March 31, 2025

BiomX Announces Positive Topline Results from Phase 2 Trial Evaluating BX211 for the Treatment of Diabetic Foot Osteomyelitis (DFO)

- *BX211 was safe and well-tolerated*
- *BX211 produced sustained and statistically significant[1] Percent Area Reduction (PAR) of ulcer size* (p = 0.046 at week 12; p=0.052 at week 13)*, with a separation from placebo starting at week 7 and a difference greater than 40% by week 10*
- *Compared to placebo, BX211 also produced statistically significant[1] improvements in both ulcer depth at week 13 (in patients with ulcer depth defined as bone at baseline) (p=0.048), and in reducing the expansion of ulcer area (p=0.017).*
- *BiomX is planning for a Phase 2/3 trial of BX211, pending U.S. Food and Drug Administration (FDA) feedback*

The Company will host a conference call and webcast today at 9:00 AM ET, followed by a Key Opinion Leader (KOL) event on April 3, 2025, at 11:00 AM ET to discuss the results

NESS ZIONA, Israel, March 31, 2025 (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, today announced positive, topline safety and efficacy results from the Company’s DFO Adaptive Novel Care Evaluation (DANCE™) Phase 2 trial evaluating its BX211 phage treatment for DFO associated with *Staphylococcus aureus* (*S. aureus*). The findings demonstrated BX211 to be safe and well-tolerated and that patients receiving BX211 exhibited statistically significant[1] and sustained reduction of ulcer size (PAR) (p = 0.046 at week 12; p=0.052 at week 13), with a separation from placebo starting at week 7 and a difference greater than 40% by week 10. In addition, BX211 also produced statistically significant[1] improvements in both ulcer depth at week 13 (in patients with ulcer depth defined as bone at baseline, ulcer depth was classified according to deepest tissue involved as measured by swab) (p=0.048), and in reducing the expansion of ulcer area (p=0.017). Over the 12-week treatment period, all patients (treatment and placebo) were treated in accordance with standard of care, including with systemic antibiotic therapy as appropriate. Following the successful Phase 2 readout of BX211, the Company is planning for a Phase 2/3 trial, pending discussions and feedback from the U.S Food and Drug Administration.

"We believe these data represent one of the strongest demonstrations to date of the therapeutic potential of phage therapy. We are grateful to all the patients who participated, and the treating teams who enrolled patients into the study, as well as the continued and ongoing support from the U.S. Defense Health Agency (DHA) for this program,” said Jonathan Solomon, BiomX’s Chief Executive Officer. “Today, 30-40% of DFO cases lead to

lower extremity amputations related to serious bacterial infections, accounting for the majority of the 160,000 lower limb amputations in diabetic patients each year in the United States. Based on the results announced today, we believe BiomX's novel phage therapy approach has the potential to help address the major unmet need in DFO. Moreover, in an era of modern conflict and rising antibiotic-resistant wounds, the need for innovative wound care solutions underscores the broader relevance of this program beyond DFO. BiomX is dedicated to the advancement of phage therapy, which we believe holds promise in redefining the treatment of chronic infections."

"Phage therapy has a critical role to play in treating infections where antibiotic resistance has emerged or existing treatments have underperformed," said Dr. Robert T. "Chip" Schooley, M.D., Distinguished Professor of Medicine, Division of Infectious Diseases and Global Public Health and Co-Director, Center for Innovative Phage Applications and Therapeutics at the University of California, San Diego. "The promising topline data in this trial provide an important inflection point for this approach and its potential to address the most challenging infections."

"Diabetic foot infections are often a complex and difficult-to-treat consequence of diabetes, leading to serious adverse effects on patient quality of life," said Dr. Benjamin A. Lipsky, M.D., FACP, FIDSA, FRCP (London), FRCPS (Glasgow), Professor of Medicine Emeritus at University of Washington, Seattle. "The most serious and feared complication of DFO is lower extremity amputation, which is associated with a five-year mortality rate of about 50%. With the progress seen so far and given the improved ulcer healing seen in this study, BX211 may have the potential to reduce amputations. BX211 is a program to watch closely as it progresses into more advanced clinical studies."

