

BiomX Presents Preclinical Results of its Phage Therapy Program Targeting Primary Sclerosing Cholangitis

- *Data presented at the presidential plenary translational session of the AASLD conference*
- *Results demonstrate in vivo use of a phage cocktail effectively eradicated a bacterial target hypothesized as a disease modifying target in Primary Sclerosing Cholangitis (PSC)*
- *Analysis of PSC patient cohorts further reveals that abundance of the bacterial target is associated with disease severity and duration*

NESS ZIONA, Israel--(BUSINESS WIRE)-- [BiomX Inc.](#) (NYSE: PHGE), a clinical-stage company developing both natural and engineered phage therapies, today presents new data from the company's *Primary Sclerosing Cholangitis* (PSC) program at the American Association for the Study of Liver Disease (AASLD) Conference in Boston.

In the study, BiomX researchers identified and characterized phages targeting pathogenic bacterial strains that are hypothesized as disease modifying in PSC, a rare progressive liver disorder with no FDA-approved treatment, affecting approximately 30,000 patients in the US. The target bacterial strains of *Klebsiella pneumoniae* (Kp) were isolated from the stool of patients with PSC and were previously shown to induce a Th17 inflammatory response in the liver and to disrupt the intestinal epithelial barrier in mice¹. Gut permeability ("leaky gut") may lead to microbial infection of bile, resulting in inflammation and fibrosis within the liver of PSC patients, suggesting that Kp may serve as a therapeutic target for phage therapy.

In the study presented today, cohort analyses based on metagenomic sequencing of stool samples collected from over 350 PSC patients and healthy controls from three countries, revealed that the prevalence and abundance of the target bacteria is higher in PSC patients compared to healthy controls, and that abundance is associated with disease severity (positively correlated with advanced liver fibrosis) and longer disease duration. BiomX researchers further conducted phage hunting efforts resulting in over 20 phages, from which over a 100 combinations (cocktails) were designed and compared for their ability to effectively eradicate Kp *in vitro*. This process allowed for the selection of a phage cocktail that was able to substantially reduce bacterial burden of the target Kp strains *in vivo* by over 3 orders of magnitude, while also efficiently limiting the emergence of mutant bacteria with resistance to the cocktail.

"We believe that phage therapy holds promise for the treatment of patients with PSC, who are in dire need of novel therapeutic approaches to this disease for which there are presently no satisfactory treatments," said Jonathan Solomon, BiomX's CEO. "We are encouraged by these results and are committed to continue moving this program forward to clinical trials, planned for the first half of 2021."

PSC is characterized by inflammation and fibrosis within the bile ducts. Scarring of the liver, or cirrhosis, eventually develops and many patients ultimately require a liver transplant. Recent studies suggest linkage between the microbiome and PSC, especially given that compromises in the intestinal barrier caused by alterations in the microbiome may expose the bile ducts and liver to altered levels of bacteria and their products, which may trigger aberrant inflammatory responses.

Safe Harbor Language

This press release contains certain “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. 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 our control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. You should review additional disclosures we make in our filings with the Securities and Exchange Commission (the “SEC”), which are available on the SEC’s website at www.sec.gov.

About BiomX

BiomX is a clinical-stage company developing both natural and engineered phage cocktails designed to target and destroy bacteria that affect the appearance of skin, as well as harmful bacteria in chronic diseases, such as IBD, PSC, and cancer. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.
www.biomx.com

¹ Nakamoto *et al.* Nature Microbiology, 2019

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