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BiomX Announces Positive Topline Data from Phase 1 Study for Lead Candidate BX001 for Acne-Prone Skin

BX001 demonstrates excellent safety, tolerability, and a statistically significant reduction of C. acnes levels on skin

Company to host conference call at 8:00 a.m. Eastern Time (U.S.)

NESS ZIONA, Israel--(BUSINESS WIRE)-- BiomX Inc. (NYSE:PHGE), a clinical-stage company developing both natural and engineered phage therapies that target specific pathogenic bacteria, today announced positive topline results from its Phase 1 cosmetic clinical study of BX001 in subjects with acne-prone skin. The study met its primary endpoint of safety and tolerability for both doses of BX001, as well as a statistically significant ($p=0.036$) reduction of *Cutibacterium acnes* (*C. acnes*) levels for the high dose of BX001 compared to placebo. *C. acnes* are bacteria implicated in the pathophysiology of acne vulgaris.

"We are excited to announce positive data demonstrating for the first time that this topically applied phage cocktail, developed through our proprietary discovery platform, showed activity against a bacterial target and was able to demonstrate a statistically significant reduction in *C. acnes* levels on the skin in a safe and tolerable manner. These results warrant advancing the program to a Phase 2 study," said Jonathan Solomon, CEO of BiomX. "We are carrying out additional analyses on the BX001 clinical data, as well as evaluating the implications of the ongoing Covid-19 pandemic on our clinical development timelines, and intend to provide an update on the timing of the Phase 2 trial when we report our first quarter 2020 financial results."

BX001 is a topical gel comprised of a cocktail of naturally-occurring phage targeting *C. acnes* to improve the appearance of acne-prone skin. Following application of the gel once daily for four weeks, measurement of *C. acnes* levels using qPCR showed a statistically significant reduction of *C. acnes* levels in the high dose cohort of BX001 compared to placebo ($p=0.036$) at week five (one week after end of treatment), the final study time point. At this time point, a 0.12 log reduction, which translates to a 24% reduction in *C. acnes* levels, was observed in the high dose cohort compared to baseline, while a 0.1 log increase, which translates to a 26% increase from baseline, was observed in the placebo cohort. As anticipated for a relatively short-duration study of four weeks, exploratory endpoints measuring reductions in inflammatory and non-inflammatory lesions were not statistically significant versus placebo. The planned Phase 2 trial will have a 12-week duration similar to most acne studies and will be powered to demonstrate a clinical effect.

The Phase 1 cosmetic clinical study was a four-week randomized, double-blind, dose-finding, placebo-controlled single center trial which enrolled 75 individuals with mild-to-

moderate acne. Enrolled individuals were randomized into one of three cohorts: a high dose cohort, a low dose cohort, and a placebo cohort (vehicle).

The Phase 2 cosmetic clinical study is planned to be a 12-week randomized, double-blind, placebo-controlled trial in 100 individuals with mild-to-moderate acne. Enrolled individuals will be randomized into one of two cohorts: BX001 or placebo (vehicle).

Conference Call Details

BiomX management will host an investor conference call today at 8:00 a.m. ET to discuss the BX001 Phase 1 results. The conference call may be accessed by dialing 1-877-270-2148 for participants based in the United States, or 1-412-902-6510 for participants based outside the United States, and asking to be joined into the BiomX, Inc. call. A live webcast of the call will be available on the Investors section of the BiomX [website](#) and a replay will be available after its completion.

About Phage

Bacteriophage, or phage, are viruses that target bacteria and are considered inert to mammalian cells. Phage are designed to target and kill specific bacterial species or strains without disrupting other bacteria or the healthy microbiota. All of BiomX's phage-based product candidates derive from its proprietary platform, which is first used to discover and validate the association and biologic rationale of specific bacterial strains with human diseases or conditions, and is then used to develop rationally-designed phage combinations ("cocktails") of naturally occurring or synthetic phage to target pathogenic bacteria. The phage cocktails contain multiple phage with complementary functions optimized through in vitro and in vivo testing.

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 harmful bacteria in chronic diseases, such as inflammatory bowel disease (IBD), primary sclerosing cholangitis (PSC), and colorectal cancer (CRC). BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.

www.biomx.com

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.

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