



Clinical Stage Predictive Therapeutics Company

Propelling the Right Drugs to the Right Patients

August 26, 2024

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# Notable: Predictive Medicine Platform to Derisk & Propel Clinical Stage Assets

## Notable is a clinical-stage oncology predictive therapeutics company with a novel responder-focused approach to drug development

### Lead Program: Volasertib

- Originally developed by Boehringer Ingelheim (“BI”) through Phase 3; 1,400 patient dataset; survival benefit in Phase 2 trial
- In-licensed following extensive BI post hoc analysis and strong performance on Notable’s Predictive Medicine Platform

### Entering Phase 2 trial in relapsed/refractory AML\*

- Trial design optimized by BI post hoc analysis
- Further enhanced by enrolling patients predicted to respond
- Phase 2 initial safety data expected in the fourth quarter of 2024 followed by initial efficacy data in the first half of 2025

### Predictive Medicine Platform (PMP)

- Measures functional cell response to treatment on a patient’s cancer sample
- Extensive, scalable database of cancer biological response
- 97% predictive precision across four clinical validation trials

### Business Model: De-risk and accelerate drug development

- License undervalued advanced-stage shelved drugs
- Improve patient selection: Enroll patients likely to respond
- Goal: Predictably exceed standard of care for urgent needs (start with AML)

# Experienced Leaders From Across Therapeutics, Diagnostics & Technology



**Joseph Wagner, Ph.D.**

*Chief Scientific Officer & Interim CEO*



**Glenn Michelson, M.D.**

*Chief Medical Officer*



**Scott McPherson, CPA**

*Chief Financial Officer*

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## Previous Experience

*President & Chief Executive Officer*  
BriaCell Therapeutics Corp

*President & Chief Executive Officer*  
OncoCyte Corporation

*President & Chief Technology Officer*  
Cell Targeting, Inc.

*VP, Clinical Development*  
CytomX Therapeutics

*VP, Clinical Development*  
Portola Pharmaceuticals Inc

*VP, Oncology & Chief Medical Officer*  
Plexxikon Inc.

*Chief Financial Officer*  
MedSec, LLC

*Chief Executive Officer*  
U.S. Environmental, Inc.

*Chief Financial Officer*  
VerifyMe, Inc.

# Independent Directors: Leaders from Premier Life Science Companies



**Tuomo Päätsi**  
*Chair*

*EVP, Commercial*  
Seagen

*President International*  
Celgene



**Thomas Graney**  
*Chair Audit Committee*

*Chief Executive Officer*  
Oxurion

*Chief Financial Officer*  
Vertex Pharmaceuticals



**Thomas Dubin**  
*Chair Compensation Committee*

*Vice Chair*  
Norwalk Hospital

*Chief Legal Officer*  
Alexion



**Michele Galen**  
*Director*

*Chief Communication Officer*  
Shire

*Chief Communication Officer*  
Novartis Oncology and  
Novartis



**Michael Rice**  
*Director*

*Founding Partner*  
LifeSci Advisors

*Co-Head, Healthcare Investment Banking*  
Canaccord Adams



**Peter Feinberg**  
*Director*

*Co-Founder*  
BridgeBio Pharma and  
Sporos Bioventures

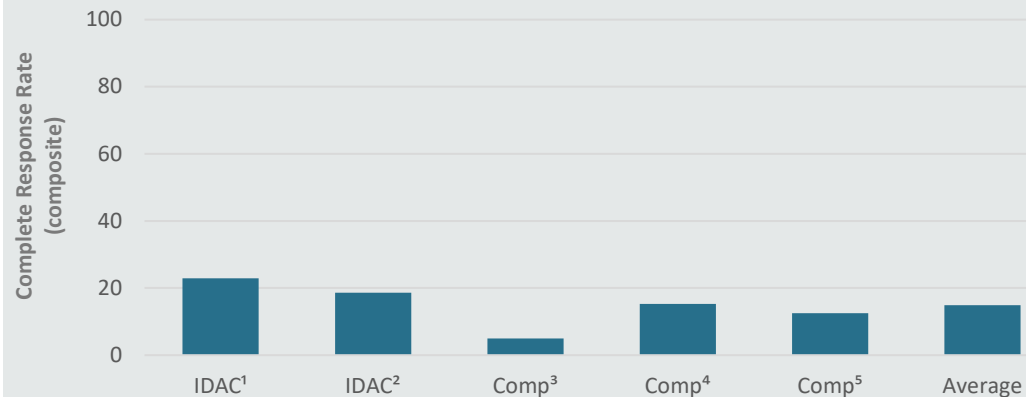
*Partner and Co-Founder*  
Boxcar Partners

