Bio-Path Holdings Announces First Patient Dosed in Phase 1/1b Clinical Trial of BP1001-A in Solid Tumors

Phase 1/1b Clinical Trial Evaluating Ability of BP1001-A to Treat Patients with Solid Tumors, Including Ovarian, Endometrial, Pancreatic and Breast Cancer

HOUSTON – December 7, 2022 – Bio-Path Holdings, Inc., (NASDAQ:BPTH), a biotechnology company leveraging its proprietary DNAbilize® antisense RNAi nanoparticle technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced the enrollment and dosing of the first patient in a Phase 1/1b clinical trial of BP1001-A (liposomal Grb2) in patients with solid tumors, including ovarian, endometrial, pancreatic and breast cancer.

"The dosing of the first patient in this study of BP1001-A is an important achievement that brings us closer to delivering this potentially life-saving treatment to patients with solid tumor cancers that have few or limited treatment options," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "Solid tumors continue to be a treatment challenge with many therapies failing to provide durable benefit to patients. We are excited and hopeful that BP1001-A will prove to be both safe and effective in fighting these most difficult to treat tumors."

BP1001-A is a modified drug product with the same drug substance as prexigebersen but includes formulation enhancements to produce smaller drug nanoparticles. The goal of this product enhancement is to produce smaller drug nanoparticles that can pass through vasculature pore spaces, thereby enabling release of the drug product into the interior of the tumor to enhance drug effectiveness.

The dose escalation portion of the Phase 1/1b clinical trial is planned to be conducted at more than six leading cancer centers in the United States, including The University of Texas MD Anderson Cancer Center, The Mary Crowley Cancer Research Center, and Karmanos Cancer Center. Initially, a total of nine evaluable patients are scheduled to be treated with BP1001-A monotherapy in a standard 3+3 design, with a starting dose of 60 mg/m2. The approved treatment cycle is two doses per week over four weeks, resulting in eight doses administered over twenty-eight days. The Phase 1b portion of the study will commence after successful completion of BP1001-A monotherapy cohorts and will assess the safety and efficacy of BP1001-A in combination with paclitaxel in patients with recurrent ovarian or endometrial tumors.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company developing DNAbilize®, a novel technology that has yielded a pipeline of RNAi nanoparticle drugs that can be administered with a simple intravenous transfusion. Bio-Path's lead product candidate, prexigebersen (BP1001, targeting the Grb2 protein), is in a Phase 2 study for blood cancers, and a Phase 1 study of BP1001-A, a drug product modification of prexigebersen, in solid tumors has commenced. The Company's second product, BP1002, which targets the Bcl-2 protein, is being evaluated for the treatment of blood cancers and solid tumors, including lymphoma and acute myeloid leukemia. In addition, an IND is expected to be filed for BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3, in the first half of 2023.

For more information, please visit the Company's website at http://www.biopathholdings.com.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws. These statements are based on management's current expectations and accordingly are subject to uncertainty and changes in circumstances. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Any statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith, Bio-Path's ability to raise needed additional capital on a timely basis in order for it to continue its operations, have success in the clinical development of its technologies, the timing of enrollment and release of data in such clinical studies, the accuracy of such data, limited patient populations of early stage clinical studies and the possibility that results from later stage clinical trials with much larger patient populations may not be consistent with earlier stage clinical trials, the maintenance of intellectual property rights, that patents relating to existing or future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, and such other risks which are identified in Bio-Path's most recent Annual Report on Form 10-K, in any subsequent quarterly reports on Form 10-Q and in other reports that Bio-Path files with the Securities and Exchange Commission from time to time. These documents are available on request from Bio-Path Holdings or at www.sec.gov. Bio-Path disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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