Bio-Path Holdings Announces Positive Results from Interim Analysis of Phase 2 Clinical Trial of Prexigebersen in Acute Myeloid Leukemia

Interim Data Analysis Demonstrates Significant Clinical Improvement and Tolerable Safety Profile in High-Risk Patients

Company Provides Clinical Development Plan Update with Pathways to Registration

HOUSTON – August 1, 2023 – 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 reports interim data from Stage 2 of the Company's Phase 2 study of prexigebersen in combination with decitabine and venetoclax for the treatment of acute myeloid leukemia (AML). Prexigebersen continues to be well-tolerated and has now shown compelling efficacy results in two reporting cohorts including evaluable newly diagnosed AML patients and evaluable refractory/relapsed AML patients, which exceed outcomes with frontline therapy. The protocol for the Phase 2 study allows Bio-Path to conduct an interim efficacy analysis on each cohort at its discretion. Additional data will become available as final efficacy reviews are conducted.

"We are delighted to report these positive interim data as they represent a potential breakthrough for these very sick patients who face a complicated disease with limited treatment options," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "Based on these favorable results, we plan to file for regulatory designations that could accelerate our ability to bring this potentially lifesaving therapeutic to patients with the greatest of unmet medical needs."

Stage 2 of the Phase 2 clinical trial is a multi-center, open label study designed with three patient cohorts that offer Bio-Path three pathways to registration:

- Newly diagnosed AML patients treated with prexigebersen in combination with decitabine plus venetoclax;
- Refractory/relapsed AML patients treated with prexigebersen in combination with decitabine plus venetoclax; and
- Refractory/relapsed AML patients, resistant or intolerant to venetoclax, treated with prexigebersen in combination with decitabine.

The primary objective of the study is to assess whether prexigebersen in combination with decitabine plus venetoclax provides higher response rates than decitabine plus venetoclax in AML patients and whether prexigebersen in combination with decitabine provides higher response rates than decitabine alone in AML patients.

Data Highlights

Fourteen newly diagnosed patients were evaluable in Cohort 1 and treated with at least one cycle of the prexigebersen, decitabine and venetoclax combination therapy. All patients in this cohort (median age 75) were adverse risk by 2017 European LeukemiaNet (ELN) guidelines (n=10) or secondary AML (n=4). Prexigebersen was well-tolerated, and adverse events (AEs) were generally consistent with decitabine and venetoclax treatment and/or for AML. Twelve of the fourteen evaluable patients (86%) achieved complete remission (CR/CRi) and two (14%) achieved partial remission (PR). In total, 100% of the evaluable patients had a response to treatment. The complete remission rate (CR/CRi) of (86%) for the evaluable patients in Cohort 1 is significantly higher than complete remission (CR/CRi) rates (62%) for newly diagnosed patients treated with the frontline combination treatment of decitabine and venetoclax. This result is further highlighted by the high-risk rating of Bio-Path's Cohort 1 evaluable patients and the inclusion of secondary AML patients (29%), both of which are classes of patients with very difficult to treat disease.

Fourteen refractory/relapsed evaluable AML patients in Cohort 2 were treated with at least one cycle of the prexigebersen, decitabine and venetoclax combination therapy. All patients in this cohort (median age 56.5) were adverse risk by 2017 ELN guidelines (n=11) or secondary AML (n=2). Prexigebersen was well-tolerated, and AEs were generally consistent with decitabine and venetoclax treatment and/or for AML. Eight of the fourteen evaluable patients (57%) achieved complete remission (CR/CRi), two (14%) achieved partial remission (PR) and three (22%) achieved stable disease. In total, 93% of the evaluable patients had a response to treatment. The complete remission rate (CR/CRi) of (57%) for the evaluable refractory and relapsed patients in Cohort 2 is significantly higher than complete remission (CR/CRi) rate (21%) for refractory/relapsed patients treated with the combination treatment of decitabine and venetoclax. As with newly diagnosed patients in Cohort 1, this result is further highlighted by the high-risk rating of Bio-Path's Cohort 2 evaluable patients and the inclusion of secondary AML patients (15%).

Next Steps

Efficacy data from the initial interim analysis of Cohort 1 and Cohort 2 are compelling and show that prexigebersen-based combination therapy was not only safely administered in Cohort 1 and Cohort 2 to high-risk newly diagnosed and refractory/relapsed AML patients considered unsuitable for standard chemotherapy, but also demonstrated efficacy signals significantly better than current therapies. This is particularly encouraging as refractory/relapsed patients are a challenging population in which current treatment options are suboptimal.

As a result of the interim review, Bio-Path has demonstrated superiority of prexigebersen combination therapy in treating AML patients and currently plans to pursue U.S. Food and Drug Administration (FDA) expedited programs for Fast Track and Breakthrough Therapy designations. Fast Track Designation is designed to expedite the development and review of drugs to treat serious conditions and to fulfill an unmet medical need. Breakthrough

Therapy Designation is a process designed to expedite the development and review of drugs that may demonstrate substantial improvement over available therapies.

The next steps for Bio-Path are to conduct an administrative review to affirm the cohorts that will continue with enrollment. Nineteen patients had been chosen as an initial sample size for a cohort to provide interim efficacy data, however, the protocol for the Phase 2 allows Bio-Path to conduct interim efficacy analysis sooner at its discretion.

Operations in the United States are expected to remain unchanged with an expected six to ten treatment sites. In addition, Bio-Path is evaluating whether to seek to expand Stage 2 of the Phase 2 clinical trial by pursuing operations in Europe, as it believes there are more potential patients for Stage 2 of the Phase 2 clinical trial there, which could meaningfully enhance enrollment and accelerate completion of clinical trial milestones.

About Prexigebersen (BP1001)

Prexigebersen is a neutral liposome incorporated with nuclease-resistant, hydrophobic P-ethoxy antisense oligodeoxynucleotides targeted to Grb2 mRNA. Grb2 is an adaptor protein that links oncogenic tyrosine kinases with downstream kinases, such as ERK and AKT, which are critical to cell proliferation and survival.

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 BP1001-A, a drug product modification of prexigebersen, is in a Phase 1 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 its drug candidates, its ability to obtain domestic and/or foreign regulatory approvals for its 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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