*Head, Institutional Equities and Sales*  
Oppenheimer & Co

# We Aim to Deliver Better and More Predictable Outcomes for Patients

## Precision Medicine (one-dimensional)

- Targets genomic mutations
- Only 15% cancer patients carry actionable mutations
- Response rate often low (considers only genetic mutations)

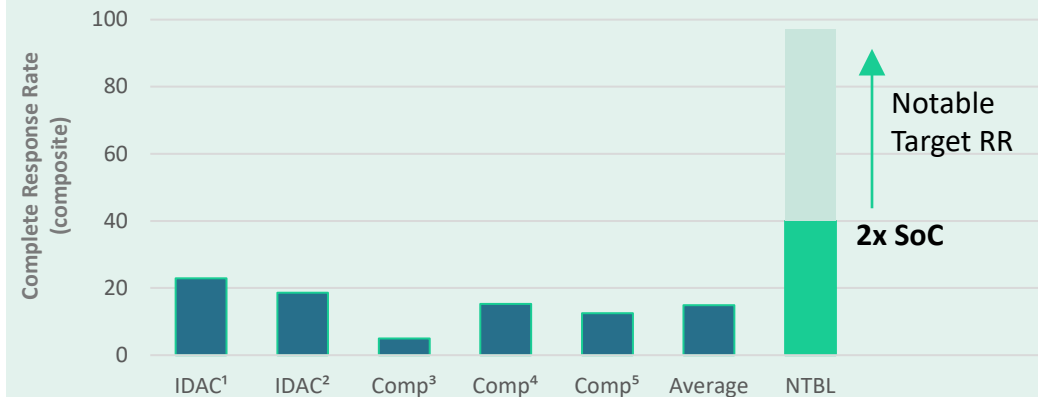


Example: R/R AML

Paradigm Shift

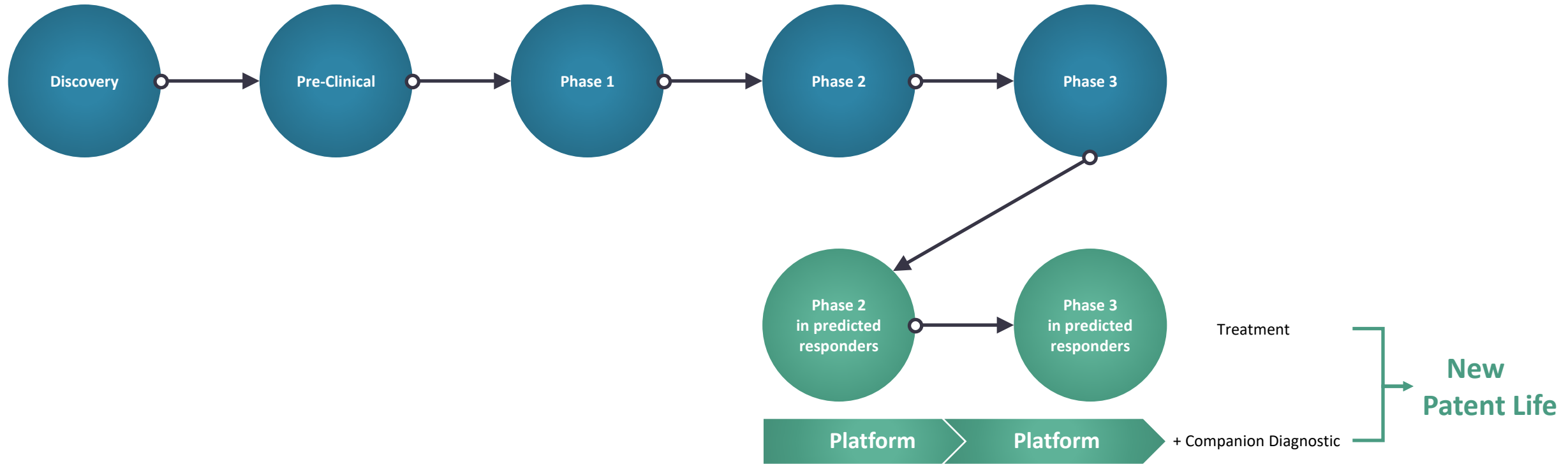
## Predictive Medicine (multi-dimensional)

- Interrogates functional cancer cell biology
- Unconstrained by actionable genetic mutations
- Predicted response rate higher (considers numerous factors)



