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# **BiomX Announces Positive Results of a Phase 1a Pharmacokinetic Study for Inflammatory Bowel Disease/Primary Sclerosing Cholangitis (IBD/PSC) Evaluating Delivery of Oral BX002 Phage Therapy**

- *BX002 demonstrated safety and tolerability with successful delivery of a high concentration of viable phage to the lower gastrointestinal tract -*
- *First clinical study detailing pharmacokinetics of oral phage therapy under a U.S. FDA IND protocol -*
- *Efficacy results in reduction of target bacteria expected by mid-2022 from planned Phase 1b/2a study -*

NESS ZIONA, Israel--(BUSINESS WIRE)-- BiomX Inc. (NYSE American: PHGE), a clinical stage company developing natural and engineered phage therapies that target specific pathogenic bacteria, today announced positive results of a first-in-human Phase 1a pharmacokinetic study of BX002. BX002 is BiomX's orally administered phage therapy candidate targeting *Klebsiella pneumoniae* (*K. pneumoniae*) bacteria in the gut, which have been linked to the pathogenesis of both inflammatory bowel disease (IBD) and primary sclerosing cholangitis (PSC). In the Phase 1a study, BX002 was demonstrated to be safe and well-tolerated, with no serious adverse events and no adverse events leading to discontinuation. In addition, the study met its objective of delivering high concentrations of viable phage to the gastrointestinal tract of approximately  $10^{10}$  PFU (plaque forming units). This equals approximately 1,000 times more viable phage compared to the bacterial burden of *K. pneumoniae* in IBD and PSC patients as measured in stool.

“Successful oral delivery of phage therapy, which to our knowledge has now been demonstrated rigorously in a clinical study for the first time, has the potential to open up a broad range of oral phage therapy applications,” commented Timothy K. Lu, M.D., Ph.D., BiomX scientific co-founder, Associate Professor of Biological Engineering, Electrical Engineering and Computer Science, and head of the Synthetic Biology Group in the Research Laboratory of Electronics, at the Massachusetts Institute of Technology. “The results show excellent safety, as expected, and the pharmacokinetics demonstrate the potential to orally administer phage in a quantity sufficient to address the gut bacterial burden of *K. pneumoniae* in IBD and PSC patients. In addition, these highly encouraging results highlight the strengths of the BiomX discovery and manufacturing platform and the extremely broad potential of phage technology for addressing challenges in human health.”

Based on the Phase 1a study results, BiomX plans to advance to a Phase 1b/2a study evaluating the efficacy of BX003 for the reduction of *K. pneumoniae* in individuals that carry the target bacteria. In November 2020, BiomX announced the consolidation of its IBD and PSC programs to develop one product candidate with a broad host range for both indications, designated BX003. Results from the Phase 1b/2a study are expected by mid-2022.

The randomized, single-blind, multiple-dose, placebo-controlled Phase 1a pharmacokinetic study was conducted under an investigational new drug (IND) application approved by the U.S. Food and Drug Administration. The study evaluated the safety and tolerability of orally administered BX002 in 18 healthy volunteers. Subjects were randomized to receive orally either BX002 (n=14) or placebo (n=4), twice daily for three days. Subjects were monitored for safety for seven days in a clinical unit, with follow-up for safety assessments done at 14 and 28 days after completion of dosing. Viable phage were detected at high concentrations in samples from all subjects in the BX002 group, compared to no detected levels prior to treatment.

## **About BiomX**

BiomX is a clinical-stage biotechnology company developing both natural and engineered phage cocktails designed to target and destroy bacteria that affect the appearance of skin, as well as target bacteria in the treatment of chronic diseases, such as inflammatory bowel disease, primary sclerosing cholangitis, cystic fibrosis and colorectal cancer. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.

Additional information is available at [www.biomx.com](http://www.biomx.com), the content of which does not form a part of this press release.

## **Safe Harbor Language**

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 and tolerability of its phage therapy, the conducting and timing of its expected Phase 1b/2a study, and its phage therapy having the potential to address bacteria broad range of oral phage therapy applications, including IBD and PSC, and other challenges in human health, 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 Current Report on Form 8-K filed with the Securities and Exchange Commission (the “SEC”) on December 4, 2020 and additional disclosures BiomX makes in its filings with

the SEC, which are available on the SEC's website at [www.sec.gov](http://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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