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BiomX Receives Orphan Drug Designation from the U.S. Food and Drug Administration for BX004 for the Treatment of Chronic Pulmonary Infection Caused by Pseudomonas aeruginosa in Patients with Cystic Fibrosis

CAMBRIDGE, Mass. and NESS ZIONA, Israel, Jan. 04, 2024 (GLOBE NEWSWIRE) -- BiomX Inc. (NYSE American: PHGE) ("BiomX"), a clinical-stage company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today announced that its phage cocktail, BX004, has been granted Orphan Drug Designation ("ODD") by the United States Food and Drug Administration ("FDA"), for the treatment of chronic pulmonary infection caused by *Pseudomonas aeruginosa* (or *P. aeruginosa*) in patients with cystic fibrosis ("CF"). As a reminder, in August 2023, the FDA granted BX004 Fast Track designation for the treatment of chronic pulmonary infections caused by *P. aeruginosa* bacterial strains in patients with CF.

"We are pleased to announce that the FDA has granted BX004 Orphan Drug Designation, which underscores the pressing need to develop new and innovative treatment options for this vulnerable patient population," said Jonathan Solomon, Chief Executive Officer of BiomX. "Persistent and deadly pulmonary infections from *P. aeruginosa*remain a major source of morbidity and mortality for CF patients, andBX004 has been designed to address this significant unmet need. Based upon positive topline results observed in our Phase 1b/2a trial, we believe BX004 holds significant potential to improve upon the current standard of care, and we look forward to working with the FDA to further advance the clinical development of BX004."

About Orphan Drug Designation (ODD)
An orphan drug is defined in the 1984 amendments of the U.S. Orphan Drug Act (ODA) as a drug intended to treat a condition affecting fewer than 200,000 persons in the United States. Orphan designation qualifies the sponsor of the product for seven-year marketing exclusivity to the first sponsor obtaining FDA approval of a designated drug, a tax credit equal to 50% of clinical investigation expenses, exemption/waiver of the Prescription Drug User Fee Act (PDUFA) application filing fees, assistance in the drug development process, and Orphan Products Grant funding eligibility.[1]

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

FDA 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. Positive topline results from Part 2 of the study were announced on November 29, 2023. In August 2023, the FDA 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, if such trial is initiated, 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.

[1] Source: https://www.fda.gov/media/83372/download

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