Bio-Path Holdings

An Oncology-Focused Biotechnology Company

January 2022

Forward looking statements

This Presentation contains forward-looking statements with respect to business conducted by Bio-Path Holdings, Inc. By their nature, forward-looking statements and forecasts involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future.

The Company does not undertake to update any forwardlooking statements. There are a number of factors that could cause actual results and developments to differ materially and investors should use their own judgment to evaluate risks. Stockholders are encouraged to review the risk factors contained in the Company's most recent Annual Report on Form 10-K and in other reports the Company files with the Securities and Exchange Commission from time to time.





Introducing Bio-Path Holdings

Advanced Oligonucleotide Therapeutics with High Efficiency Systemic Delivery



Technology Highlights

DNAbilize[®] Technology, next generation single-stranded DNA antisense Robust clinical pipeline with novel oncology targets

www.biopathholdings.com

Robust Oncology Pipeline

	Preclinical	IND	PHASE 1	PHASE 2
Prexigebersen (BP1001, Lip	osomal Grb2)			AML*
Prexigebersen-A (BP1001-A	(ovar pancre	ian, endometrial, atic)	*Orphan drug des EMA for AML	ignation from the USFDA and
BP1002 (Liposomal Bcl-2) L	ymphoma, CLL			
BP1002 (Liposomal Bcl-2) A	ML venetoclax failures			
BP1003 (Liposomal Stat3)	Pancreatic cancer, lung			



DNAbilize[®] Technology

Proven As Safe, Robust and Targeted Method for Treating Disease

No Toxicity

With human patients to date in prexigebersen clinical trial.

- DNAbilize[®] liposome structure is similar to the cellular membrane
- P-ethoxy DNA does not induce hepatotoxicity or thrombocytopenia

Systemic Treatment

I.V. delivery to the main organs via blood flow.

High Cellular Uptake

Liposome structure is similar to the cellular membrane enhancing cellular uptake.

Nanoparticle Liposomes

Enable penetration into tumors for delivery of drug.

Proven Target Inhibition

Demonstrated that DNAbilize[®] method inhibits target protein, proving delivery technology works.



No Toxicity







High Cellular uptake



Nanoparticle liposomes



Proven target inhibition

Stage 1 of the Phase 2 Efficacy Trial Design for AML Prexigebersen Combination Therapy

- Treatment of untreated AML patients who are induction therapy ineligible and unfit for stem cell transplant
- Efficacy trial conducted at 6 leading cancer centers in the U.S., including the MD Anderson Cancer Center
- Primary Endpoint: # patients who achieve CR, (accepted surrogate endpoint)



With this Phase 2 design, plans for a pivotal trial would be discussed with FDA if the Interim Analysis significantly exceed current therapy



Results of Stage 1 Interim Analysis

Patient evaluation summary



- 5 Patients achieved CR (30%) Note: LDAC alone CR rate 7-13%
 6 Patients achieved stable disease (35%)
- 2 Stable disease patients had >50% bone marrow blasts reductions
- CR patient was eligible for and received a bone marrow transplant

Importantly, no toxicity associated with prexigebersen

Based on the recommendations of the study PIs, protocol amendments have been made for Stage 2 in the ongoing study

- A cohort of refractory/resistant AML patients added
- LDAC cohort discontinued
- Triple combination treatment of prexigebersen/decitabine/venetoclax
- Resulted in 2 cohorts, one with untreated AML and a second with refractory/relapsed AML being treated with the triple combination
- A third cohort was added to treat AML refractory/relapsed and venetoclax intolerant patients with prexigebersen and decitabine



Of the evaluable patients 65% showed some form of response, including CR and stable disease, to the combination treatment



Data from Ongoing Phase 2 Study of Prexigebersen at 2021 American Society of Hematology Annual Meeting

