Bio-Path Holdings Announces Clearance of Investigational New Drug Application for BP1002 in Refractory/Relapsed Acute Myeloid Leukemia Patients

Phase 1/ 1b Clinical Trial to Evaluate Ability of BP1002, Targeting Bcl-2 Protein, to Treat Refractory/Relapsed AML Patients

HOUSTON – August 24, 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 for BP1002 (liposomal Bcl-2), the Company's second drug candidate, for an initial Phase 1/ 1b clinical trial that will evaluate the ability of BP1002 to treat refractory/relapsed acute myeloid leukemia (AML) patients.

"AML patients that fail frontline venetoclax-based therapy have very poor prognosis with a median overall survival of less than three months and a novel treatment modality is urgently needed for such patients. Preclinical studies indicate that the BP1002 and decitabine combination is effective against venetoclax-resistant cell lines, suggesting that the BP1002 and decitabine combination therapy may provide benefits to patients who have relapsed from venetoclax-based treatment," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings.

By targeting Bcl-2 at the DNA level rather than the protein, BP1002 might overcome and prevent some of the mechanisms of resistance that affect venetoclax. The current standard of care for patients with AML not eligible for intensive chemotherapy is venetoclax, an oral Bcl-2 inhibitor that targets the BH3 domain of the Bcl-2 protein, in combination with a hypomethylating agent or with low-dose cytarabine. High expression of Bcl-2 has been correlated with adverse prognosis for patients diagnosed with AML. Preclinical studies have shown BP1002 to be a potent inhibitor against the Bcl-2 target, and its benign safety profile should enable BP1002 combination therapy with approved agents, such as decitabine.

"We are excited to move into these advanced clinical studies and look forward to generating data that not only support the DNAbilize platform but bring us one step closer to bringing these potentially lifesaving drugs to patients," 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 Weill Medical College of Cornell University, The

University of Texas MD Anderson Cancer Center and the Georgia Cancer Center. Initially, a total of six evaluable patients are scheduled to be treated with BP1002 monotherapy in a standard 3+3 design, with a starting dose of 20 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 completion of BP1002 monotherapy cohorts and will assess the safety and efficacy of BP1002 in combination with decitabine in refractory/relapsed AML patients.

Gail J. Roboz, M.D., will serve as Principal Investigator for the Phase 1/1b trial. Dr. Roboz is professor of medicine and director of the Clinical and Translational Leukemia Program at the Weill Medical College of Cornell University and the New York-Presbyterian Hospital in New York City.

The IND review process was performed by the FDA's Office of Oncologic Diseases, Division of Hematologic Malignancies 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 and is in the process of filing an IND for a Phase 1 clinical trial for solid tumors. 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 late 2021 or 2022.

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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