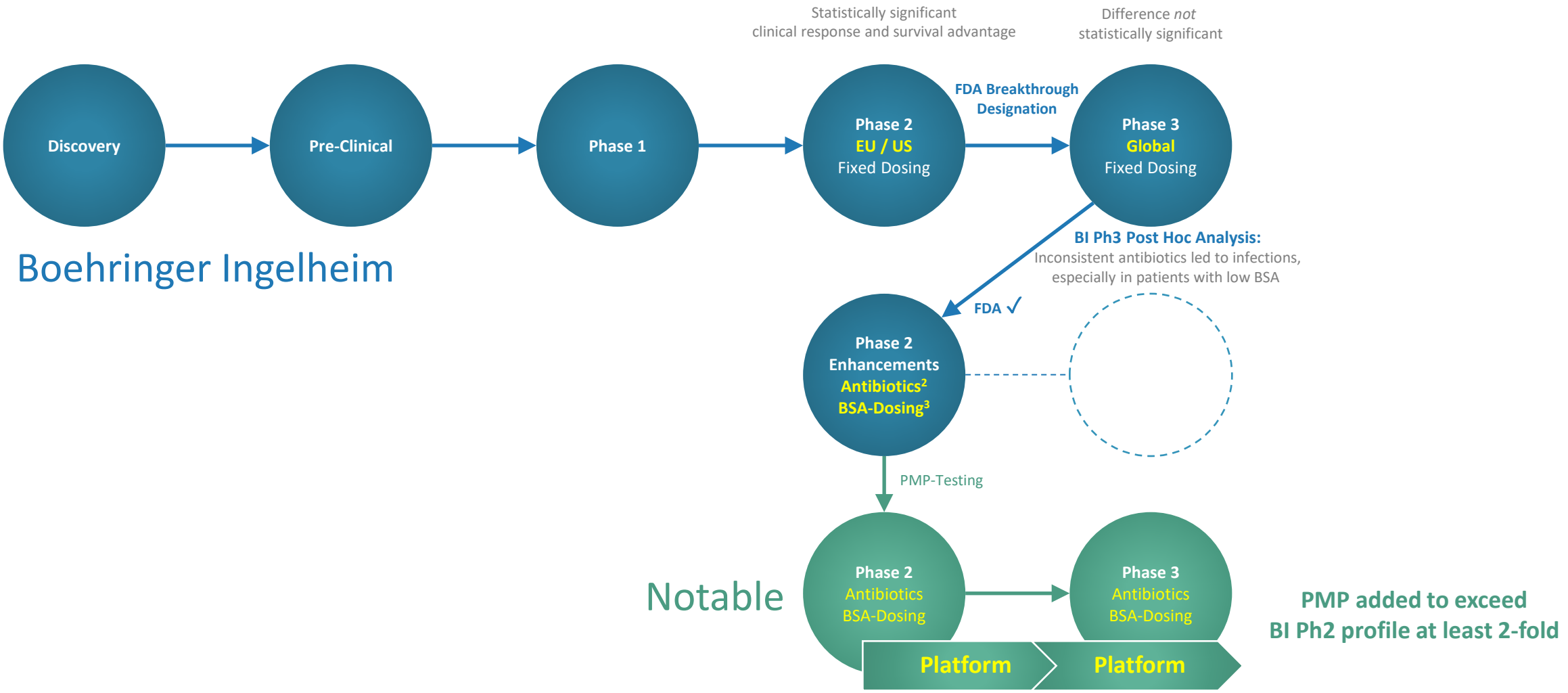
# Taking Advantage of Years and Millions of Dollars in Drug Development

**Standard Model: From Discovery to Phase 3 – Takes 15 years and \$2.5 billion/drug on average**



**Notable Model: Propel Advanced-Stage Drugs Over Finish Line – Bypass years of risk and millions of dollars of investments**

# Notable PMP Leverages & Further De-risks BI's Enhanced, FDA-Supported Program<sup>1</sup>



<sup>1</sup> FDA supported enhanced BI Phase 2 trial at MD Anderson Cancer Center/Yale/Washington University which had already enrolled cohort A when BI stopped Volasertib's development overall  
<sup>2</sup> Standard-of-care prophylactic antibiotics mandated for all trial patients to reproduce BI Phase 2 profile  
<sup>3</sup> Body Surface Area-based dosing of 200mg/m<sup>2</sup> on Day 1 (vs. Days 1+15 in original BI Phases 2/3 trials) to exceed BI Phase 2 profile

