BIO-PATH HOLDINGS ANNOUNCES CLEARANCE OF INVESTIGATIONAL NEW DRUG APPLICATION FOR BP1002

Phase 1 Clinical Trial to Evaluate Ability of BP1002, Targeting Bcl-2 Protein, to Treat Refractory/Relapsed Lymphoma and Chronic Lymphocytic Leukemia Patients

HOUSTON – November 21, 2019 – Bio-Path Holdings, Inc., (NASDAQ:BPTH), a biotechnology company leveraging its proprietary DNAbilize® antisense RNAi nanoparticle technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced that the U.S. Food and Drug Administration (FDA) has reviewed and cleared the Investigational New Drug (IND) application for BP1002 (liposomal Bcl-2), the Company's second drug candidate. An initial Phase 1 clinical trial will evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and chronic lymphocytic leukemia patients.

BP1002 targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. High expression of Bcl-2 has been correlated with adverse prognosis for patients diagnosed with relapsed, aggressive non-Hodgkin's lymphoma. Preclinical studies have shown BP1002 to be a potent inhibitor against the Bcl-2 target, and its benign safety profile should enable BP1002 combination therapy with approved agents.

"With this IND submission now accepted by the FDA, the path is now cleared for us to advance our important first-in-human clinical work for BP1002 in cancers with unmet medical need," said Jorge Cortes, M.D., Director of the Georgia Cancer Center and Chairman of the Bio-Path Scientific Advisory Board. "Importantly, BP1002 activity is based on blocking the Bcl-2 messenger RNA and not the BH3 domain, as is the case with venetoclax. As a result, we believe BP1002 may provide an alternative for relapsed venetoclax patients."

The Phase 1 clinical trial is expected to be conducted at several leading cancer centers, including The University of Texas MD Anderson Cancer Center and the Georgia Cancer Center. Initially, a total of six evaluable patients are scheduled to be treated with BP1002 monotherapy in a standard 3+3 design, with a starting dose of 20 mg/m^2. The approved treatment cycle is two doses per week over four weeks, resulting in eight doses administered over twenty-eight days.

William G. Wierda, M.D., Ph.D. will serve as Principal Investigator for the trial. Dr. Wierda is a Professor and Center Medical Director for the Department of Leukemia at The University of Texas MD Anderson Cancer Center. Dr. Wierda also serves as Section Chief - Chronic Lymphocytic Leukemia in the Department of Leukemia at MD Anderson.

“This IND clearance for BP1002 marks an important regulatory milestone for Bio-Path, as we progress our second drug candidate into the clinic. Given the encouraging pre-clinical data and safety profile we have seen to-date, we are eager to begin this first-in-human study,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings.

The IND review process was performed by the FDA’s Office of Oncologic Diseases, Division of Hematologic Malignancies and involved a comprehensive review of data submitted by the Company covering pre-clinical studies, safety, chemistry, manufacturing and controls, and the protocol for the Phase 1 clinical trial.

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 the treatment of blood cancers and is in the process of filing an IND for a Phase 1 clinical trial for solid tumors. The Company’s second product BP1002, which targets the Bcl-2 protein, will be evaluated for the treatment of lymphoma and solid tumors. 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 2020.

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, Bio-Path's ability to 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, the maintenance of intellectual property rights, that patents relating to existing for future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, risks relating to maintaining Bio-Path's listing on the Nasdaq Capital Market 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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