



Bio-Path Holdings Initiates Development of Liposomal Grb-2 for Triple Negative and Inflammatory Breast Cancers

July 22, 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 it is initiating preclinical testing of its lead product candidate, BP-100-1.01 (Liposomal Grb-2), 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. 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 clinical trial and research is being conducted at The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center).

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. Following successful completion of the preclinical studies, Bio-Path expects to start a Phase I clinical trial in TNBC and IBC in 2014.

“We are pleased to move development of Liposomal Grb-2 forward into two additional high need indications,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “The observations that we learn from the on-going Phase I trial in blood cancers will be helpful as we evaluate the compound in TNBC and IBC. As such, we would expect the Phase I trial for TNC and IBC to progress relatively quickly since the toxicity profile of Liposomal Grb-2 is already being established.”

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 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. 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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