treatment period, result in a positive treatment effect in CF patients with chronic *P. aeruginosa* infections. These results take us one step closer toward bringing forward a new and effective phage-based treatment option that CF patients desperately need to address these deadly pulmonary infections, and I look forward to its continued clinical advancement.”

Summary of Part 2 Results

The objectives of Part 2 of the Phase 1b/2a trial were to evaluate the safety and tolerability of BX004 in a larger number of CF patients dosed for a longer treatment duration than Part 1 of the study, with the anticipation that the longer treatment might result in greater effects than in the Part 1. In Part 2, 34 CF patients received nebulized study drug twice daily for 10 days and were randomized in a 2:1 ratio with 23 CF patients receiving BX004 and 11 patients receiving placebo. Endpoints included safety and tolerability, decrease in *P. aeruginosa* burden, sputum pharmacokinetics, FEV1, CFQ-R (CF Questionnaire-Revised) and CFRSD-CRISS (Cystic Fibrosis Respiratory Symptom Diary - Chronic Respiratory Infection Symptom Score).

Similar to Part 1, patients enrolled in Part 2 were also on standard of care inhaled antibiotics, which included either continuous regimen (same antibiotic before, during, and after study drug), alternating regimen (alternating between two types of antibiotics every month) or cycling regimen (one month on / one month off). Patients were on the same inhaled antibiotic (tobramycin, aztreonam, or colistin) from Day 1-10 (treatment period) and through Day 28 of the study.

Highlights included:

- Study drug was safe and well-tolerated, with no related SAEs (serious adverse events)

or related APEs (acute pulmonary exacerbations) to study drug.

- BX004 vs. placebo showed a positive clinical effect in a predefined subgroup of patients with reduced baseline lung function (FEV1<70%). Difference between groups at Day 17: relative FEV1 improvement of 5.67% (change from baseline +1.46 vs. -4.21) and +8.87 points in CFQR respiratory symptom scale (change from baseline +2.52 vs. -6.35).
- In the BX004 arm, 3 out of 21 (14.3%) patients converted to sputum culture negative for *P. aeruginosa* after 10 days of treatment (including 2 patients after 4 days) compared to 0 out of 10 (0%) in the placebo arm[3].
- In full population, BX004 vs. placebo*P. aeruginosa* levels were more variable in sputum, potentially driven by the standard of care antibiotic treatment regimen. In a prespecified subgroup of patients on standard of care inhaled antibiotics on continuous regimen, BX004 vs. placebo reduced sputum *P. aeruginosa* levels at Day 10: difference in change from baseline between groups of -2.8 $\log_{10}$ CFU/g sputum (change from baseline -2.91 vs -0.11), exceeding Part 1 results.
- Alternating/cycling background antibiotic regimen likely associated with fluctuations in *P. aeruginosa* levels potentially confounding the ability to observe a*P. aeruginosa* reduction in this subgroup.
- During the study period, based on current available data, no evidence of treatment-related phage resistance was observed in patients treated with BX004 compared to placebo.

Today's Conference Call and Webcast Information
BiomX management will host a conference call and webcast today at 9:00 am ET to review the results of Part 2 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), or click on the webcast link here. A live and archived webcast of the call will also be available on the Investors section of the Company's website at www.biomx.com.

BiomX to Host Virtual Key Opinion Leader (KOL) Event – December 4, 2023
The Company has scheduled a virtual KOL Event to discuss results from Part 2 of the Phase 1b/2a trial. The event will take place on December 4, 2023, at 12:00 pm ET, and will include participation from BiomX senior management and two Key Opinion Leaders. Dr. Robert T. "Chip" Schooley, M.D., Distinguished Professor of Medicine, Division of Infectious Diseases and Global Public Health and Co-Director, Center for Innovative Phage Applications and Therapeutics at the University of California, San Diego, and Dr. 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 and former board member of the European Cystic Fibrosis Society. To register for the event, please click here.

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 to initiate a Phase 1b/2a study in CF patients with

chronic pulmonary infections caused by *P. aeruginosa*. The Phase 1b/2a trial was composed of two parts. Part 1 of the study 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 evaluated the safety and efficacy of BX004 in 34 CF patients randomized to treatment or placebo in a 2:1 ratio. In August 2023, the U.S. Food and Drug Administration granted BX004 Fast Track designation for the treatment of chronic pulmonary infections caused by *P. aeruginosa* 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, 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 safety, tolerability and efficacy of BX004 and its potential ability to treat CF patients, as well as the potential to advance the BX004 program to a larger, pivotal Phase 2b/3 trial, including, among other things, timing, design, enrollment, regulatory approvals and funding of such trial, 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. In addition, past and current pre-clinical and clinical results, as well as compassionate use, are not indicative and do not guarantee future success of BiomX clinical trials. 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.

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Source: BiomX Inc.

[1] FEV1 (or ppFEV1) – percent predicted forced expiratory volume in 1 second. CFU – colony-forming units
[2] Baseline FEV1<70%, predefined subgroup
[3] In patients that had quantitative CFU levels at study baseline

Source: BiomX