Bio-Path Holdings to Expand Development of Liposomal Grb-2 into two Additional Indications: Triple Negative and Inflammatory Breast Cancers

The Associated Press

HOUSTON--(BUSINESS WIRE)--Dec 6, 2012--Bio-Path Holdings, Inc., (OTCQX: BPTH) ("Bio-Path"), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, today announced it is initiating development of its lead cancer drug BP-100-1.01 (Liposomal Grb-2) to treat triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC), two cancers characterized by formation of aggressive tumors and relatively high mortality rates. 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). The trial is being conducted at The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center).

Bio-Path has been in discussions over the last six months with senior breast cancer researchers at the MD Anderson Cancer Center regarding the potential of its lead drug candidate Liposomal Grb-2 to treat TNBC and IBC. These researchers have made a strong scientific case that blocking over-expression of the Grb-2 protein using Bio-Path's drug candidate Liposomal Grb-2 has the potential to be an effective treatment for TNBC and IBC. Grb-2 is an adaptor protein that acts as a critical linker between growth factor receptors and the RAS pathway, a pathway commonly activated in cancer. TNBC and IBC often over-express multiple growth factor tyrosine kinase receptors involved in growth proliferation, survival and invasion. These are important tyrosine kinases involved in TNBC and IBC progression and have been shown to utilize the Grb-2 protein in their signaling pathways. Bio-Path's drug candidate Liposomal Grb-2 has an antisense drug substance that prevents the cell from producing the Grb-2 protein. In addition, since Grb-2 is involved in multiple cancer signaling pathways, blocking Grb-2 provides multiple opportunities to interrupt or limit tumor progression.

Bio-Path's plan is to develop Liposomal Grb-2 as a targeted therapy against TNBC and IBC. Treatment goals are two-pronged: the first being to develop Liposomal Grb-2 as a tumor reduction agent in combination with other approved drugs in pre-operative settings, and the second is to develop Liposomal Grb-2 as a drug to treat and control or eliminate cancer metastasis in TNBC and IBC patients. Both of these treatment goals address high need situations for patients.

The developmental plan will be comprised of preclinical testing in cell lines to determine the inhibitory effects of Liposomal Grb-2 on cell growth and invasion. From there, preclinical studies in TNBC and IBC animal models would study Liposomal Grb-2 suppressive effects on tumor growth and tumor metastasis in these cancers. If the preclinical studies confirm benefit, Bio-Path anticipates that it

would then proceed to a Phase I clinical trial. The Phase I trial could progress relatively quickly since the toxicity profile of Liposomal Grb-2 is already being established in the Company's current Phase I trial in blood cancers. The preclinical programs are expected to start in 2013 and last one year, after which time the Phase I clinical trial could begin after FDA approval to proceed.

The plan is for Dr. Naoto T. Ueno, M.D., Ph.D., to be the lead researcher for the preclinical studies, which will be conducted at the MD Anderson Cancer Center. Dr. Ueno is a Professor at the MD Anderson Cancer Center, Executive Director of the Morgan Welch Inflammatory Breast Cancer Program and Chief, Section of Translational Breast Cancer Research.

"The potential of Liposomal Grb-2 as a frontline treatment for triple negative breast cancer and inflammatory breast cancer is a major new development for Bio-Path that has the opportunity to produce substantial value for the Company. Successful development of these applications will be of great benefit to TNBC and IBC patients who are afflicted with these two very aggressive forms of breast cancer. Further, the treatment goal for tumor inhibition and reduction in a pre-operative setting provides a potential pathway for rapid approval by the FDA of Liposomal Grb-2, while the longer term effects of controlling or eliminating metastasis will build long term use of our drug," commented Peter Nielsen, President and Chief Executive Officer of Bio-Path.

Mr. Nielsen continued, "Over the course of the next 12-months, Bio-Path will be developing Liposomal Grb-2 for treatments for three high priority disease areas, including TNBC, AML and MDS. In a recent September 2012 news release, MD Anderson Cancer Center announced a Moon Shots Program that was targeting eight cancers for intensive development of treatments; three of these targeted cancers are indications for which Bio-Path will be focusing its development efforts. Bio-Path's drug candidate Liposomal Grb-2 has what researchers describe as 'disruptive technology' and is a potential game changer that can make significant advances in these priority disease areas." About Triple Negative Breast Cancer Triple negative breast cancer (TNBC) tumors do not express estrogen receptors, progesterone receptors, and low HER2. These negative results mean that the growth of the cancer is not supported by the hormones estrogen and progesterone, or by the presence of too many HER2 receptors. Therefore, TNBC does not respond to hormonal therapy or therapies that target HER2 receptors. In addition, TNBC tumors are very aggressive. Approximately 15 to 20 percent of breast cancers are triple-negative.

About Inflammatory Breast Cancer Inflammatory breast cancer (IBC) is a rare and very aggressive disease in which cancer cells block lymph vessels in the skin of the breast. This type of breast cancer is called "inflammatory" because the breast often looks swollen and red, or "inflamed." IBC accounts for two to five percent of all breast cancers. IBC tumors are very aggressive and are frequently hormone receptor negative, which means hormone therapies may not be effective. Five year survival rate for IBC is 40 percent versus 87 percent for all breast cancers combined, making IBC a priority area for development of new treatments.

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 . 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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