Bio-Path Holdings Provides Key Clinical Updates

First Solid Tumor Patient Treated with Second, Higher Dose in Phase 1/1b BP1001-A Clinical Trial Experienced Tumor Reduction and Continued Stable Disease

Reports Continued Patient Progress from Phase 2 Triple Combination Study of Prexigebersen in Acute Myeloid Leukemia (AML)

HOUSTON – February 13, 2025 – 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 and obesity drugs, today provides an update from the Company's ongoing Phase 1/1b clinical trial of BP1001-A in solid tumor patients and reports continued patient progress from the Company's ongoing Phase 2 triple combination study of prexigebersen in Acute Myeloid Leukemia (AML).

"These continued positive responses mark a significant milestone for Bio-Path as they suggest our DNAbilize® platform technology has the potential to produce multiple drug candidates capable of target-specific protein inhibition for over-expressed, disease-causing gene products," said Peter H. Nielsen, President and Chief Executive Officer of Bio-Path. "As previously reported in August 2024, we were thrilled to see that our first patient treated with the higher dose (90 mg/m^2) in our Phase 1/1b study of BP1001-A who has shown tumor regression and stable disease continued successful treatment through a tenth treatment cycle. We believe this is significant, particularly considering the heavily pretreated and fragile patient population involved."

"This elderly female patient with gynecologic cancer had previously been treated with multiple lines of chemotherapy along with multiple surgeries for her disease, and only now is showing positive clinical results with BP1001-A treatment. Importantly, we are not seeing the onerous side effects typically seen in patients with advanced solid tumors being treated with standard chemotherapies," continued Mr. Nielsen.

"In addition, we previously noted extended treatment durability in two elderly patients in our Phase 2 triple combination study of prexigebersen, venetoclax and decitabine in AML patients. We are pleased to report that each of these patients remain in complete remission after two years of treatment. These ongoing positive outcomes underscore the potential for prexigebersen to treat fragile AML patients for extended periods. We are particularly pleased with these results, as elderly AML patients are typically unable to tolerate intensive chemotherapy and thus experience very poor clinical outcomes," concluded Mr. Nielsen.

Solid Tumor Patient Response in Second, Higher Dose Cohort – Previously, Bio-Path reported its first patient in the second dose cohort in its Phase 1/1b advanced solid tumor clinical trial experienced a positive response that may signal that this analog of prexigebersen has potential as a new treatment for advanced solid tumors. The patient appears to be doing well on study after

failing extensive chemotherapy and surgical treatment for gynecologic cancer, demonstrating a 15% reduction in her primary tumor through six cycles of treatment. Moreover, it appears that these positive outcomes may have contributed to allowing her to continue with rigorous exercise and improved quality of life.

As of January 2025, this patient continues doing well on treatment, recently completing nine cycles and is now in her tenth treatment cycle.

The dose finding portion of the Phase 1/1b trial is comprised of BP1001-A monotherapy with no accompanying chemotherapy. This clinical trial of BP1001-A in patients with advanced or recurrent solid tumors has successfully completed the initial prescribed dose in the first cohort of 60 mg/m^2 and began enrollment in the higher dose cohort of 90 mg/m^2. The Phase 1b portion of the study is expected to commence after completion of three planned BP1001-A monotherapy dose level cohorts and is intended to assess the safety and efficacy of BP1001-A in combination with paclitaxel in patients with recurrent ovarian or endometrial tumors. Phase 1b studies are also expected to be opened in combination with gemcitabine in late-stage pancreatic cancer

AML Patients Demonstrate Extended Treatment Durability – Previously, Bio-Path reported two patients were identified in the Phase 2 clinical trial treating AML patients who demonstrated continued treatment durability. As of January 2025, both these patients are receiving treatment and are continuing to do well. The first patient is an elderly female who had received 16 cycles of treatment over 21 months when first reported on. She continues on study having received 20 cycles over 26 months and she remains in complete remission. The second patient is an elderly male who had received 12 cycles of treatment over 14 months when first reported on. He continues on study having received 16 cycles over 20 months and remains in complete remission. Both patients are being treated with the triple combination of prexigebersen, decitabine and venetoclax.

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 and as a treatment for obesity and related metabolic diseases is being assessed preclinically. 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 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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