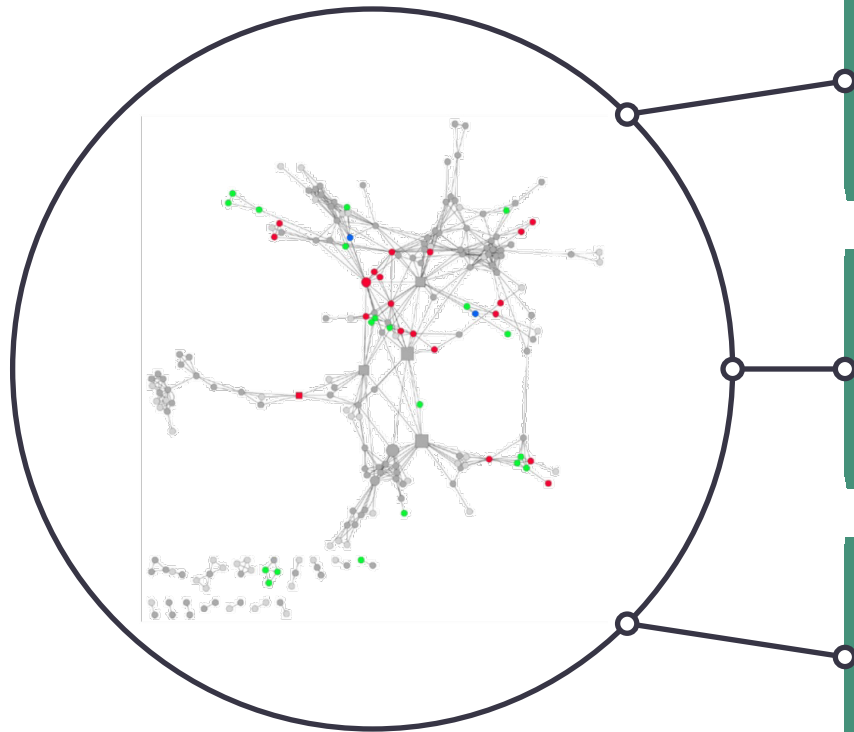




# Predictive Medicine Platform

# Genomics-Based Precision Medicines are Limited

## Patients Urgently Need an Approach That Goes Beyond Genetic Mutations



Less than 15% of cancer patients<sup>1</sup> carry a known actionable genetic marker, and thus can benefit from traditional precision medicines

In many clinical settings, genomics-based precision medicines deliver moderate or low clinical response rates<sup>1</sup>

Example: Precision medicine gilteritinib targets FLT3, a genetic mutation found in AML, yet only 34%<sup>2</sup> of Flt3+ patients respond

# Predictive Medicine Platform Merges Biology and Advanced Technology

## Robotic Automation

## Computation

Fresh Patient Sample  
Includes Cancer and Immune Cells



Biosimulation Assay

Microenvironment Parameters



Protocol Parameters



Multiple Readouts  
at the Single Cell Level

- Live
- Dying (Apoptosis)
- Dead
- Proliferating
- Maturing (Differentiating)
- Quiescent
- Drug Pumps
- T-cell Activation
- Immune Evasion

Patient Response Prediction

Predictive Algorithms

Computational algorithms translate data across multiple dimensions into patient response score

