BiomX Announces Dosing of First Subject in Phase 2 Study of BX001 for Acne-Prone Skin

- Interim data readout expected in the third quarter of 2021 -

NESS ZIONA, Israel--(BUSINESS WIRE)-- BiomX Inc. (NYSE American: PHGE), a clinical-stage company developing both natural and engineered phage therapies that target specific pathogenic bacteria, today announced that the first subject has been dosed in a Phase 2 cosmetic clinical study of BX001 in subjects with mild-to-moderate acne. BX001 is a topical gel comprised of a cocktail of naturally-occurring phage targeting *Cutibacterium acnes* (*C. acnes*). *C. acnes* are bacteria implicated in the pathophysiology of acne vulgaris. The aim of the study is to provide clinically meaningful improvement of the appearance of acne-prone skin.

“The initiation of this study with BX001 marks an important inflection point in the Company’s growth as this is our first Phase 2 clinical study,” said Jonathan Solomon, Chief Executive Officer of BiomX. “We are encouraged by our prior positive Phase 1 results, in which the BX001 phage cocktail demonstrated a statistically significant reduction of *C. acnes* levels compared to placebo. This Phase 2 trial of BX001 will evaluate a larger number of subjects with acne-prone skin over 8 to 12 weeks, a duration common in Phase 2 acne studies, with the intention of observing a clinically meaningful effect.”

The Phase 2 cosmetic clinical study is a 12-week randomized, single center, double-blind, placebo-controlled trial in 140 individuals with mild-to-moderate acne vulgaris. Subjects enrolled will be randomized into two cohorts: BX001 or placebo (vehicle) in a 1:1 ratio and will self-administer BX001 or placebo twice daily. The key endpoints will evaluate the safety, tolerability and efficacy of BX001. The specific efficacy parameters include the measurements of inflammatory and non-inflammatory lesions, Investigator’s Global Assessment (IGA) score and reduction of *C. acnes* bacterial levels on skin. Results from the 8-week time point are expected to be available in the third quarter of 2021 and full analysis including the 12-week time point is expected to be available in the fourth quarter of 2021.

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 target bacteria in the treatment of chronic diseases, such as inflammatory bowel disease, primary sclerosing cholangitis, cystic fibrosis, atopic dermatitis 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 design, aim and expected timing of interim and final results of its Phase 2 clinical trial in acne and the potential of its product candidates, 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 Securities and Exchange Commission (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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