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ACS Scholar Adunoluwa Obisesan
BS, Massachusetts Institute of Technology, June 2021
(Chemical-biological Engineering, Computer Science & Molecular Biology)

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🖐 Say hello in the questions window!

How Artificial Intelligence is Changing Drug Discovery

ROBERT T. FOSTER, PhD
Chief Executive Officer, Hepion Pharmaceuticals Inc.

PATRICK R. MAYO, PhD
Senior Vice President, Clinical Pharmacology, Hepion Pharmaceuticals Inc.

PANNA SHARMA
Chief Executive Officer, President, and Director, Lantern Pharma, Inc.

MARIA L. MACCECCHINI, PhD
Founder, President, and CEO, Annovis Bio

BILL TUSZYNSKI, PhD
Partner, The Unami Group, LLC.

This ACS Webinar® is co-produced with the Science History Institute.
We are in the Midst of a Massive Healthcare Crisis
For the most part, people are asymptomatic in the earlier stages of disease

NAFLD
non-alcoholic fatty liver disease
“Fatty liver” disease associated with obesity, diabetes, hypertension, etc.
Approx. 25% of global population
Up to 100 million in U.S.

NASH
non-alcoholic steatohepatitis
A more severe form of NAFLD, with inflammation and liver scarring (fibrosis)
1.5 – 6.5% globally
Up to about 20 million people in U.S.

HCC
hepatocellular carcinoma
Most prevalent type (90%) of liver cancer & liver cancer is 2 most common cancer-related death*
>905,000 new cases and >830,000 deaths globally*
>30,000 new cases annually in U.S.* with 5-year survival of 18%**

Why Develop a Drug for NASH?
• No currently approved drugs for the treatment of NASH
• NAFLD/NASH may be asymptomatic with no simple and convenient diagnostic to identify subjects early in disease progression
• Symptoms may only appear when disease has progressed to the point where disease associated fibrosis is well established
• Consequences of NASH may be severe (need for liver transplant, cancer, cardiovascular disease, and death)
The Challenges
Nash Drug Development

Regulatory agencies require improvement in several indices of NASH by analysis of liver biopsies:
- Fatty deposits, cell death, inflammation and/or liver scarring (fibrosis)

Most study outcomes have been disappointing:
- Relatively high placebo responses
- Low responses on histologic endpoints from most candidate drugs
- Several drug candidates have been discontinued

How can we fix the poor response rates?

Challenges to Achieve Development and Commercial Success
AI can provide a pathway to success

1. Need for Disease Modifying Drugs
   - Need to develop drugs that target later stages of disease and reverse fibrosis

2. Need for Companion Diagnostic(s)
   - Disease typically asymptomatic
   - Biopsies problematic
   - Develop an AI to monitor subjects in clinical trials

3. Need for Commercial Strategy
   - Identify which subjects are best suited for our drug – target the best patient population
   - Address Market Access considerations
WHAT IS ARTIFICIAL INTELLIGENCE (AI)!

A STRICT DEFINITION
The area of computer science that studies how machines can closely imitate human intelligence.

A WORKING DEFINITION
The area of computer science that studies how machines can perform tasks that would normally require a sentient agent.
Source for Image above: Andrew Cochran, What is Artificial Intelligence?
AI/ML USE IS CHANGING DRUG DEVELOPMENT ACROSS THE FULL SPECTRUM OF DEVELOPMENTAL FUNCTIONS

Applications of AI

Subject enrollment/selection
Clinical trial design and monitoring
Pharmaceutical product management

Clinical trial

Market positioning
Drug discovery
Pharmaceutical product development

Understand critical process parameters
QA and QC
Drug design

Regulation of in-line quality
Ensure QA with aid of ELN and other techniques
Drug screening

Automated manufacturing
Personalized manufacturing
Correlating manufacturing errors to set parameters
Pharmaceutical manufacturing

Aid in deciding suitable excipients
Monitoring and modifying development process
Ensuring in-process specification compliance

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AI-POWR: AI/ML DRUG-DISEASE MODEL BASED DRUG DEVELOPMENT

Integrate Multi-Omics with Clinical Outcomes
- Biomarker for Disease
- Biomarker for Drug

Clinical Trial Study
- Enrichment
  - Phase 3
  - Sample Size
  - Cost
  - Derisk

A priori Responder Identification
- NDA Approval
- Post Market Payor
- Optimize COG

Quantitate Drug/Concentration Exposure – Response
Individualized Optimal Dose
AI-Guided Biomarker Based Prescribing
Precision Medicine

Integrated system to tissue based
Mechanistic modeling for MoA and Drug target interactions

NASH Specific Goals
- Replace Liver Biopsy
- Identify Drug Responsive Patients

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NASH Specific Goals
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AI IN DRUG DISCOVERY