- Prexigebersen data show signs of safety and efficacy in high-risk AML patients
- In the Poster we reported the safety run-in and efficacy data of AML patients treated with prexigebersen + decitabine or prexigebersen + decitabine + venetoclax.
- Six patients, including four patients (67%) with de novo AML and two secondary AML patients (33%), were treated with at least one cycle of prexigebersen + decitabine combination therapy.
 - All patients in this cohort (median age 72 years) were considered high risk
 - Three of the six patients (50%) had a response, including two de novo patients (33%) who achieved a CRi (complete remission with incomplete blood count recovery) and one secondary AML patient (17%) who achieved a partial remission (PR)
 - ◆ Patients with these conditions generally have a less than 20% CR/CRi response rate.
- Six patients were treated with at least one cycle of prexigebersen + decitabine + venetoclax combination therapy.
 - ♦ Of the six patients, two (33%) had de novo AML and four (67%) were relapsed/refractory
 - Four patients (67%) achieved a complete remission (CR)/CRi/morphological leukemia free state (MLFS) (n=1/2/1) and one (17%) achieved a PR.
 - Of these five patients, three were relapsed/refractory (75% of relapsed/refractory patients) (1 CR/1 CRi/1 MLFS) and two were de novo (1 CRi/1 PR) (100% of the de novo patients).
 - CR rates to combination treatment with decitabine and venetoclax for relapsed/refractory AML patients are 42-52%^{1,2} and 0-39%^{1,2} for relapsed/refractory secondary AML patients.

Prexigebersen-A Phase 1 Study in Solid Tumors

- Prexigebersen-A is a modified product that incorporates the same drug substance as prexigebersen but has a slightly modified formulation designed to enhance nanoparticle properties
- Prexigebersen-A efficacy against ovarian tumors was enhanced when combined with paclitaxel

(Lara et al., Therapeutic Efficacy of Liposomal Grb2 antisense oligodeoxynucleotide (L-Grb2) in preclinical models of ovarian and uterine cancer. Oncotarget *11*: 2819-2833, 2020)

- Prexigebersen-A in combination with gemcitabine is efficacious against pancreatic tumors
- The FDA approved the IND application and a Phase1/1b clinical trial will be opened
- Clinical Plans
 - Open a Phase 1 study of prexigebersen-A in patients with advanced or recurrent solid tumors, including ovarian and uterine, pancreatic and breast cancer
 - Second open Phase 1b studies of prexigebersen-A + paclitaxel in recurrent ovarian or endometrial tumors and prexigebersen-A + gemcitabine in patients with metastatic pancreatic tumors



BP1002 – A Phase 1 Study in Lymphoma and CLL

- BP1002 is an RNAi antisense nanoparticle targeting Bcl-2 (Liposomal Bcl-2)
- BP1002 decreased viability of lymphoma cells (11 of 15 lymphoma cell lines)
- By blocking BcI-2 protein expression, BP1002 allows chemotherapy and radiation to activate apoptosis
- BP1002 extended survival of mice bearing lymphoma xenografts
- Focus in CLL will be on patients who have relapsed on venetoclax treatment
- Phase 1 clinical trial is open for lymphoma and CLL and the first patient has been dosed.



BP1002 – A Phase 1/1b Study in Relapsed/Refractory AML

- The FDA cleared the Investigational New Drug (IND) application for BP1002 Phase 1/ 1b clinical trial in relapsed/refractory AML patients.
- High expression of BP1002 target Bcl-2 has been correlated with adverse prognosis for patients diagnosed with AML
- Preclinical studies have shown BP1002 to be a potent inhibitor against the Bcl-2 target
- AML patients that fail frontline venetoclax-based therapy have very poor prognosis with median overall survival of less than three months
- Focus in AML will be on patients who have relapsed on venetoclax treatment

BP1003 Targeting STAT3

- BP1003 has efficacy against non-small cell lung cancer, AML, and pancreatic cancer cells
- BP1003 + gemcitabine combination is efficacious in pancreatic cancer-derived tumors in animals
- IND enabling studies during 2020 2022
- Goal is to submit a new IND in 2022
- Conduct a Phase 1 study of BP1003 in patients with refractory, metastatic solid tumors (pancreatic, non-small cell lung cancer)



Experienced Leadership Team



Peter Nielsen

Co-Founder, President, Chief Executive Officer and Chief Financial Officer Officer and Director since founding Company in 2007

Manufacturing development and evolution of engineered product design



Michael Hickey

Director Clinical Program Management 20+ years experience across all phases of drug development

Point of escalation Amgen for South East regional CRO monitoring

Ana Tari Ashizawa, PhD, MBA

Sr Vice President, Research, Development & Clinical Design Key member of the research team that developed our liposomal delivery technology



Anthony Price, MBA

Sr Vice President, Finance, Accounting & Administration Former Associate Director of Accounting and Finance at Lexicon Pharmaceuticals



