



## **Bio-Path Holdings Successfully Completes Second Cohort in Phase I Clinical Trial of Lead Product Candidate Liposomal Grb-2 in Leukemia**

*- Drug Well-Tolerated and Possible Anti-Leukemia Activity Again Demonstrated -*

### **FOR IMMEDIATE RELEASE**

**February 7, 2012 HOUSTON, TX** – Bio-Path Holdings, Inc., (OTC BB: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, today announced that it has completed treatment of the second dosage cohort in the Company’s Phase I clinical trial of its lead product candidate, BP-100-1.01 (Liposomal Grb-2), which is a systemic treatment for blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). The trial is being conducted at the MD Anderson Cancer Center. The drug was well tolerated with no treatment-related serious adverse events reported and data continues to suggest some possible anti-leukemia activity.

A total of six patients were enrolled and dosed in the second cohort of the study. Three evaluable patients completed the 28-day treatment cycle and comprised the completed second dose cohort. Three other patients failed to complete a full 28-day cycle because of disease progression. Liposomal Grb-2 is systemically delivered by intravenous injection. Patients received a dose of 10 mg/m<sup>2</sup> twice a week for four weeks, for a total of eight doses. Preliminary results suggest that Liposomal Grb-2, at a dose of 10 mg/m<sup>2</sup> is well tolerated. In addition, there is a suggestion of possible anti-leukemia activity, even at the low doses used in the first and second cohorts. The protocol for the clinical trial includes dose escalation of 5, 10, 20, 40 and 50 mg/m<sup>2</sup>. The expected dose for treatment is 45 mg/m<sup>2</sup> based on pre-clinical studies in animals.

“The preliminary results being reported today for the second cohort of our clinical trial continue to be promising. As we have noted previously, the suggestion of possible anti-leukemia activity with the low doses used in the first and second cohorts is encouraging,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “Enrollment in the trial is also picking up momentum, evidenced by the dramatically shorter time frame it took to complete the second cohort. The third cohort is currently enrolling and we believe that this is a trend that can continue for the balance of the trial.”

### About the Delivery Technology

Bio-Path's drug delivery technology involves microscopic-sized liposome particles that distribute nucleic acid drugs systemically and safely throughout the human body, via simple intravenous infusion. The delivery technology can be applied both to double stranded (siRNA) and single stranded (antisense) nucleic acid compounds with the potential to revolutionize the treatment of cancer and other diseases where drugable targets of disease are well characterized. Bio-Path also anticipates developing liposome tumor targeting technology, representing next-generation enhancements to the Company's core liposome delivery technology.

### About Growth Receptor Bound protein-2 (Grb-2)

The adaptor protein Growth Receptor Bound protein-2 (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 Grb2 should interrupt its vital signaling function and have a therapeutic application in cancer. BP-100.1.01 is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb-2 expression.

### About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing its proprietary liposomal delivery technology designed to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path's lead product candidate, Liposomal Grb-2, is in a Phase I study for blood 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, and its third candidate is a liposomal siRNA cancer drug that is in the final pre-clinical development stage.

*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](http://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.*

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

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