



## **Bio-Path Holdings' Liposomal Delivery Technology Achieves Major Milestone in Development of Antisense Therapeutics**

*Scientific Assay Confirms Treating Patients with Its Drug BP-100-1.01 Inhibits Disease-Causing Target Protein*

**August 9, 2013; HOUSTON, TX** – Bio-Path Holdings, Inc., (OTCQX: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, today announced that a scientific assay has confirmed that its lead product candidate BP-100-1.01 (Liposomal Grb-2) inhibits the disease-causing target protein in patients with blood cancers. The assay was applied to patient samples taken from Bio-Path’s Phase I clinical trial which is evaluating Liposomal Grb-2 in blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). This discovery is a significant milestone in the development of Bio-Path’s liposomal delivery technology and the specific data from this testing is planned to be reviewed at the Annual Society of Hematology (ASH) meeting in December by Jorge Cortes, M.D., Professor and Deputy Chair, Department of Leukemia, The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center).

Inhibition of the disease-causing protein has the effect of down regulating the disease. This will allow for Liposomal Grb-2 to be used potentially in combination with current frontline treatments. This discovery also points to the potential use of a liposomal antisense treatment as a standalone treatment to transform and manage a disease, which has a disease causing protein, as a chronic disorder.

Bio-Path is currently evaluating Liposomal Grb-2 in a Phase I clinical trial as a systemic treatment for blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). Bio-Path has also initiated pre-clinical development of BP-100-1.01, into two additional indications: triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC), two cancers characterized by formation of aggressive tumors and relatively high mortality rates. The clinical trial and research is being conducted at the MD Anderson Cancer Center (MD Anderson Cancer Center).

“This confirmation that Bio-Path’s drug delivery technology inhibits Grb-2 is a major development milestone for the Company,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “This accomplishment is potentially a significant breakthrough for antisense therapeutics, whose development, to date, as a class of therapeutics has been severely limited by a lack of a systemic delivery mechanism that can safely distribute the drug throughout

the body and get the antisense drug substance across the cell membrane into interior of the cell. Further, we expect that scientific proof of principal for our delivery technology may lead to licensing and business development opportunities, furthering our business model.”

The data obtained by Bio-Path confirm that BP-100-1.01 blocks the production of its target protein Grb-2 in clinical trial patient samples. BP-100-1.01 was designed to block the protein production of Growth factor Receptor Bound protein-2 (Grb-2), and disrupt the activity (i.e. phosphorylation) of its downstream effector extracellular signals regulated kinases 1,2 (ERK1,2). To verify that BP-100-1.01 decreases Grb-2 protein production and ERK1,2 phosphorylation, flow cytometric analysis was performed on the samples. Fluorescent-labeled antibodies for Grb-2 and phosphorylated ERK1,2 were purchased from commercial suppliers which have previously demonstrated the reactivity and specificity of these antibodies. Leukemic cell lines as well as peripheral blood samples from healthy volunteers and diseased patients were used to validate the precision and the reproducibility of our flow cytometry protocol. Peripheral blood samples were obtained from patients prior to study initiation (baseline) and during the course of therapy. The medium fluorescence of Grb-2 and the median fluorescence of phosphorylated ERK1,2 on CD33-expressing leukemic cells were compared to baseline to assess inhibition of the target proteins. The testing was performed by a third party certified Good Laboratory Practice (GLP) testing laboratory.

The significance of this testing is that it confirms Bio-Path’s delivery technology value proposition. Bio-Path’s product candidates are administered to the patient by simple intravenous transfusion and are perfused throughout the body via blood flow. As evidenced to date in the Company’s clinical trial, the liposomal drug product produces no toxic side effects, and safely transports the antisense drug substance throughout the body to reach the diseased cell for insertion across the cell membrane. Success of Bio-Path’s delivery technology affirmed through testing opens several avenues to maximize growth in the value of the Company.

#### 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 and in preclinical studies for triple negative and inflammatory breast 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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