



Bio-Path Holdings' Initial Phase I Data in Leukemia Clinical Trial Demonstrates that Its Neutral Lipid Delivery Technology Antisense Drug BP-100-1.01 (Liposomal Grb-2) Is Well Tolerated with Activity Seen at Low-Starting Dose

- **Data from Phase I Clinical Trial Presented at the 53rd Annual Meeting of the American Society of Hematology** -

FOR IMMEDIATE RELEASE

December 13, 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, announced that results from Cohort 1 of the Phase I clinical trial of its lead product candidate, BP-100-1.01 (Liposomal Grb-2) were disclosed yesterday in a poster presentation at the 53rd Annual Meeting of the American Society of Hematology (ASH) held in San Diego, California. BP-100-1.01 is a novel, systemic liposomal antisense 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. The drug was well tolerated with no treatment-related serious adverse events reported and data suggests some possible anti-leukemia activity at a low starting dose.

In a poster presentation entitled, “Safety, Pharmacokinetics, and Efficacy of BP-100.1.01 (L-Grb-2 Antisense Oligonucleotide) in Patients with Refractory or Relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL), and Myelodysplastic Syndrome (MDS)”, Jorge Cortes, M.D., Professor at the MD Anderson Cancer Center, lead author and Principal Investigator for the clinical trial, reported that preliminary results suggest that BP-100-1.01, at a dose of 5 mg/m² is well tolerated and there is suggestion of some possible anti-leukemia activity. Lab parameters for the six evaluable patients show each of these patients experienced transient reductions for blasts and bone marrow results. Two patients had transient improvement and/or stable disease and received a total of five cycles each. Two patients also had transient improvements in leukemia cutis lesions. In addition to the six evaluable patients, one patient with CML blast phase who had failed all available tyrosine kinase inhibitors 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 in central nervous system disorder, unrelated to drug, and had to discontinue therapy. The study continues to accrue patients and Cohort 2 is currently open with dosing at 10 mg/m².

In commenting on the initial results from the trial, Dr. Cortes said, "BP-100-1.01 has a novel mechanism of action with potential to become an important therapy for patients with CML and other leukemias. The early data, with some suggestions of activity at very low doses, are very encouraging."

The results presented suggest that Bio-Path's proprietary, neutral lipid delivery technology has been able to deliver the antisense drug substance Grb-2 systemically throughout the body without toxic side effects and with uptake of the drug substance into the target cancer cells. Bio-Path is in the final stages of developing an assay that will allow direct testing of patient blood samples to provide direct scientific evidence of the effectiveness of the Company's delivery technology.

"Grb-2 is an important protein involved in cancer cell proliferation and survival in CML and other leukemias," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "BP-100-1.01 is a novel treatment approach that uses neutral liposomes to safely deliver an antisense drug substance that blocks the formation of the Grb-2 protein, thereby acting like a light-switch to turn off the cancer. Our liposome delivery technology can become an important platform for numerous drugs to treat cancer and other diseases."

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 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, and its third candidate is a liposomal siRNA cancer drug that is in the final pre-clinical development stage. These product candidates and the delivery technology have been licensed from The University of Texas MD Anderson Cancer Center.

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.

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

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