Bio-Path Holdings Announces First Patient Dosed in Phase 1 Clinical Trial of BP1002

Trial to Evaluate Ability of BP1002, Targeting Bcl-2 Protein, to Treat Refractory/Relapsed Lymphoma and Chronic Lymphocytic Leukemia Patients

HOUSTON—November 19, 2020 – Bio-Path Holdings, Inc., (NASDAQ:BPTH), a biotechnology company leveraging its proprietary DNAbilize™ liposomal delivery and antisense 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 clinical trial evaluating the ability of BP1002 to treat refractory/relapsed lymphoma and chronic lymphocytic leukemia (CLL) patients.

BP1002 targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. High expression of Bcl-2 has been correlated with adverse prognosis for patients diagnosed with relapsed CLL or with relapsed, aggressive non-Hodgkin's lymphoma. Preclinical studies have shown BP1002 to be a potent inhibitor against the Bcl-2 target, and the Company believes that its benign safety profile should enable BP1002 combination therapy with approved agents.

A total of six evaluable patients will be treated with BP1002 monotherapy in a standard 3+3 design, with a starting dose of 20 mg/m^2. The treatment cycle consists of two doses per week over four weeks, resulting in eight doses administered over twenty-eight days. The primary objectives of the study include safety and tolerability of escalating doses of BP1002, recommended Phase 2 dose of BP1002, pharmacokinetics of BP1002 and BP1002 activity on Bcl-2 expression. Secondary endpoints include several efficacy measurements of tumor response.

"This study will mark a critical step in understanding the potential benefits that BP1002 may bring to patients suffering with advanced lymphoid malignancies," said Jorge Cortes, M.D., Director of the Georgia Cancer Center and Chairman of the Bio-Path Scientific Advisory Board. "Importantly, BP1002 activity is based on blocking the Bcl-2 messenger RNA and not the BH3 domain, as is the case with venetoclax. As a result, we believe BP1002 may provide a much-needed alternative for patients with malignancies that relapsed or are refractory to venetoclax."

"We are delighted to initiate this first-in-human clinical study of our second drug product candidate derived from the DNAbilize platform. Given the encouraging pre-clinical data and safety profile seen to date, we are very excited to begin this study, which is expected to demonstrate safety and to show initial efficacy signals in these indications with significant

unmet medical need," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings.

Ian W. Flynn, M.D. will serve as the national coordinating Principal Investigator for the Phase 1 trial. Dr. Flynn is the director of lymphoma research at the Sarah Cannon Research Institute. Other sites for the clinical trial include the Georgia Cancer Center at Augusta University and The University of Texas M.D. Anderson Cancer Center.

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 infusion. Bio-Path's lead product candidate, prexigebersen (BP1001, targeting the Grb2 protein), is in a Phase 2 study for blood cancers and prexigebersen-A, a drug product modification of prexigebersen, is under consideration by the FDA to commence Phase 1 studies in solid tumors. This is followed by BP1002, targeting the Bcl-2 protein, where it is being evaluated in lymphoma clinical studies.

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 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, 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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