BiomX Provides Update on BX004 Phase 2b Trial for the Treatment of Patients with Cystic Fibrosis

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U.S. FDA has placed a clinical hold on the Phase 2b study as it reviews data submitted by BiomX on third-party nebulizer used to deliver BX004; no concerns were raised in the clinical hold notification regarding the BX004 drug candidate

Enrollment and dosing of patients outside the US is continuing in accordance with protocol

NESS ZIONA, Israel, Aug. 19, 2025 (GLOBE NEWSWIRE) -- BiomX Inc. (NYSE American: PHGE) ("BiomX" or the "Company"), a clinical-stage company advancing novel natural and engineered phage therapies targeting specific pathogenic bacteria, today announced that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on the Phase 2b trial of BX004 for the treatment of patients with cystic fibrosis (CF).

In its notification, the FDA solely focused on the third-party nebulizer device utilized to deliver BX004. The BX004 drug product candidate has already been reviewed by the FDA and has been cleared for clinical investigational use with no concerns indicated to BiomX. Following the FDA's hold notification, which the company believes to be temporary, BiomX promptly submitted the additional requested data which was generated independently by the well-established manufacturer of the nebulizer device, and this data is expected to provide the information required by the FDA to lift the hold. As a result of the FDA's notification, patient screening and enrollment in the U.S. portion of the Phase 2b trial of BX004 have now been paused. In Europe, all components of the third-party nebulizer device are CE marked and thus have been deemed to meet applicable regulatory requirements. The study in the EU has been approved and enrollment and dosing of patients is continuing in accordance with the protocol.

"We are actively engaged with the FDA to promptly address their queries regarding the third-party nebulizer," said Jonathan Solomon, Chief Executive Officer of BiomX. "Importantly, the FDA's notification relates solely to the nebulizer, and we remain optimistic and confident that in response to the hold, we have provided the FDA with data that can satisfactorily support the use of the nebulizer and that this can be resolved promptly so that we may resume treating patients with cystic fibrosis in the U.S., BiomX remains committed to providing timely updates and full transparency to patients, physicians, and investors as the situation develops."

About BX004
BiomX is developing BX004, a fixed multi-phage cocktail, for the treatment of CF patients with chronic pulmonary infections caused by *Pseudomonas aeruginosa* (*P. aeruginosa*), a main contributor to morbidity and mortality in patients with CF. In February 2023, BiomX announced positive results from Part 1 of the Phase 1b/2a study, showing safety, tolerability, and microbiologic activity. In November 2023, BiomX announced positive topline results from Part 2 of the Phase 1b/2a trial, in which 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%). Pending resolution of the clinical hold imposed by the FDA, BiomX is expects to enroll up to approximately 60 patients in a randomized, double blind, placebo-controlled, multi-center Phase 2b trial of BX004 in CF patients with chronic *P. aeruginosa* lung infections. The 8-week study will assess lung function, bacterial load, and quality of life metrics. BX004 has received U.S. FDA Fast Track and Orphan Drug Designations.

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 refers to the clinical hold imposed by the FDA, the possibility that the data BiomX provided will allow the FDA to lift such clinical hold, that such clinical hold will be lifted soon, if at all, the timing, process and potential outcomes of review and other measures by the European regulatory authorities, resumption of patient enrollment and timing thereof and the impact of the FDA clinical hold on the BX004 Phase 2b trial, 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. 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. These risks and uncertainties include, but are not limited to, 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; decisions made by 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. 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 25, 2025, 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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