Drug Treatment

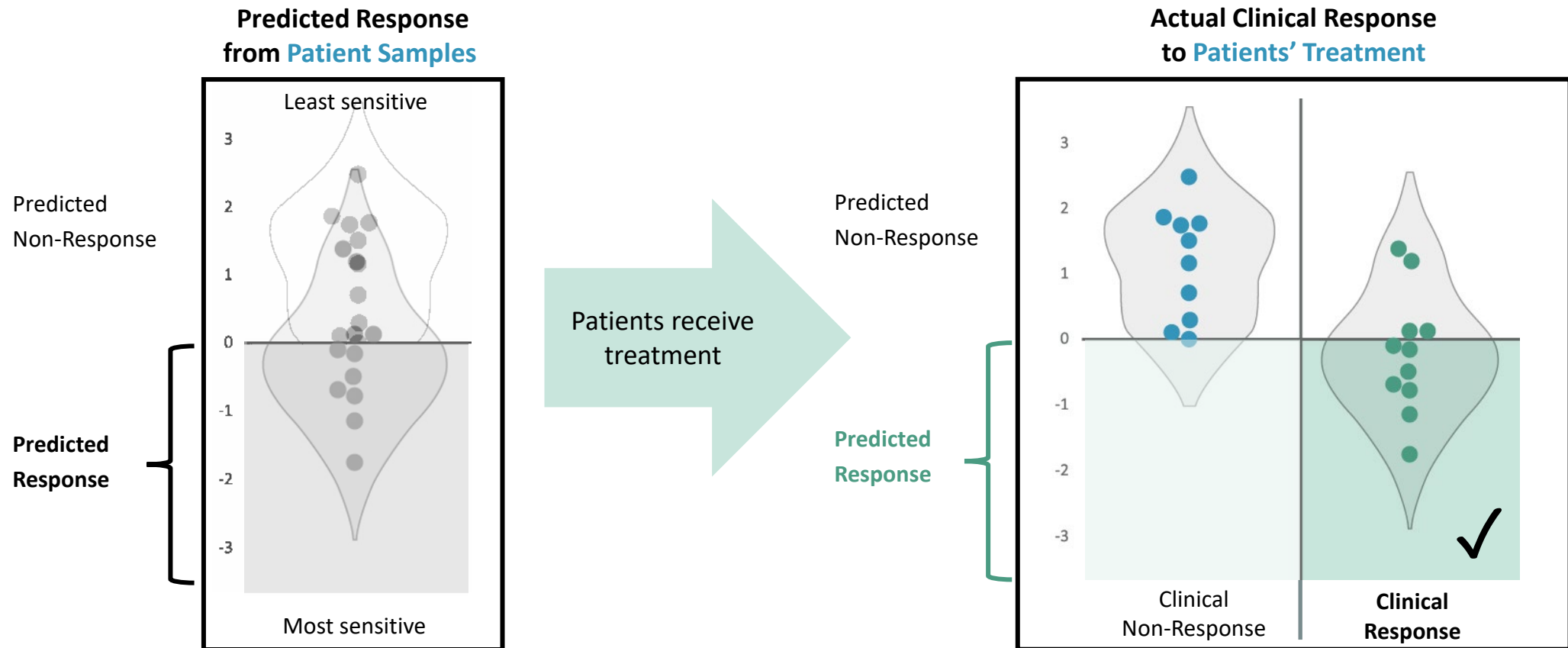


Response Prediction Results in Seven Days or Less



# All Platform-Predicted Responders Clinically Responded to Their Actual Treatment

Clinical Validation Trial with Stanford in MDS<sup>1</sup>: Results of the 21 Patients Treated with Platform-Screened Compounds<sup>2</sup>



<sup>1</sup> MDS = Myelodysplastic Syndromes; Response Rate reflects direct Positive Predictive Value (PPV)

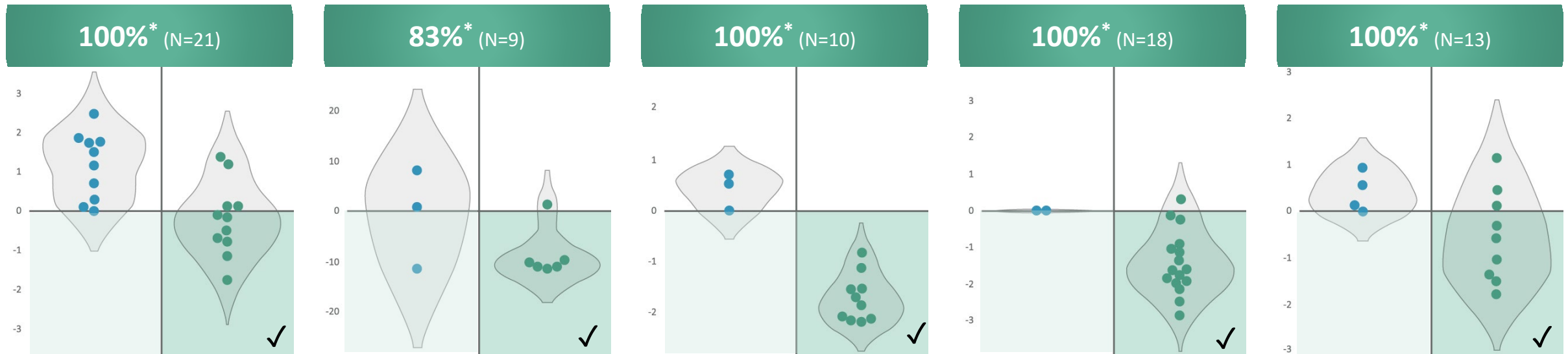
<sup>2</sup> Blood Adv (2020) 4 (12): 2768–2778. Mean PPV 0.92, 95% CI [0.69–1.0] in publication reflect statistical bootstrapping methodology

# 97% Predicted Responders Achieved Clinical Response Across 4 Validation Trials

● Clinical Non-Responder

● Clinical Responder

■ Predicted Responders



**Stanford University**  
Myelodysplastic Syndromes, MDS

Blood Adv (2020) 4 (12): 2768–2778.  
Mean PPV 0.92, 95% CI [0.69-1.0]†

**MD Anderson Cancer Center**  
Acute Myeloid Leukemia, AML

ASH Poster (2021)  
<https://notablelabs.com/category/scientific-poster/> Mean PPV 0.80, 95% CI [0.50-1.0]†

