



## **Bio-Path Holdings' Data from Phase I and Safety Segment of Phase II Clinical Trials in Blood Cancers Presented at 57<sup>th</sup> American Society of Hematology (ASH) Annual Meeting**

*Two of the three evaluable patients achieved complete remission in safety segment of the Phase II combination therapy trial of BP1001 (Liposomal Grb2 antisense)*

**HOUSTON—December 8, 2015** – Bio-Path Holdings, Inc., (NASDAQ: BPTH) (“Bio-Path”), a biotechnology company leveraging its proprietary DNAbilize™ liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced that data from the Phase I and safety segment of the Phase II clinical trials of its lead product candidate BP-100-1.01 (or BP1001, Liposomal Grb2 antisense) in the treatment of blood cancers were presented yesterday by Dr. Jorge Cortes, Deputy Chair of the Department of Leukemia at The University of Texas MD Anderson Cancer Center and Chair of Bio-Path’s Scientific Advisory Board, during a poster session at the 57<sup>th</sup> American Society of Hematology (ASH) Annual Meeting in Orlando, Florida.

The poster, titled “Safety, Pharmacokinetics, and Efficacy of BP-100.1.01 (Liposomal Grb2 Antisense Oligonucleotide) in Patients with Refractory or Relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML), Acute Lymphoid Leukemia (ALL), and Myelodysplastic Syndrome (MDS),” included data from the first seven cohorts of the study. The eighth and final cohort is ongoing.

Data from Cohorts 1 through 6 of the dose-finding monotherapy study demonstrated that BP1001 at doses up to 90 mg/m<sup>2</sup> is well tolerated and suggests possible anti-leukemia activity. Of the evaluable patients, all showed a transient drop in circulating blast percentage.

Cohort 7 was the first cohort in the safety segment of the Phase II clinical trial (also referred to as Phase Ib) and evaluated the toxicity of BP1001 at the 60 mg/m<sup>2</sup> dose level, combined with low-dose cytarabine (LDAC) chemotherapy in patients with advanced acute myeloid leukemia (AML). Bio-Path previously reported that one evaluable patient in Cohort 7 had achieved complete remission (CR) during treatment, and a second patient who demonstrated improvement in bone marrow blasts at the end of the first treatment cycle was continuing BP1001 treatment as part of an additional treatment cycle. The second patient has achieved CR after two treatment cycles and is continuing therapy in a fourth treatment cycle.

“We are thrilled that two of the three evaluable patients suffering from advanced AML in our first cohort of the safety segment of the Phase II trial have now achieved complete remission during treatment with Liposomal Grb2 combined with low-dose cytarabine,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “The data we have seen to date are especially encouraging because the patients evaluated in our study were refractory and treatment resistant, having been on an average of four prior therapies. We continue to make progress with the eighth

cohort of the trial, which is evaluating three patients being treated with 90 mg/m<sup>2</sup> of Liposomal Grb2 antisense in combination with frontline LDAC, and look forward to successfully completing the safety portion of the Phase II clinical study.”

### **About BP1001**

BP1001 is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb-2 protein expression. The protein Grb-2 is essential to cancer cell signaling because it is utilized by oncogenic tyrosine kinases to induce cancer progression. Suppressing the function or expression of Grb-2 should interrupt its vital signaling function and have a therapeutic application in cancer.

### **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 II study for blood cancers and in preclinical studies for triple negative and inflammatory breast cancers. 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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