Bio-Path Holdings Initiates Development of Therapeutic Program for Treatment of Obesity

Company Also Announces Completion of Enrollment for Third Dosing Cohort of Phase 1/1b Clinical Trial of BP1002 in Venetoclax-Resistant Acute Myeloid Leukemia (AML) Patients

HOUSTON – October 8, 2024 – 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 the initiation of a therapeutic program to develop BP1001-A for the treatment of obesity and related metabolic diseases. This program marks the first application of DNAbilize technology for development of a non-cancer application, which highlights the broad therapeutic potential of this technology.

The Company also reported completion of enrollment in the third dosing cohort of its ongoing Phase 1/1b clinical trial evaluating BP1002 for the treatment of refractory/relapsed acute myeloid leukemia (AML) patients, including venetoclax-resistant patients. The cohort enrolled more quickly than projected, which underscores the ongoing need for new treatment options for these relapsed/refractory patients.

"Initiating a DNAbilize development program for the treatment of obesity is an exciting expansion opportunity with the potential to treat a growing epidemic. Developing BP1001-A for the treatment of obesity should have a high probability of success as its mechanism of action has the potential to treat insulin resistance, which is the underpinning of obesity, Type 2 diabetes and other related diseases," said Peter H. Nielsen, President and Chief Executive Officer of Bio-Path. "We expect to initiate Investigational New Drug (IND)-enabling testing of BP1001-A in the fourth quarter of 2024."

"In addition, we are pleased to report enrollment for the third dosing cohort of the Phase 1/1b clinical trial of BP1002 in refractory/relapsed AML patients has completed faster than projected. AML patients who had relapsed from frontline venetoclax-based treatment and are refractory to salvage therapy face dire survival prospects and we believe that BP1002 therapy can help these patients," concluded Mr. Nielsen.

BP1001-A for Treatment of Obesity – The disease pathology leading to obesity suggests that BP1001-A, which suppresses the adaptor protein Grb2, has the potential to treat insulin resistance, a major contributor to obesity, Type 2 diabetes and other related metabolic diseases. Bio-Path expects downregulating Grb2 expression with BP1001-A will enhance insulin sensitivity. The Company expects to begin preclinical studies to confirm these assumptions in the fourth quarter of 2024. These studies are expected to provide crucial insights into the mechanism and efficacy of BP1001-A in enhancing insulin sensitivity and reveal its therapeutic potential for obesity and Type 2 diabetes. Following successful preclinical studies, Bio-Path anticipates that a Phase 1 clinical trial would follow.

Completion of Enrollment for Third Dosing Cohort of Phase 1/1b Clinical Trial of BP1002 in Refractory/Relapsed AML Patients - After the U.S. Food and Drug Administration (FDA) completed its review of data from the first two dosing cohorts in the Phase 1/1b clinical trial in refractory/relapsed AML patients, Bio-Path initiated enrollment for the third, higher-dosing cohort of 60 mg/m^2. Enrollment was completed faster than projected within six weeks, which underscores the continuing need for new treatment options. By targeting the key protein involved in the venetoclax treatment at the mRNA level, BP1002 may overcome and prevent some of the mechanisms of resistance that affect venetoclax treatment.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company developing DNAbilize®, a novel technology that has yielded a pipeline of RNAi nanoparticle drugs that can be administered with a simple intravenous infusion. Bio-Path's lead product candidate, prexigebersen (BP1001, targeting the Grb2 protein), is in a Phase 2 study for blood cancers, and BP1001-A, a drug product modification of prexigebersen, is in a Phase 1/1b study for solid tumors. The Company's second product, BP1002, which targets the Bcl-2 protein, is being evaluated for the treatment of blood cancers and solid tumors, including lymphoma and acute myeloid leukemia. In addition, an IND application is expected to be filed for BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3.

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

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws. These statements are based on management's current expectations and accordingly are subject to uncertainty and changes in circumstances. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be 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, 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, the maintenance of intellectual property rights, that patents relating to existing or future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, the impact, risks and uncertainties related to global pandemics, including the COVID-19 pandemic, and actions taken by governmental authorities or others in connection therewith, and such other risks which are identified in Bio-Path's most recent Annual Report on Form 10-K, in any subsequent quarterly reports on Form 10-Q and in other reports that Bio-Path files with the Securities and Exchange Commission from time to time. 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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