**Texas Children's Hospital**  
Pediatric AML

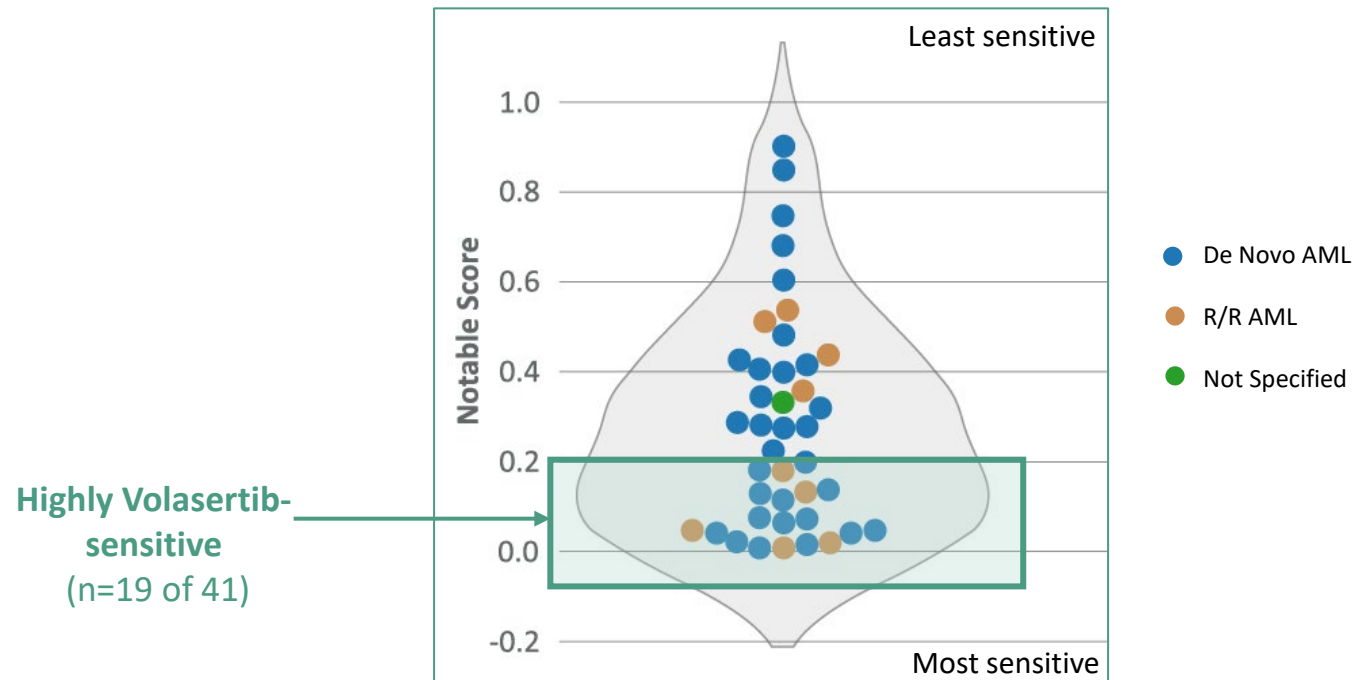
Blood (2021) 138 (Supplement 1): 2361.  
Mean PPV 1.0, 95% CI [1.0-1.0]†

**Washington University**  
AML (Cohort A)

AACR 2023 – Cancer Res (2023) 83 (7\_Supplement): 4342. A: Mean PPV 1.0, 95% CI [1.0-1.0]; B: Mean PPV 0.86, 95% CI [0.63-1.0]†

**Washington University**  
MDS + AML (Cohort B)

# Volasertib: Strong Predictive PMP Performance Further De-Risks Program



Highly sensitive samples included 50% of R/R AML patients



# Volasertib Lead Candidate

# Acute Myeloid Leukemia (AML) is an Urgent Unmet Need

## Acute Myeloid Leukemia (AML)

Estimated in 2024 (US): 20,800 cases; 11,220 deaths<sup>1</sup>

### Not Eligible for Intensive Chemotherapy (>50% of AML<sup>9</sup>)

- Standard of care: Venetoclax + hypomethylating agents (Ven/HMA)
- Response rate 60-70%<sup>2</sup> + improved survival
- Worse outcomes if complex cytogenetics/TP53 mutations<sup>2,3,5,6</sup>
- All patients will relapse

