# Bio-Path Holdings Announces Clearance of Investigational New Drug Application for Phase 1/1b Clinical Trial of Prexigebersen-A in Solid Tumors

*Phase 1/1b Clinical Trial to Evaluate Ability of Prexigebersen-A to Treat Patients with Solid Tumors, Including Ovarian, Endometrial, Pancreatic and Triple Negative Breast Cancer*

**HOUSTON – October 27, 2021 –** 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 that the U.S. Food and Drug Administration (FDA) has reviewed and cleared the Investigational New Drug (IND) application to initiate a Phase 1/1b clinical trial of prexigebersen-A (liposomal Grb2-A or BP1001-A) in patients with solid tumors, including ovarian, endometrial, pancreatic and triple negative breast cancer.

"This IND clearance for prexigebersen-A marks an important regulatory milestone for Bio-Path, as we progress our fourth drug candidate into the clinic. Given the formulation enhancements, encouraging pre-clinical data and safety profile we have seen to-date, we are eager to begin this first-in-human study," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "We are particularly encouraged as prexigebersen-A has been shown to enhance chemotherapy efficacy in preclinical solid tumor models and we look forward to confirming these earlier results."

Prexigebersen-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 was to produce smaller drug nanoparticles that could pass through vasculature pore spaces, thereby enabling release of the drug product into the interior of the tumor to enhance drug effectiveness.

In April 2018, data were presented demonstrating the treatment of solid tumors in gynecologic malignancies with prexigebersen-A at the American Association for Cancer Research (AACR) Annual Meeting. The data showed an eighty-six percent (86%) decrease in tumor burden ($p<0.05$), and multinodular burden ($p<0.01$) in the combination prexigebersen-A/paclitaxel group compared with control. In addition, there was no apparent toxicity with mice on combination therapy losing less weight than the control group. This work was subsequently published in the journal *Oncotarget* in 2020.

"Given the encouraging pre-clinical results that have been generated to-date, we are optimistic that prexigebersen-A may offer much needed respite to patients suffering with solid tumors who face limited treatment options," said Jorge Cortes, M.D., Director of the Georgia Cancer Center and Chairman of the Bio-Path Scientific Advisory Board.

The Phase 1/1b clinical trial is anticipated to be conducted at several leading cancer centers in the United States, including The University of Texas MD Anderson Cancer Center and the Mary Crowley Research Center. Eventually, we expect to have six sites to conduct the clinical trial. Initially, a total of six evaluable patients are scheduled to be treated with prexigebersen-A monotherapy in a standard 3+3 design, with a starting dose of 60 mg/m$^2$. 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 prexigebersen-A monotherapy cohorts and will assess the safety and efficacy of prexigebersen-A in combination with paclitaxel in patients with recurrent ovarian or endometrial tumors.

The IND review process was performed by the FDA's Division of Oncology 1, Office of Oncologic Diseases and involved a comprehensive review of data submitted by the Company covering pre-clinical studies, safety, chemistry, manufacturing and controls, and the protocol for the Phase 1/1b clinical trial.

**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 the treatment of blood cancers. 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 2022. The Company's fourth product, prexigebersen-A, or BP1001-A, has been cleared to initiate a Phase 1/1b clinical trial of prexigebersen-A in patients with solid tumors, including ovarian, endometrial, pancreatic and triple negative breast cancer.

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 Bio-Path's ability to raise needed additional capital on a timely basis in order for it to continue its operations, Bio-Path's ability to have success in the clinical development of its technologies, the timing of enrollment and release of data in such clinical studies and 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 for future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, risks relating to maintaining Bio-Path's listing on the Nasdaq Capital Market 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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