AI in drug discovery

- Predicting 3D structure of target protein
- Predicting drug-protein interactions
- AI in determining drug activity
- AI in de novo drug design

- Designing biospecific drug molecules
- Designing multitarget drug molecules

- AI in polypharmacology
- AI in chemical synthesis
- AI in drug repurposing
- AI in drug screening

- AI in drug design
- AI in polypharmacology
- AI in chemical synthesis
- AI in drug repurposing
- AI in drug screening

- Identification of therapeutic target
- Prediction of new therapeutic use

- Prediction of toxicity
- Prediction of bioactivity
- Prediction of physicochemical property
- Identification and classification of target cells

Forward Looking Statements

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, among other things, statements relating to: future events or our future financial performance; the potential advantages of our RADR® platform in identifying drug candidates and patient populations that are likely to respond to a drug candidate; our strategic plans to advance the development of our drug candidates and antibody drug conjugate (ADC) development program; estimates regarding the development timing for our drug candidates and ADC development program; expectations and estimates regarding clinical trial timing and patient enrollment; our research and development efforts of our internal drug discovery programs and the utilization of our RADR® platform to streamline the drug development process; our intention to leverage artificial intelligence, machine learning and genomic data to streamline and transform the pace, risk and cost of oncology drug discovery and development and to identify patient populations that would likely respond to a drug candidate; estimates regarding patient populations, potential markets and potential market sizes; sales estimates for our drug candidates and our plans to discover and develop drug candidates and to maximize their commercial potential by advancing such drug candidates ourselves or in collaboration with others. Any statements that are not statements of historical fact (including, without limitation, statements that use words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “seek,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “target,” “model,” “objective,” “aim,” “upcoming,” “should,” “will,” “would,” or the negative of these words or other similar expressions) should be considered forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated by the forward-looking statements, such as (i) the impact of the COVID-19 pandemic, (ii) the risk that our research and the research of our collaborators may not be successful, (iii) the risk that none of our product candidates has received FDA marketing approval, and we may not be able to successfully initiate, conduct, or conclude clinical testing for or obtain marketing approval for our product candidates, (iv) the risk that no drug product based on our proprietary RADR® AI platform has received FDA marketing approval or otherwise been incorporated into a commercial product, and (v) those other factors set forth in the Risk Factors section in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 20, 2023. You may access our Annual Report on Form 10-K for the year ended December 31, 2022 under the investor SEC filings tab of our website at www.lanternpharma.com or on the SEC’s website at www.sec.gov. Given these risks and uncertainties, we can give no assurances that our forward-looking statements will prove to be accurate, or that any other results or events projected or contemplated by our forward-looking statements will in fact occur, and we caution investors not to place undue reliance on these statements. All forward-looking statements in this presentation represent our judgment as of the date hereof, and, except as otherwise required by law, we disclaim any obligation to update any forward-looking statements to conform the statement to actual results or changes in our expectations.
Using AI, Lantern is Transforming Drug Discovery Timelines and Cost

Lantern has launched 9 programs in two years, and is anticipating launching Multiple Phase 1 trials in 2023.

Lantern’s Drug Development Model

**Transforming** Early Stage Discovery & Development

**Traditional Model**
- 3 - 5 + Years
- $10 - 50 Million

**Lantern’s Model**
- Reduces Significant Time & Cost
- 2 Years
- $1.5 Million

“In around two years, Lantern has progressed its GBM program from initial RADR® insights, to wet lab validation, to late stage IND enabling studies - significantly cutting typical drug development timelines and cost”

(Patna Sharma)

**Sharpening** Later Stage Clinical Trials

**Traditional Model**
- 6 - 12 + Years
- $100 - 500 Million

**Lantern’s Model**
- Reduces Significant Time & Cost
- 3-5 Years
- $25-100 Million

“AI-driven patient stratification helps to focus clinical trials with potentially fewer and more select patients, which are more likely to respond, ultimately saving time and money”

(Radha Sharma)

RADR® is Lantern’s AI and ML Platform that Powers Oncology Drug Discovery and Development

Response Algorithm for Drug Positioning & Rescue

A proprietary integrated data analytics, experimental biology, oncology-focused, machine-learning-based platform focused on drug development

80+% Prediction Success
130K+ Patient Records
154+ Drug-tumor interactions
200+ Advanced ML Algorithms

- **Leverages** cutting edge machine-learning approaches and techniques to generate powerful data-driven insights
- **Enables** rapid informatics based hypothesis generation which can be validated in wet-lab
- **Uses** biology driven machine-learning algorithms to achieve higher prediction accuracy in real world settings
- **Employs** a platform that is scalable, robust, expanding and replicable to support a range of drug development needs

