



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

*- Drug Well-Tolerated and Possible Anti-Leukemia Activity Continues to be Demonstrated -*

### **FOR IMMEDIATE RELEASE**

**June 6, 2013 HOUSTON, TX** – Bio-Path Holdings, Inc., (OTCQX: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid antisense cancer drugs, today announced that it has completed treatment of the fifth 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 University of Texas MD Anderson Cancer Center (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 possible anti-leukemia activity.

A total of three patients were enrolled and dosed in the fifth 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 60 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 60 mg/m<sup>2</sup> is well tolerated.

As was the case with the four previous cohorts, there continues to be a suggestion of possible anti-leukemia activity. All three patients in this cohort were of the more proliferative AML type compared to some of the more indolent patients that have been enrolled into the study and treated in the past. Two of the three patients had a transient decrease in the peripheral blood blast percentage with Liposomal Grb-2. The third AML patient had more than a 90 percent blast count and did not respond to treatment at this dose level to the degree that the other two patients responded.

As a result of the favorable safety profile, the Company closed Cohort 5 of the trial and opened Cohort 6 for enrollment, in which patients will be treated at a dose of 90 mg/m<sup>2</sup>.

“Cohort 5 results continue to be consistent with earlier cohorts of the trial, demonstrating consistent safety. We are particularly encouraged that in this more proliferative AML population, there continues to be a suggestion of possible anti-leukemia activity related to the drug” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “Particularly

noteworthy is that two of the three patients in Cohort 5 had a response to treatment with Liposomal Grb-2 in terms of transient reduction in circulating blasts. Higher dose levels of Liposomal Grb-2 increase the duration of response in the more proliferative AML patients, as well as refractory or relapsed CML and MDS patients. Liposomal Grb-2 used in combination with frontline treatments may represent new treatment options for resistant and refractory patients who currently have no viable therapies.”

Mr. Nielsen continued, “Operationally, Cohort 5 of the trial went very quickly, taking approximately two months once drug supplies arrived. In regard to drug manufacture, we continue to improve our efficiency and we anticipate a significant increase in the yield of drug product from our next manufacturing batch. The increase in manufacturing efficiency and yield is needed to support manufacturing the quantity of drug vials needed for our Phase II program. Once Cohort 6 is completed, we plan to meet with our Principle Investigator to determine if the Cohort 6 dose of 90 mg/m<sup>2</sup> dose should be used for the planned Phase II clinical program.”

#### 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 is applied to 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. The Company is currently focused on 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 Grb-2 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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