

# BiomX Announces Publication in *Cell of Research Demonstrating Proof-of-*Concept Assessment of Orally Administered Phage Treatment in Preclinical Model of Inflammatory Bowel Disease

Provides Further Rationale for BiomX's BX003 Phage Candidate Targeting Klebsiella Pneumoniae for Treatment of IBD

Positive Results Also Demonstrated in a First-in-Human Randomized, Single-Blinded, Placebo-Controlled
Clinical Trial

**BRANFORD, Conn.** and **NESS ZIONA, Israel** – **August 4, 2022** – BiomX Inc. (NYSE American: PHGE) ("BiomX"), a clinical-stage microbiome company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today announced the publication of a scientific paper titled "**Targeted suppression of human IBD-associated gut microbiota commensals by phage consortia for treatment of intestinal inflammation**" in the journal, *Cell*. The research was conducted across several organizations, including scientists from BiomX and the Weizmann Institute of Science (Rehovot, Israel).

This research is based on prior work by Prof. Honda et al. from Keio University (Tokyo, Japan) identifying strains of *Klebsiella pneumoniae* ("Kp") as potentially disease-causing bacteria in IBD. Looking across four geographically distinct IBD cohorts (n=537), researchers identified a clade of *Kp* strains, featuring a unique antibiotics-resistance and mobilome signature that were strongly associated with IBD disease exacerbation and severity. These strains were then transferred into colitis-prone germ-free and colonized mice to enhance intestinal inflammation. Researchers then demonstrated proof-of-concept assessment of Kp-targeting phages by generating an orally administered, lytic 5-phage combination product specifically designed to target sensitive and resistant IBD-associated Kp clade members through distinct mechanisms. The lytic 5-phage treatment enabled effective Kp suppression in the colitis-prone mice and drove attenuated inflammation and disease severity.

Furthermore, the research initially tested Kp-targeting phage in an *ex-vivo* human gut system and then in a first-in-human, randomized, single-blinded, placebo-controlled clinical trial. Both phage therapies were stable, withstanding shifting biophysical conditions along the human gastrointestinal tract, resulting in accumulation of viable phages in doses expected to enable Kp2 suppression in IBD patients.

IBD is a chronic, inflammatory autoimmune disease impacting the gastrointestinal tract, and the bacteria, *Klebsiella pneumoniae*, has been implicated in the pathogenesis of the disease. BiomX's novel phage candidate, BX003, targets bacterial strains of Kp present in the gut of IBD and primary sclerosing cholangitis ("PSC") patients. As outlined in the research, results from Phase 1a study demonstrated safety and tolerability of the administered phages as well as successful delivery of a high concentration of viable phage to the lower gastrointestinal tract, in alignment with data generated in a human-gut like system.

"We are very pleased to announce the publication of these validating research findings in one of the world's leading scientific publications," said Prof. Eran Elinav, M.D, of the Weizmann Institute and Co-Scientific Founder of BiomX. "This research not only supports our BX003 program in IBD, which also



targets Kp bacteria, but also demonstrates how industry and leading academic researchers can effectively collaborate to help drive new treatment approaches for difficult-to-treat diseases."

### **About BX003**

BX003 is an orally administered phage cocktail targeting a bacterial target present in the gut of IBD and PSC patients and thought to be associated with the onset or exacerbation of these diseases. Although different organs are affected in IBD and PSC (gut in IBD and liver in PSC) the two diseases are thought to be related since approximately 70% of PSC patients also suffer from IBD. Results from a pharmacokinetic and safety Phase 1a study demonstrated safety and tolerability with successful delivery of a high concentration of viable phage to the lower gastrointestinal tract. Currently, the development efforts on BX003 are temporarily paused.

### **About BiomX**

BiomX is a clinical-stage microbiome 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.

Additional information is available at 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 potential ability of BX003 to target bacterial strains of Kp, as well as resumption of the development efforts in BX003, timing thereof and any potential results in future clinical trials of BX003, 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. 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 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 30, 2022 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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