Bio-Path Holdings Announces First Patient Dosed in Phase 2 Trial Evaluating BP1001 in Acute Myeloid Leukemia

HOUSTON—November 2, 2016 – 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 the efficacy portion of its Phase 2 clinical study of BP1001, a liposomal Grb2 antisense for the treatment of acute myeloid leukemia (AML). The objective of the Phase 2 study is to further assess the efficacy and safety of BP1001, Bio-Path's lead development candidate.

The Phase 2 clinical trial is a multicenter study of BP1001 in combination with low dose cytarabine (LDAC) in patients with previously untreated AML who are not otherwise eligible for standard or high-intensity chemotherapy regimens or who have elected a low-intensity regimen.

The trial is a single arm, open label, two-stage design to assess the safety profile, pharmacokinetics, pharmacodynamics, and efficacy of 60 mg/m^2 of BP1001 in combination with LDAC compared to historical response rates documented for LDAC alone. Evaluable patients will receive an initial dose intravenous (IV) infusion of BP1001 over 60 minutes and every three days thereafter, as eight doses per 28-day cycle of 60 mg/m^2 BP1001, and will be administered LDAC as a subcutaneous (SQ) injection, twice daily for 20 consecutive doses per 28-day cycle.

The primary endpoint of the study is the number of patients who achieve Complete Remission (CR), including CR with incomplete hematologic recovery (CRi) and CR with incomplete platelet recovery (CRip). Secondary endpoints assessing the safety and efficacy of BP1001 include overall survival, time to response, duration of response, and adverse events as evaluated by physical examination findings, vital signs and clinical laboratory tests.

The full trial design includes approximately 54 evaluable patients with an interim analysis performed after 19 patients. In the event the interim results exceed the primary endpoint in a number of patients that meets or exceeds statistically determined thresholds, the Company may seek to convert the trial into a registration trial for accelerated approval.

Among the sites registered to conduct the study are Weill Medical College of Cornell University, Baylor Scott & White Health, The University of Kansas and The University of Texas MD Anderson Cancer Center.

"This is an exciting milestone for Bio-Path as it will be the first study to confirm the efficacy of BP1001 as a treatment for AML and to validate our DNAbilize™ platform," said Peter H. Nielsen, Chief Executive Officer of Bio-Path Holdings. "We are particularly pleased with the Phase 2 trial design, which has a built-in interim analysis that offers a pathway to an accelerated approval should the efficacy results for the first 19 evaluable patients demonstrate the high response rate seen in the safety segment of our Phase 2 trial. We look forward to the completion of this study and expect its results to replicate these very promising early data," added Mr. Nielsen.

Patients in the safety segment of the trial treated with 60 mg/m^2 and 90 mg/m^2 of BP1001 twice a week over a four-week period, in combination with a standard regimen of frontline low-dose cytarabine (LDAC), showed BP1001 to be safe and well tolerated, with signs of significant anti-leukemia activity. Of the six evaluable patients included in both cohorts of the safety segment, three achieved complete remissions, while two others achieved partial remission. There were no attributable adverse events reported.

As previously reported, BP1001's pharmacokinetics at a dose of 60 mg/m^2 had a 30-hour half-life, significantly better than the half-life with a dose of 90 mg/m^2. The final analysis of these data, along with the demonstrated reductions in bone marrow blasts, suggested that 60 mg/m^2 is the appropriate dose for use in the Phase 2 trial. Administratively, this required Bio-Path to reformat documents for the Phase 2 trial with the 60 mg/m^2 dose and resubmit for approvals with the U.S. Food and Drug Administration (FDA) and site Institutional Review Boards, requiring additional time prior to starting the Phase 2 trial.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing DNAbilize™, its proprietary liposomal delivery and antisense technology, to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path's lead product candidate, BP1001 (Liposomal Grb2 antisense), is in a Phase 2 study for blood cancers and in preclinical studies for solid tumors. Bio-Path's second drug candidate, also a liposomal antisense drug, is ready for the clinic where it will be evaluated in lymphoma and solid tumors.

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

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, 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 the Company's most recent Annual Report on Form 10-K and in any subsequent quarterly reports on Form 10-Q. 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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