Scientific Advisory Board

Jorge Cortes, M.D. Chairman	•	Director, Cancer Center at Augusta University Georgia Research Alliance Eminent Scholar in Cancer Formerly, Jane and John Justin Distinguished Chair in Leukemia Research, Chief of the AML and CML sections, and Deputy Chair of the Department of Leukemia at The University of Texas MD Anderson Cancer Center
D. Craig Hooper, Ph.D.	•	Professor of Cancer Biology and Neurological Surgery and the Section Chief for Translational Research, Tumor Division, in the Department of Neurological Surgery at Thomas Jefferson University His work has led to novel immune therapies for rabies infection, neuro-inflammation, and cancer with 10 issued U.S. patents and 19 international patents that have been licensed to five companies in the U.S. and abroad He is the founding president of the Jefferson Chapter of the National Academy of Inventors and a fellow of the National Academy of Inventors.
Ana Tari Ashizawa, PhD, MBA	•	Senior Vice President Research, Development and Clinical Design Bio-Path Holdings, Inc.
Jason B. Fleming, M.D., F.A.C.S.	• • •	Newly appointed Chair of the Department of Gastreroenterology at H. Lee Moffitt Cancer Center and Research Institute. Professor with tenure in the Department of Surgical Oncology at the University of Texas MD Anderson Cancer Center in Houston. Served as as chief of Pancreas Surgery and executive director of Perioperative Services and created the first xenograft program in gastrointestinal cancer. Received the Castle Connolly Top Doctor award every year since 2013 President's Faculty Recognition Award for Outstanding Contribution to the University of Texas MD Anderson Cancer Center in 2016.

IP and Financial Snapshot

Intellectual Property

- Original patents licensed from MD Anderson
- New composition and methods of use patent issued covers DNAbilize[®] technology, solely owned by Bio-Path
 - Five patents issued in the U.S., two foreign patents issued
 - Six additional applications pending in the U.S.

Financial Snapshot

- Ticker: NASDAQ: BPTH
- Cash: \$26.6 million as of September 30, 2021.
- Market Cap: \$36 million as of September 30, 2021
- Burn rate:
 - Approximately \$3 million per quarter



Accomplishments in 2021

- We presented a poster at the 2021 American Association for Cancer Research (AACR) Annual Meeting in April that summarized preclinical studies that demonstrated the effectiveness of BP1002 + decitabine combination treatment in venetoclax resistant cells opening potential new therapies.
- In April 2021 we announced the completion of the safety run-in of Stage 2 of the Phase 2 clinical trial in AML testing of the combination treatment prexigebersen + decitabine + venetoclax in six patients.
- In August 2021 the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug (IND) application for BP1002 for an initial Phase 1/1b clinical trial the treatment of refractory/relapsed AML patients. By targeting Bcl-2 at the DNA level rather than the protein, BP1002 might overcome and prevent some of the mechanisms of resistance that affect venetoclax.
- In February 2021, we announced that the United States Patent and Trademark Office (USPTO) granted U.S. Patent No. 10,898,506 titled "P-ethoxy nucleic acids for liposomal formulation."
- In June 2021, we announced that the USPTO had granted a new patent relating to our BP1003 program, a novel liposome-incorporated oligodeoxynucleotide inhibitor against Signal Transduction and Activator of Transcription-3 (STAT3).
- Our patent portfolio currently includes five issued patents in the U.S. We have six additional pending patent applications. These patents build on earlier patents that have been granted that protect the platform technology for DNAbilize[®], our novel RNAi nanoparticle drug platform.
- > Published review article in the journal Biomedicines discussing liposome technology.
- In February 2021, we closed a public offering pursuant to which we raised \$12.2 million in net proceeds. In addition, during 2020 and the first nine months of 2021, we raised an additional \$8.0 million in net proceeds in an offering conducted pursuant to our At-The-Market Offering Agreement with H.C. Wainwright & Co. This followed \$4.3 million raised in 2020. This followed \$29.3 million raised in 2019.
- In October 2021, we announced that the FDA reviewed and cleared the IND application to initiate a Phase 1/1b clinical trial of prexigebersen-A (liposomal Grb2-A or BP1001-A) in patients with solid tumors, including ovarian, endometrial, pancreatic and triple negative breast cancer.
- In December 2021, a poster was presented at the American Society of Hematology in reporting progress in our Phase 2 clinical trial in AML that reported no safety issues and efficacy that exceeded frontline treatment.
- In December 2021, we launched a redesigned Company website.



Bio-Path Holdings Thank you

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