Bio-Path Announces Patient Dosing in Amended Phase 2 Prexigebersen Trial in Acute Myeloid Leukemia

HOUSTON— August 26, 2019 – 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 patient dosing in Bio-Path's amended Phase 2 trial of prexigebersen for the treatment of acute myeloid leukemia (AML), as announced in March 2019.

The key change in the amended Phase 2 study is the inclusion of patients with high risk myelodysplastic syndrome (MDS) and refractory/relapsed AML patients. The restructured Phase 2 clinical trial has two cohorts of patients. The first being untreated AML patients as existed in the pre-amended trial but with the addition of high risk MDS patients, and a second cohort comprised of refractory/relapsed AML patients and high risk MDS patients.

The amended Phase 2 study will continue evaluating the safety of prexigebersen in combination with decitabine in both cohorts of patients at a dose of 60 mg/m^2 in combination with decitabine. The study will include a total of six evaluable patients for a safety assessment of prexigebersen and decitabine. To date, the Company has enrolled five evaluable patients: three untreated AML patients in who received therapy prior to amending the trial, and two patients who are now being treated under the amended Phase 2 trial. Assuming a successful completion of this safety assessment, the study will then modify testing of both cohorts of patients to add venetoclax to the prexigebersen/decitabine combination treatment.

After a six-patient safety assessment of the prexigebersen/decitabine/venetoclax combination, the Company intends to commence the efficacy segment of this trial. It is anticipated that each cohort will include an interim assessment of 19 evaluable patients that would assess whether the treatment efficacy of the combination of prexigebersen/decitabine/ venetoclax exceeds the efficacy of current standard-of-care therapy with statistical significance. Upon such favorable data, Bio-Path would petition the U.S. Food and Drug Administration (FDA) for accelerated approval. The efficacy segment of the trial is expected to be conducted at up to ten clinical sites in the United States. Moving forward, the Company intends to evaluate potential clinical sites in Europe with an emphasis on patient accruals.

"We are excited to have dosed the first patient in our amended protocol of this important clinical trial, confident that the changes made to the protocol, along with the inclusion of MDS patients, will further demonstrate the potential of prexigebersen in a number of cancer indications for which there are limited treatment options," said Peter Nielsen, President and Chief Executive Officer of Bio-Path. "We are encouraged about the outcome

for this study, as preclinical work showed the benefit of prexigebersen in combination with decitabine and venetoclax. We look forward to advancing this development program with the goal of bringing new therapies to cancer patients in need."

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 is also developing BP1002, which targets the Bcl-2 protein and is expected to be evaluated for the treatment of lymphoma and solid tumors. In addition, BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3, is expected to enter Phase 1 studies in 2020.

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, 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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