Bio-Path Announces Orphan Drug Designation in the European Union for BP1001 for the Treatment of Acute Myeloid Leukemia

HOUSTON—November 3, 2016 – Bio-Path Holdings, Inc., (NASDAQ: BPTH), a biotechnology company leveraging its proprietary DNAbilize™ liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced that the European Medicines Agency (EMA) granted orphan drug designation to BP1001 for the treatment of acute myeloid leukemia (AML).

"We are pleased that BP1001 has received orphan drug designation from the EMA, recognizing the urgent need for an effective treatment for AML and the potential of BP1001 to improve outcomes for patients facing this debilitating disease," stated Peter H. Nielsen, Chief Executive Officer of Bio-Path Holdings. "This marks an important regulatory milestone for Bio-Path now that we have entered the efficacy portion of our Phase 2 trial of BP1001 for the treatment of AML."

To receive orphan drug designation from the EMA, a therapy must be intended for the treatment of a life-threatening or chronically debilitating rare condition with a prevalence of less than five in 10,000 in the European Union. Orphan drug designation provides incentives designed to facilitate development including fee reductions for protocol assistance, scientific advice and importantly, may provide up to ten years of market exclusivity in the EU following product approval.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing DNAbilize™, its proprietary liposomal delivery and antisense technology, to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path's lead product candidate, BP1001 (Liposomal Grb2 antisense), is in a Phase 2 study for blood cancers and in preclinical studies for solid tumors. 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.

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

Forward-Looking Statements

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.

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