



## **First Cohort Successfully Completed in Bio-Path Holding's Phase I Clinical Trial of Lead Product Candidate Liposomal Grb-2 in Leukemia**

*- Drug Well-Tolerated and Activity Seen at Low-Starting Dose*

### **FOR IMMEDIATE RELEASE**

**August 11th, 2011 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 first 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 suggests some possible anti-leukemia activity.

A total of 14 patients were enrolled in the first cohort of the study. All patients had failed prior therapies. Of the 14 patients, one patient withdrew prior to treatment and 13 were treated. Of the treated patients, six were evaluable and seven 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 5 mg/m<sup>2</sup> twice a week for four weeks, for a total of eight doses. Six evaluable patients comprised the completed first dose cohort. Preliminary results suggest that Liposomal Grb-2, at a dose of 5 mg/m<sup>2</sup> is well tolerated. In addition, there is already a suggestion of possible anti-leukemia activity, even at the low starting dose used in the first cohort. The protocol for the clinical trial includes dose escalation of 5, 10, 20, 40 and 50 mg/m<sup>2</sup>.

Of the six evaluable patients, lab parameters for blasts and bone marrow demonstrated possible anti-leukemia activity. Two patients had transient improvement and/or stable disease and received a total of five cycles each, representing five months on treatment with the drug. In addition, two patients had transient improvement on leukemia cutis lesions.

In addition to the six evaluable patients, a patient with CML blast phase who had failed all available TKI (tyrosine kinase inhibitor) and other experimental options showed a significant reduction in blasts from 81 percent to four percent. Unfortunately, this patient discontinued

study treatment due to progression of disease into the central nervous system and had to discontinue therapy.

“The preliminary results being reported today for the first cohort of our clinical trial are extremely promising. The suggestion of possible anti-leukemia activity, in particular, was an unexpected and very positive result, especially because of the low dose used in the cohort. For reference, efficacy studies of Liposomal Grb-2 in animals used a dose of 45 mg/m<sup>2</sup>,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “We look forward to proceeding through the next cohorts of the clinical trial to determine if higher doses of the drug will increase favorable anti-leukemia effects on patients.”

The Principal Investigator for the clinical trial is preparing, with the assistance of the Company, an abstract for submission to the American Hematology Society Annual Meeting later this year in San Diego and potential other important scientific conferences later in the year. The study continues to accrue patients and Cohort 2 is open with dosing at 10 mg/m<sup>2</sup>.

#### 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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