PathAI: Liver Forum
October 27, 2020
Company Overview

PathAI’s platform promises substantial improvements to the accuracy of diagnosis and the measurement of therapeutic efficacy for complex diseases like cancer, IBD and NASH, leveraging modern approaches in machine learning.

- Founded in 2016 by Andy Beck, MD PhD and Aditya Khosla, PhD
- Headquartered in Boston with offices in New York & Austin
- World class team of >150 people
- Research with majority of top 20 pharma companies
- Signed industry first AI-driven CDx program in early 2020
- 11 Presentations on Liver Diseases in 2019-2020

OUR MISSION

Improve patient outcomes with AI-powered pathology
**PathAI has made Significant Progress in NASH: 2019-2020**

<table>
<thead>
<tr>
<th>Grading and Staging NASH</th>
<th>Monitoring Treatment Response in NASH</th>
<th>Grading, Staging, and Monitoring Treatment Response in PSC &amp; HBV</th>
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<tbody>
<tr>
<td>• AASLD - Machine Learning Models Accurately Interpret Liver Histology in Patients With Nonalcoholic Steatohepatitis (NASH)</td>
<td>• EASL (late breaker) - Safety and efficacy of combination therapies including cilofexor/firsocostat in patients with bridging fibrosis and cirrhosis due to NASH: Results of the phase 2b ATLAS trial</td>
<td>• EASL - Machine learning models accurately interpret liver histology and are associated with disease progression in patients with primary sclerosing cholangitis</td>
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<td>• AASLD - Machine Learning Fibrosis Models Based on Liver Histology Images Accurately Characterize the Heterogeneity of Cirrhosis due to Nonalcoholic Steatohepatitis (NASH)</td>
<td>• AASLD - Validation of a machine learning-based approach (DELTA Liver Fibrosis Score) for the assessment of histologic response in patients with advanced fibrosis due to NASH</td>
<td>• EASL (late breaker) - Machine Learning Identifies Histologic Features Associated with Regression of Cirrhosis in Treatment for Chronic Hepatitis B</td>
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<td>• EASL - Machine learning models identify novel histologic features predictive of clinical disease progression in patients with advanced fibrosis due to nonalcoholic steatohepatitis</td>
<td>• AASLD - A machine learning model based on liver histology predicts the hepatic venous pressure gradient (HVPG) in patients with compensated cirrhosis due to nonalcoholic steatohepatitis (NASH)</td>
<td>• AASLD - Machine learning enables quantitative assessment of histopathologic signatures associated with ALT normalization in chronic hepatitis B patients treated with tenofovir disoproxil fumarate (TDF)</td>
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<td>• AASLD - Integration of AI-powered Liver Histopathology with RNA-seq Identifies Gene Network Signatures Associated with Prognosis in Patients with Nonalcoholic Steatohepatitis (NASH)</td>
<td>• AASLD - Machine learning based quantification of histology from patients treated for chronic hepatitis B identifies features associated with viral DNA suppression and e-antigen loss</td>
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Machine Learning Models Identify Novel Histologic Features Predictive of Clinical Disease Progression in Patients With Advanced Fibrosis Due to Nonalcoholic Steatohepatitis


Presented at The Digital International Liver Congress, 27–29 August 2020
Validation of a Machine Learning-Based Approach (DELTA Liver Fibrosis Score) for the Assessment of Histologic Response in Patients With Advanced Fibrosis Due to NASH


#1572 at AASLD: The Liver Meeting® Digital Experience, November 13–16, 2020

PathAI supports all phases of biomarker and diagnostic development

**Exploratory**
- Retrospective exploratory analysis
- Drug target identification
- Mechanisms of action
- Hypothesis generation: patient selection and stratification
- Trial design / indication selection

**Early Phase Efficacy**
- Prospective/Scalable Quantitative Pathology Data
- Hypothesis Generation/Testing
- Dose Selection/PD
- Selection/Stratification

**Late Phase / Registration**
- FDA approved IVD/CDx
- Lab Developed Test (CLIA)
- Drug Development Tool (DDT)

**Translational Research**
- Retrospective exploratory analysis
- Drug target identification
- Mechanisms of action
- Hypothesis generation: patient selection and stratification
- Trial design / indication selection

**Clinical Trial Services**
- Prospective/Scalable Quantitative Pathology Data
- Hypothesis Generation/Testing
- Dose Selection/PD
- Selection/Stratification

**Device Development**
- FDA approved IVD/CDx
- Lab Developed Test (CLIA)
- Drug Development Tool (DDT)
PathAI Clinical Trial Platform

Key platform features

- Upload WSI and pathology scores (as needed)
- One click algorithm initiation
- Standardized, quantitative biomarker results
- Study-level data organization
- Participant level & cumulative reporting
- Automated trend analysis for quality control
  - Drifts in data
  - Variability across sites / pathologist scores
- Monitoring capabilities

Product offerings

- Fit for purpose locked algorithms
- Pre-configured custom project-specific workflows
- Pre-configured interactive analytics module
PathAI is Well Positioned for Regulatory Success with Active FDA Engagement and Quality Achievements

Industry Progress: FDA’s approach advanced regarding Digital Pathology
- >30 510(k) clearances for product codes NOT, NQN, OEO (image analysis for IHC)
- 4x 510(k) clearances for WSI Primary Diagnosis on Digital Pathology Devices

PathAI FDA Interactions
- 3 x pre-subs meetings w FDA regarding “follow-on” and CDx products, 3 more planned
- Breakthrough Designation Status Submission in progress
- FDA accepted LOI for Biomarker Qualification Program for PathAI NASH Drug Development Tool (DDT) (2020)

PathAI Quality and Regulatory
- PathAI has achieved ISO27001 and ISO13485 certification as well as 21 CFR Part 820 compliance to ensure the highest quality and standards to achieve regulatory approval
Thank You