25+ Billion Data points from oncology focused real-world patient and clinical data and preclinical studies
Lantern Pharma is a Top 10 End-to-End AI Drug Discovery Company

Comparison of Top-40 Leading AI for Drug Discovery Companies Expertise in Drug Discovery R&D

RADR® has 4 Multi-Faceted Modules that are Facilitating Oncology Drug Discovery and Development of Lantern and its Collaborators

**Discover Mechanism of Action**

Use RADR® to find potential Mechanism of Action (MoA) of the Compound / Drug

**Identify New Disease Indications**

Identify and prioritize type/subtype of cancer for your compound with use of RADR®

**Determine Optimal Drug Combinations**

Use different algorithms and methods from RADR® to find potential Drug combinations

**Generate ML-Driven Biomarker Signatures for Patient Selection**

RADR® can derive Machine Learning based gene signatures, which can guide biomarker strategies and CDx ( Companion Diagnostics)
**RADR®’s Library of Over 200+ Advanced Algorithms Powers its Multi-Faceted Modules**

- **Example RADR® Algorithms**
  - Ensemble
  - Deep Learning
  - Bayesian Based
  - Tree Based
  - Rule Based
  - Clustering
  - Others

**Examples**
- Predicting drug sensitivity values, e.g. IC50
- Predicting blood brain barrier (BBB) permeability of a compound
- Predicting synergy values by combining compounds
- Identifying patient populations that can be targeted through a MoA
- Stratifying patients as responder, partial-responder, or non-responder
- Biomarker pattern-based patient clustering
- Predicting outcomes for companion diagnostic usage in a clinical trial

- Diversity of algorithms allow us to handle various input data types and solve different biological problems
- Lantern has filed patents for ensemble algorithms in cancer drug development

---

**RADR®’s Framework to Develop Actionable AI Insights Using Billions of Datapoints**

**Input Data**
- NIH
- TCGA
- Drug response
- Multi-omics

**RADR® Derived Insights**
- Identified PTGR1 as a biomarker that predicts LP-184 response
- Identified glioblastoma as target indication using PTGR1

**Validation of RADR® Derived Insights**
- PTGR1 validation using gene knockdown
- Validation of LP-184’s efficacy in GBM animal models

**Actionable Insights**
- FDA Orphan Drug Designation
- Phase 1 clinical trial in planning
RADR® Facilitates the Rapid and Cost-effective Development of Drug Assets

Framework of Lantern’s RADR® collaboration with Actuate Therapeutics

**Input Data**
- Drug response
- Patient survival
- In vitro potency
- Patient mutation panel

**RADR® Derived Insights**
- A neural network model for patient response prediction (accuracy 0.8)
- A biomarker connectivity network to map MoA
- Model for prediction-based drug indication expansion
- Survival modeling using selected biomarkers

**Actionable Insights**
- Developing a biomarker panel for use in Phase II clinical trials
- Proposing additional indications in cancers that have high likelihood of response

**RADR® Is a Top Performing A.I. Platform for Predicting a Drug’s Blood Brain Barrier Permeability**

Using the drug SMILE structure information, RADR® can create more than 4500 features that represent the atomic properties of a drug, including fingerprints and descriptors

Comparing the RADR derived model performance using the TDC (Therapeutics Data Commons)

**RADR® derived model is the top ranked model on the TDC leaderboard**
**RADR®’s Blood Brain Barrier Predictions Validated in the Wet Lab**

**A.**
RADR®, *in silico*, Predicted Blood Brain Barrier Permeability of LP-184

- **CsA**
- **LP-184**
- **TMZ**

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Probability of BBB Permeability</th>
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<tbody>
<tr>
<td>CsA</td>
<td>0.80</td>
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<tr>
<td>LP-184</td>
<td>0.20</td>
</tr>
<tr>
<td>TMZ</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**B.**
Wet Lab, *in vitro*, validated Blood Brain Barrier Permeability of LP-184

- **CsA**
- **LP-184**
- **TMZ**

<table>
<thead>
<tr>
<th>Molecule</th>
<th>BBB Permeability Score</th>
</tr>
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<tbody>
<tr>
<td>CsA</td>
<td>2.0 × 10^-4</td>
</tr>
<tr>
<td>LP-184</td>
<td>1.5 × 10^-4</td>
</tr>
<tr>
<td>TMZ</td>
<td>5.0 × 10^-5</td>
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</tbody>
</table>

**LP-184 has a Unique Mechanism of Action Leveraging Synthetic Lethality**

LP-184’s MoA was predicted by RADR® and validated with in-vitro/in-vivo studies

**A.**
RADR® Insight (*in silico*)

**PTGR1** activates LP-184 into its highly potent and cytotoxic form

In-vitro experiments confirmed the RADR® insight and that LP-184 was highly potent in cells with overexpression of PTGR1

