BiomX Announces Positive FDA Feedback Supporting Next-Generation Phage Cocktail Program for Diabetic Foot Infections

November 4, 2025

New FDA feedback confirms clinical pathway for fixed multi-phage cocktail BX011, expanding development into diabetic foot infections (DFI) and unlocking a major commercial opportunity

NESS ZIONA, Israel, Nov. 04, 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 it has received positive feedback from the U.S. Food and Drug Administration (FDA) on the proposed clinical developmental pathway for BX011, a next-generation fixed multi-phage cocktail targeting *Staphylococcus aureus (S. aureus)* in diabetic foot infections (DFI).

FDA feedback supports BiomX's plan to advance its phage-based therapy into DFI as the next clinical indication, following the Company's previous Phase 2 study of BX211, a phage product for the treatment of diabetic foot osteomyelitis (DFO) caused by *S. aureus*. The decision to focus on DFI reflects three key factors: a broader patient population with a significant unmet medical need, a large commercial opportunity, and a clear regulatory path supported by established FDA guidance. The two indications share the same *S. aureus* pathogen, making DFI the appropriate initial indication for regulatory approval prior to potential development in DFO.

The new formulation, BX011, includes multiple proprietary phages, among them phage previously evaluated in the BX211 study. BiomX's development of phage therapies for *S. aureus* has been supported by approximately $40 million in non-dilutive funding from the U.S. DHA and Department of Navy funding under an Other Transaction Authority (OTA) award through the Medical Technology Enterprise Consortium (MTEC) and managed by the Naval Medical Research Command (NMRC) – Naval Advanced Medical Development (NAMD). BX011's advancement will continue in alignment with ongoing discussions with the U.S. Defense Health Agency (DHA) and subject to the availability of necessary financial resources, with plans to initiate a Phase 2a clinical trial in DFI.

The FDA provided detailed guidance supporting a path toward a potential Biologics License Application (BLA). No additional non-clinical studies are expected, and the FDA's comments on Chemistry, Manufacturing, and Controls (CMC) are consistent with BiomX's existing manufacturing and quality strategy. The feedback confirms that the BX011 development plan is in accordance with current FDA guidance for DFI product development.

"By targeting what is usually an earlier stage of disease, where infection remains in the ulcer rather than progressing to the bone, we aim to reach a broader patient population and maximize both the commercial and therapeutic impact of our program" said Jonathan Solomon, Chief Executive Officer of BiomX. "The FDA's comments reinforce our goal of bringing phage therapy into mainstream infectious disease care."

In March 2025, BiomX reported statistically significant positive topline results from its Phase 2 BX211 trial targeting *S. aureus* in DFO. BX211 was safe and well tolerated, achieving significant and sustained reductions in ulcer size, with a clear separation from placebo starting at week 7, and improvements in ulcer depth observed at week 13. All patients received standard of care, including systemic antibiotic therapy, throughout the 12-week treatment period.

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 potential benefits of BX011, the next steps in development of BX011, the potential of this product candidate, including BLA, any need for additional non-clinical studies or other actions before clinical trial (if such trials are initiated at all), future compliance of the development of BX011 with FDA guidance, discussions with the DHA and sufficiency of financing resources, 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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Source: BiomX Inc