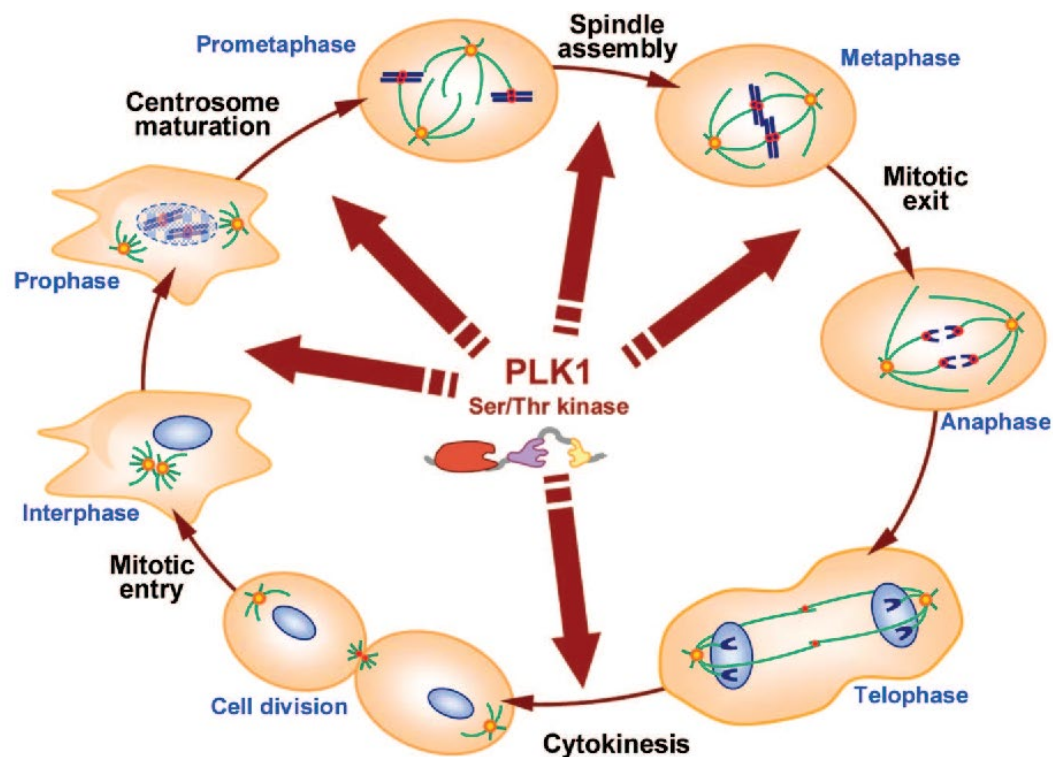
### Relapsed/Refractory AML<sup>7</sup>

- Response rate of available treatments approx. 15%
- No defined standard of care
- Except for few patients with genetic mutations<sup>7,8</sup>  
(but time to genetic results may jeopardize timely clinical decisions)



# Volasertib: PLK1 Plays Central Role in Leukemia and Other Cancers

## Mechanism of Action



## Demonstrated Over-Expression

- Polo-like kinase 1 (PLK1) plays central role in cancer cell proliferation
- PLK1 over-expression has been found in multiple cancers and associated with poor prognoses
- PLK1 inhibition leads to death of cancer cells by interfering with multiple stages of mitosis

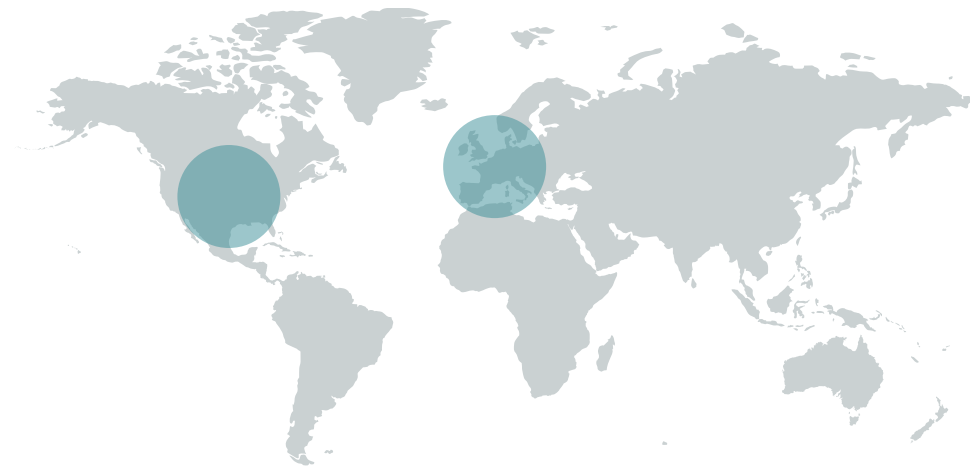
Cancer Type	P Value	Fold Change
Lung squamous cell carcinoma	7.41E-157	20.8
Breast invasive carcinoma	5.88E-126	11.3
Lung adenocarcinoma	1.18E-63	9.7
Kidney renal clear cell carcinoma	2.33E-55	6.1
Head and neck squamous cell carcinoma	6.52E-50	4.2
Liver hepatocellular carcinoma	3.59E-40	11.7
Uterine corpus endometrial carcinoma	1.96E-36	21.3
Colon adenocarcinoma	5.97E-33	2.5
Stomach adenocarcinoma	8.45E-27	4.8
Esophageal carcinoma	9.52E-27	10.2
Bladder urothelial carcinoma	4.96E-26	9.1
Prostate adenocarcinoma	1.29E-22	3.3
Kidney renal papillary cell carcinoma	6.76E-22	4.7
Cholangiocarcinoma	6.97E-14	24.3
Glioblastoma multiforme	5.63E-12	12.4
Kidney chromophobe	1.63E-06	3.3
Rectum adenocarcinoma	1.06E-05	2.3
Pancreatic adenocarcinoma	0.04	2.2

