Bio-Path Holdings Announces Successful Completion of Safety Cohort of Triple Combination of Prexigebersen, Decitabine and Venetoclax in Stage 2 of Phase 2 Clinical Trial in Acute Myeloid Leukemia

HOUSTON – April 5, 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 the successful completion of the safety run-in of the Stage 2 of the Phase 2 clinical study of prexigebersen (BP1001), a liposomal Grb2 antisense, for the treatment of acute myeloid leukemia (AML), in combination with frontline therapies, decitabine and venetoclax, in acute myeloid leukemia (AML) patients. The safety run-in of Stage 2 of the Phase 2 clinical trial was comprised of six evaluable patients who were treated with the triple combination of prexigebersen, decitabine and venetoclax.

"We are particularly pleased with the clean side effect profile and lack of toxicity shown in this segment of the study, as our Phase 2 efficacy segment will include *de novo* fragile AML patients for whom drug side effect profiles are particularly important. We are also very encouraged by the efficacy signals shown in this dataset, with five of six evaluable relapsed, refractory and newly diagnosed AML patients demonstrating clinical activity. These positive signals give us further confidence in the potential for this program in these late-stage and compromised patients," stated Peter H. Nielsen, Chief Executive Officer of Bio-Path Holdings.

"We look forward to advancing this Phase 2 study, as we believe its unique design provides us with several definable registration pathways. We believe that prexigebersen, with its promising efficacy and safety profile, has the potential to be an ideal combination candidate with frontline therapies," concluded Mr. Nielsen.

In the safety run-in, six evaluable patients were treated with the combination of prexigebersen, decitabine and venetoclax. These patients included four relapsed/refractory AML patients, and two newly diagnosed AML patients. In the preliminary safety data review, five of the patients (83%) responded to treatment, including four (67%) achieving complete response (CR) and one (17%) complete response with incomplete hematologic recovery (CRi). CR rates to combination treatment with decitabine and venetoclax for relapsed/refractory AML patients is 42-52%[1,2] and 0-39%[1,2] for relapsed/refractory secondary AML patients. Response rates to frontline treatment decitabine and venetoclax for newly diagnosed AML patients is 62-71%[3,4]. These preliminary data showed the treatment was well-tolerated and there were no dose limiting toxicities attributed to prexigebersen. Three patients remained on treatment for more than one cycle.

Stage 2 of the Phase 2 clinical trial has three treatment cohorts, which the Company believes provides for several potential regulatory pathways. The first two cohorts will treat patients with the triple combination of prexigebersen, decitabine and venetoclax. The first cohort includes newly diagnosed AML patients and the second cohort includes relapsed/refractory AML patients. Finally, the third cohort treats relapsed/refractory AML patients who are venetoclax resistant or intolerant with the two-drug combination of prexigebersen and decitabine.

The Phase 2 clinical trial continues with 21 patients currently enrolled across all three cohorts. Enrollment of 19 patients in each cohort should enable a data review to determine if there is a comparative increase in efficacy versus the decitabine and venetoclax combination therapy sufficient to support petitioning the FDA for approval to switch to breakthrough therapy for accelerated approval. The Phase 2 trial will be conducted at up to ten clinical sites in the U.S. For more information on the Phase 2 study, visit www.clinicaltrials.gov.

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 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 will be evaluated in lymphoma and solid tumors clinical studies.

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

1) DiNardo et al. Lancet Haematology, 2020, Oct;7(10):e724-e736.
2) Aldoss et al. Haematol, 2018, 103:e404-e407.
3) DiNardo et al. Blood, 2019, 133(1): 1-7.
4) Venclexta Package Insert.

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, 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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