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BiomX to Present Positive Phase 1b/2a Clinical Trial Data for BX004 at the European Respiratory Society (ERS) Congress 2024

GAITHERSBURG, Md., Sept. 03, 2024 (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, announces the Company will present data from BiomX's Phase 1b/2a study of BX004 for the treatment of cystic fibrosis patients with chronic *Pseudomonas aeruginosa* pulmonary infections. The findings will be presented as a poster at the European Respiratory Society (ERS) Congress in Vienna, Austria taking place September 7-11, 2024. The poster will be presented on Monday, September 9, 2024, 8:00AM – 9:30AM local time, at Poster Session 234: "Navigating the journey of adult cystic fibrosis: past and future perspectives" (Room PS-21; Board Number 2, Poster ID 2341).

The poster, titled "Novel nebulized phage cocktail in CF patients with chronic *P. aeruginosa* pulmonary infection: a Ph1b/2a randomized, double-blind, placebo-controlled trial," reports that the Company's phage cocktail, BX004-A, demonstrated favorable safety and notable microbiologic and clinical efficacy in cystic fibrosis patients with chronic *P. aeruginosa* pulmonary infections, including in patients on standard of care treatment of elexacaftor / tezacaftor / ivacaftor (ETI). The poster will be available on the Company's website following the poster session.

"These data, which encapsulate our previously announced Phase 1b/2a study, continue to be encouraging and support our novel approach to treating cystic fibrosis. The European Respiratory Society is an important opportunity to share these results with the European scientific community, and we are grateful to share these positive data," commented Jonathan Solomon, BiomX Chief Executive Officer.

Abstract data shows initial results from the two-part study, which will be expanded upon in the poster. In the first part of the study, subjects receiving the BX004-A cocktail showed a greater reduction in *P. aeruginosa* (PsA) colony-forming units (CFU)/g of sputum at day 15 vs. baseline, compared to placebo. Importantly, in part two of the trial, 14% of subjects receiving BX004-A had a negative PsA sputum culture on day 10 (end of treatment), compared to placebo (0%)*. In addition, lung function, as measured by forced expiratory volume in 1 second (FEV1), increased in subjects receiving the cocktail (+5.66%) compared to placebo (-3.23%), in the subgroup on continuous inhaled antibiotics (same antibiotic with no cycling or alternating regimen), on ETI and with lower lung function (FEV1 <70%). Furthermore, phage was detected in the sputum of all BX004-A subjects, with no treatment-related phage resistance, and no serious adverse events during therapy. BiomX indicated the importance of a longer treatment period to assess enhanced activity.

About the European Respiratory Society
ERS is one of the leading medical organizations in the respiratory field, with a growing membership spanning over 160 countries. ERS prioritizes science, education and advocacy in order to promote lung health, alleviate suffering from disease and drive standards for respiratory medicine globally**.**

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 November 2023, BiomX announced positive topline results from Part 2 of the Phase 1b/2a trial where 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 expects to initiate a randomized, double blind, placebo-controlled, multi-center Phase 2b trial in CF patients with chronic *P. aeruginosa* pulmonary infections. The trial is designed to enroll approximately 60 patients randomized at a 2:1 ratio to BX004 or placebo. Treatment is expected to be administered via inhalation twice daily for a duration of 8 weeks. The trial is designed to monitor the safety and tolerability of BX004 and is designed to demonstrate improvement in microbiological reduction of *P. aeruginosa* burden and evaluation of effects on clinical parameters such as lung function measured by FEV1 and patient reported outcomes. Pending progress of the trial, results are expected in the third quarter 2025. The U.S. Food and Drug Administration ("FDA") has granted BX004 Fast Track designation and Orphan Drug Designation.

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 discusses the expected timing and results of clinical trials and the potential efficacy and benefits of BX004, 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. 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, as a result of various important factors, including BiomX's ability to regain compliance with the listing standards set forth in the NYSE American Company Guide; 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; 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. 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. 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 April 4, 2024, 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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