



## **Bio-Path Holdings Successfully Completes Third 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* -
  - *All Patients in Cohort 3 Stabilized and On Extended Treatment Plan* -
  - *Trend in Reduced Time To Complete Cohort Continues* -

### **FOR IMMEDIATE RELEASE**

**May 29, 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 third dosage cohort in its 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’s safety profile continues to be favorable with no treatment-related serious adverse events reported and data continues to suggest some possible anti-leukemia activity.

A total of three patients were enrolled and dosed in the third cohort of the study. All three patients completed the 28-day treatment cycle and were evaluable. Liposomal Grb-2 is systemically delivered by intravenous injection. Patients received a dose of 20 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 20 mg/m<sup>2</sup> is well tolerated. 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.

As was the case with the two previous cohorts, there continued to be a suggestion of possible anti-leukemia activity, as all three patients stabilized. As such, all three patients are receiving or will receive additional treatment cycles. In the protocol of the clinical trial, a patient exhibits stable disease if, in the opinion of the principal investigator, there is no clinically significant change in the disease. One patient, from this cohort, with AML had bone marrow blasts reduced by 60 percent during the first treatment cycle to within normal parameters and continued with a second treatment cycle.

As the chart below demonstrates, time for completion of a cohort, number of patients enrolled and the percentage of evaluable patients that received extended treatments has shown significant

improvement. An important measure of benefit from treatment with the drug is stabilization and being placed on extended treatment cycles. This trend is also very positive, with all three patients from cohort 3 being placed on extended treatment plans.

**Bio-Path Holdings' Phase I Clinical Trial  
Key Tracking Parameters**

	Time (weeks)	Patients			Patients on Extended Treatment	
		Enrolled	Evaluable	% Eval.	#	% of Eval.
<b>Cohort 1</b>	55	14	6	43%	2	33%
<b>Cohort 2</b>	26	6	3	50%	1	33%
<b>Cohort 3</b>	11	3	3	100%	3	100% a/

a/ The last patient in the cohort is waiting on additional drug supplies to start extended treatment.

“The preliminary results being reported today for the third cohort of our clinical trial demonstrate consistent safety results with the previously reported data, as well as a continuation of possible anti-leukemia activity related to the drug. Patients in our clinical trial are refractory or relapsed to current therapies and have failed other approved treatments. These patients have very advanced stages of the disease, and are often in very poor condition. The fact that all three patients in the third cohort stabilized to qualify for extended treatment is very promising,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “It is clear that the momentum of the trial has significantly changed to the better, with markedly shortened times to complete a cohort and the minimum number of patients needed. The increase in the number patients needing drug for extended treatments has caused us to accelerate our plans to upgrade the capacity of our supply chain. We expect new supplies to become available to continue treatment of patients in June. The fourth cohort is ready to be opened for enrollment once the new drug supplies have arrived, as well as the continued treatment of third cohort patients on extended treatment plans.”

About Bio-Path's 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 single stranded (antisense) nucleic acid compounds and double stranded (siRNA) with the potential to revolutionize the treatment of cancer and other diseases where drugable targets of disease are well characterized. However, the Company is currently only developing liposomal antisense drug candidates. 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.

*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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