Bio-Path Holdings Provides Clinical and Operational Update

Company Expects to Achieve Several Near-Term Clinical Milestones

HOUSTON – March 16, 2023 – 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 provides a clinical development and operational update.

"Throughout 2022, we laid the foundation to meaningfully advance our DNAbilize antisense RNAi nanoparticle technology in a number of important oncology indications for which there are limited treatment options," said Peter H. Nielsen, President and Chief Executive Officer of Bio-Path. "In addition to our clinical progress, we made significant investment towards shoring up our manufacturing supply and intellectual property armamentarium. Given these advancements and the proven safety and efficacy profile shown to date across our portfolio, we look forward to several near-term clinical milestones."

Important Near-Term Clinical Milestones

BP1001-A Phase 1/1b Clinical Trial in Solid Tumors

- Important trial with advanced or recurrent solid tumors, including ovarian and uterine, pancreatic and breast cancer with initial cohort completion and data readout expected before mid-year.

BP1002 Phase 1/1b Clinical Trial in Relapsed/Refractory AML

- Focus on patients who relapsed on venetoclax treatment with initial cohort completion and readout expected in the second quarter of 2023.

Prexigebersen (BP1001) Phase 2 Clinical Trial in AML

- Two of the three cohorts in the clinical trial already exceed the minimum efficacy required for enrollment expansion.
- Assess safety and efficacy of each cohort treatment combination therapy with potential to qualify for expedited program status after cohort's initial interim analysis, which are expected to commence by cohort in the second quarter of 2023.

Clinical Program Overview

Bio-Path's clinical development program consists of one Phase 2 clinical trial and three Phase 1 or 1/1b clinical trials. There is one additional drug candidate that is in preclinical development, which may be submitted to the FDA later in the year in an Investigational New Drug (IND) application.

Phase 2 Clinical Trial – Bio-Path's Phase 2 clinical trial is treating Acute Myeloid Leukemia (AML) patients. This trial is comprised of three separate cohorts of patients and treatments, each separately approvable by the FDA as a new drug treatment. The first two cohorts are treating patients with the triple combination of prexigebersen (Bio-Path's drug candidate BP1001), decitabine and venetoclax. The first cohort includes untreated AML patients, and the second cohort includes relapsed/refractory AML patients. Finally, the third cohort is treating relapsed/refractory AML patients, who are venetoclax-resistant or -intolerant, with the two-drug combination of prexigebersen and decitabine. The interim analysis of each cohort to assess the safety and efficacy of treatment combination therapy is expected to commence by cohort in the second quarter of 2023, with the potential to qualify for expedited regulatory status.

Phase 1/1b Clinical Trial in BP1001-A in Advanced Solid Tumors – Phase 1/1b clinical trial of BP1001-A in patients with advanced or recurrent solid tumors, including ovarian and uterine, pancreatic and breast cancer. BP1001-A is a modified product candidate that incorporates the same drug substance as prexigebersen but has a slightly modified formulation designed to enhance nanoparticle properties. Completion of the first dose escalation cohort is expected in the coming months.

Phase 1/1b Clinical Trial in BP1002 in Relapsed/Refractory AML. Phase 1/1b clinical trial for BP1002 to treat relapsed/refractory AML patients, including venetoclax-resistant patients. BP1002 targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. AML patients that fail frontline venetoclax-based therapy have very poor prognosis with median overall survival of less than three months. Completion of the first dose escalation cohort is expected in the coming months.

Phase 1 Clinical Trial in BP1002 in Refractory/Relapsed Lymphoma and Chronic Lymphocytic Leukemia (CLL). Phase 1 clinical trial for refractory/relapsed lymphoma and CLL. The Phase 1 clinical trial is being conducted at several leading cancer centers, including the Georgia Cancer Center, The University of Texas Southwest and New York Medical College. Completion of the current patient cohort is expected in 2023.

Preclinical Work for BP1003. The Company continues to advance its drug candidate, BP1003, for the treatment of advanced solid tumors, including pancreatic cancer. BP1003 is an antisense RNAi nanoparticle targeting the STAT3 protein. Plans are to conduct a Phase 1 study of BP1003 in patients with refractory, metastatic solid tumors (pancreatic, non-small cell lung cancer).

Manufacturing Supply

The COVID-19 pandemic created manufacturing interruptions over the last several years. The Company experienced manufacturing shutdowns in supply chain manufacturing plants and an increase in lost manufactured product batches that created supply disruptions. In addition, the onset of messenger RNA vaccine development for COVID-19 created increased backlog time at oligonucleotide suppliers. These conditions created drug candidate supply shortfalls that caused enrollment challenges for Bio-Path's clinical trials.

The result of these factors led Bio-Path to double the Company's supply chain, increase capacity, quality and improve scheduling flexibility. These goals were achieved in 2022 and have resulted in increased drug candidate supply, quality and patient enrollment.

Intellectual Property Protection

Bio-Path's composition of matter patents protect encroachment from third parties on its proprietary products. This technology is solely owned by Bio-Path. These composition patents allow the Company to apply its core technology to new protein targets and receive new 20-year patents. Bio-Path's patent portfolio is as follows:

- New composition and methods of use patent issued covers DNAbilize technology, solely owned by Bio-Path.
- Five patents issued in the United States; eight foreign patents issued; one additional foreign patent application allowed.
- Five applications pending in the United States along with 60+ applications pending in foreign jurisdictions.

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 transfusion. Bio-Path's lead product candidate, prexigebersen (BP1001, targeting the Grb2 protein), is in a Phase 2 study for blood cancers and a Phase 1 study BP1001-A, a drug product modification of prexigebersen, in solid tumors has commenced. 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 is expected to be filed for BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3, in 2023.

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 the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith, 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, 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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Contact Information:

Investors

Will O'Connor
Stern Investor Relations, Inc.
212-362-1200
will@sternir.com

Doug Morris
Investor Relations
Bio-Path Holdings, Inc.
832-742-1369