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BiomX to Provide Latest Update on Positive Phase 1b/2a Clinical Trial Data for BX004 at the North American Cystic Fibrosis Conference

GAITHERSBURG, Md., Sept. 18, 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 further 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 in two sessions at the North American Cystic Fibrosis Conference in Boston. First, a poster titled "Safety and efficacy of nebulized phage in CF patients with chronic *Pseudomonas aeruginosa* pulmonary infection: A phase 1b/2a randomized, double-blind placebo-controlled, multicenter study" will be displayed with lead author present on Friday, September 27, 2024, 1:15-2:15 PM ET. The poster will be available on the Company's website following the end of the poster session. On Saturday, September 28, 2024, Urania Rappo, MD (Senior Director of Clinical Development at BiomX) will discuss the findings in Workshop 38 "Epidemiology & Management of Infection in CF" from 10:15 AM to 12:15 PM ET, Room 257AB.

"Our Phase 1b/2a trial continues to garner strong support among the scientific community. It is particularly important that these findings are recognized at the prestigious North American Cystic Fibrosis Conference, which is the premiere scientific event in the field. We look forward to connecting with the strong CF community of researchers, advocates and patients at the event, and to discussing these findings and our path forward in more detail," commented Jonathan Solomon, BiomX Chief Executive Officer.

Study data shows results from the two-part study where in Part 1, 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 2 of the trial, in subjects with quantitative sputum PsA CFU at baseline, 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 elexacaftor / tezacaftor / ivacaftor (ETI) and with lower lung function (FEV1 <70%). As of these data being presented, all study subjects have completed the six-month follow up.

About the North American Cystic Fibrosis Conference

NACFC provides a collaborative and educational forum for all CF professionals. The educational elements of the meeting program are targeted to physicians, nurses, research scientists, respiratory therapists, physical therapists, nutritionists, social workers, and pharmacists.

This annual meeting brings together scientists, clinicians, and caregivers from around the world to discuss and share ideas on the latest advances in CF research, care, and drug development and to exchange ideas about ways to improve the health and quality of life for people with CF.

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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