Summary of Phase 2 BX211 Results

BiomX's Phase 2 trial is a randomized, double-blind, placebo-controlled, multi-center study investigating the safety, tolerability, and efficacy of BX211 for individuals with DFO associated with *S. aureus*. The study enrolled a total of 41 patients randomized for treatment at a 2:1 ratio, 26 of whom received intravenous (IV) and topical administration of BX211 on week 1 followed by a topical weekly dose through week 12, while 15 patients were assigned to the placebo arm. Over the 12-week treatment period, all subjects (treatment and placebo) were also treated in accordance with standard of care, including with systemic antibiotic therapy as appropriate. A readout of study results at week 13 evaluated healing of the wound associated with osteomyelitis. The primary efficacy endpoint was PAR of study ulcer through week 13. Study design was guided in part by experience with numerous compassionate cases using phage therapy for the treatment of DFO and osteomyelitis.

The topline Phase 2 results included:

- *BX211 was found to be safe and well-tolerated.*
- *BX211 produced sustained and statistically significant[1] PAR of ulcer size (*p = 0.046 at week 12; p=0.052 at week 13*), with a separation from placebo (standard of care) starting at week 7 and a difference greater than 40% by week 10.*
- *BX211 produced statistically significant[1] improvements in both ulcer depth at week 13 (in patients with ulcer depth defined as bone at baseline) (p=0.048), and in reducing the expansion of ulcer area (p=0.017), compared to placebo.*

- *BX211 demonstrated favorable trends compared to placebo across several additional clinical parameters, including: proportion of visits with no clinical evidence of infection; evidence of resolving DFO by MRI/X-ray at week 12; proportion of patients with abnormal C-Reactive Protein at baseline that achieved a reduction of CRP of at least 50% at any point in the study; and greater Wagner scale improvement[2].*
- *Through week 13, BX211 demonstrated comparable efficacy against both Methicillin-susceptible and resistant strains, as well as against high and low biofilm producers—consistent with the orthogonal mechanism of phage therapy to antibiotics and its inherent anti-biofilm capabilities.*

BiomX expects to present additional data from the Phase 2 study at upcoming scientific conferences.

Today's Conference Call and Webcast Information
BiomX management will host a conference call and webcast today at 9:00 AM ET to review the topline Phase 2 trial results, accompanied by a slide deck presentation, which will be available on the Company's website and filed via Form 8-K. To participate in the conference, please dial +877-407-0724 (U.S.), or +1 201-389-0898 (International), or click on the webcast link here.

A live and archived webcast of the call will also be available on the Investors section of the Company's website at www.biomx.com.

BiomX to Host Virtual KOL Event – April 3, 2025
The Company has scheduled a virtual KOL Event to discuss the topline results from the Phase 2 trial. The event will take place on April 3, 2025, at 11:00 am ET, and will include participation from BiomX senior management and two KOLs, Dr. Robert T. "Chip" Schooley, M.D., Distinguished Professor of Medicine, Division of Infectious Diseases and Global Public Health and Co-Director, Center for Innovative Phage Applications and Therapeutics at the University of California, San Diego, and Dr. Benjamin A. Lipsky, M.D., FIDSA, FRCP (London), FRCPS (Glasgow) Professor of Medicine Emeritus at University of Washington, Seattle. To register for the event, please click here.

About BX211
BX211 is a phage treatment for the treatment of DFO associated with *S. aureus*. DFO is a bacterial infection of the bone that usually develops from an infected foot ulcer and is a leading cause of amputation in patients with diabetes. Pending feedback from the FDA, BiomX is planning for a Phase 2/3 clinical trial of BX211.

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 safety and toleration of BX211, the potential benefits of BX211, future clinical development of BX211 and the relevance and potential of phage therapy in the treatment of chronic infections, 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; 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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[1] All p-values described in this release are non-adjusted

[2] The Wagner Scale is a clinical grading system used to classify the severity of diabetic foot ulcers, ranging from 0 (intact skin) to 5 (extensive gangrene).

Source: BiomX