**B.**
In-vitro Gene Editing Studies (CRISPR)

**C.**
LP-184 in NERD Cancers

**D.**
LP-184 in HRD Cancers

PTGR1 activates LP-184 into its highly potent and cytotoxic form

In-vitro experiments confirmed the RADR® insight and that LP-184 was highly potent in cells with overexpression of PTGR1

LP-184 shows exquisite potency in cancers with deficiencies in DNA damage repair (DDR) pathways including cancers with nucleotide excision repair (NERD) and homologous repair deficiencies (HRD)
Cancer Models with Common DNA Damage Response Deficiencies are Highly Sensitive to LP-184 Treatment

<table>
<thead>
<tr>
<th>PDX model</th>
<th>Cancer type</th>
<th>IC50 (nM)</th>
<th>DDR Mutations</th>
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<td>ATM, BRCA1, BRCA2</td>
</tr>
</tbody>
</table>

- PDX–derived cell lines with mutations in key HR and NER genes are highly sensitive to LP-184
- Only 1 model was not highly sensitive to LP-184 (highlighted in blue)

LP-184 Completely Inhibits Tumor Growth in Triple Negative Breast Cancer (TNBC) PDX Mouse Models

- Across 10 TNBC PDX mouse models LP-184 treatment resulted in 107–141% tumor growth inhibition
- All 10 TNBC PDX models were HR deficient
- 7/10 TNBC models were resistant to PARP inhibitors Olaparib/ Niraparib and to doxorubicin/ cyclophosphamide

Lantern and NCI A.I.-Driven Collaboration Identify ATRT Sensitivity to LP-184 - Published in Frontiers in Drug Discovery

- Systematic comparison of drug activity demonstrated key differences among alkylating agents that inform positioning
- Integrated multi–omic data bioinformatic analysis provides a rationale to examine potential use of LP–184 in cancers with loss of SMARCB1 and SMARCA4, such as ATRT
- Using small number of patient tumor RNA-seq samples, RADR® predicted extreme drug responsivity of LP-184 for ATRT
- RADR® A.I. Insights were validated by in vitro and in vivo experiments.
- A.I. driven models for drug discovery can be widely used for other rare cancers.
Gene Enrichment Analysis Predicts Cancers Deficient in DNA Damage Repair/Chromatin Remodeling to be Uniquely Sensitive to LP-184

LP-184 Response is Strongly Correlated With Gene Sets Involved with DNA Repair and Chromatin Remodeling

Gene’s Associated with Chromatin Remodeling are Strongly Negatively Correlated with LP-184

Sensitivity to LP-184 is Significantly Negatively Correlated With Driver Mutations of ATRT

A. LP-184 Sensitivity is Negatively Correlated with SMARCB1 Gene Expression

B. LP-184 Sensitivity is Negatively Correlated with SMARCA4 Gene Expression
**RADR® Predicts ATRT Sensitive in Patients with Limited Patient Gene Expression Data**

M.L. model prediction of LP-184 sensitivity in ATRT patients with either no SMARCB1, or SMARCA4

M.L. prediction of LP-184 sensitivity in ATRT patients with different genetic SMARCB1 genetic subtypes

**Atypical Teratoid Rhabdoid Tumor Cancer Cells are Exceptionally Sensitive to LP-184 - Validating RADR® Predictions**

CDX ATRT mouse model treated with LP-184

LP-184 treatment leads to near-complete tumor regression in ATRT mouse xenograft models

A. Time Course of ATRT CDX Mouse Tumors Treated with LP-184

B. Terminal ATRT Mouse Tumor Sizes After Treatment of Vehicle or LP-184
Lantern’s A.I.-Driven Collaborative Model for the Rapid and Cost-effective Development of Drug Candidates

Framework of Lantern’s RADR® collaboration with Actuate Therapeutics

Input Data
- Drug response
- Patient survival
- In vitro potency
- Patient mutation panel

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- Model for prediction-based drug indication expansion
- Survival modeling using selected biomarkers

Actionable Insights
- Developing a biomarker panel for use in Phase II clinical trials
- Proposing additional indications in cancers that have high likelihood of response

RADR® and A.I. Technologies Have the Potential to Make Rapid and Meaningful Advancements for Therapies for Rare Cancer Patients

How A.I. and M.L. Can Help Drug Development for Rare Cancers:
- Build M.L. models of drug response from existing preclinical/clinical data
- Generate M.L.-driven biomarker signatures for patient selection
- Discover a drug’s mechanism of action for a rare disease
- Identify potential responders and non-responder patients with small amount of patient data

Contact Lantern if You or Your Organization Would Be Interested in an A.I.-Driven Collaboration
IR Contact:
IR@lanternpharma.com
1-972-277-1136

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