# Boehringer Ingelheim Volasertib Front Line AML Clinical Summary

753 AML Patients Across Phase 2 and Phase 3 Trials  
Treatment<sup>1</sup>: LDAC + Fixed/Flat Dose Volasertib Vs. LDAC + Placebo

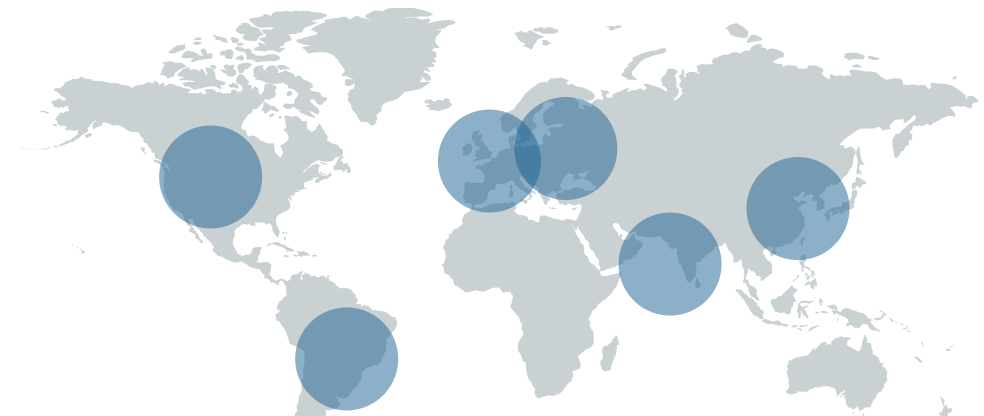
## Phase 2 (US/Western Europe)<sup>3</sup>

- Volasertib arm
- CR + Cri<sup>\*\*</sup>: 31%; durable remissions, some >2 years
- 8.0 months median overall survival (significant benefit)



## Phase 3 (Worldwide)<sup>4</sup>

- Volasertib arm
- CR + CRi: 27.7%
- 5.6 months median overall survival (no significant difference)

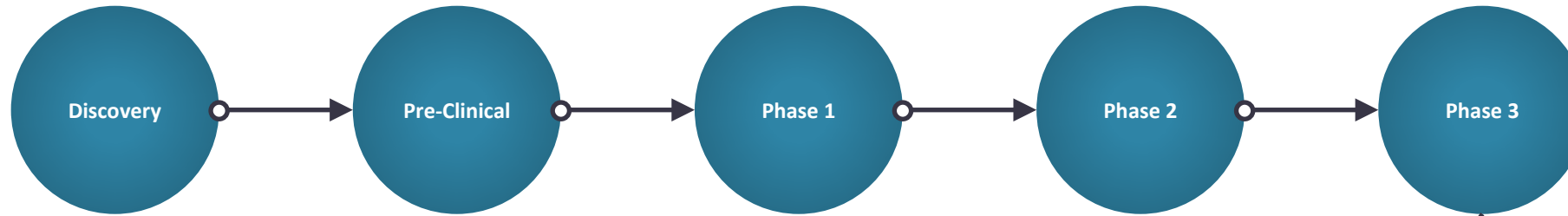


Inconsistent Antibiotic Prophylaxis /Management

# Volasertib Phase 2 and Phase 3 Trial Results Summary

Summary of AML Trial Results	Phase 2 <sup>1</sup>		Phase 3 <sup>2</sup>	
	LDAC	LDAC + Vola	LDAC + Placebo	LDAC + Vola
Treatment	45	42	222	444
Complete Response (CR)	6.7% (3)	14.3% (6)	12.2% (27)	15.1% (67)
CRi	6.7% (3)	16.7% (7)	5.0% (11)	12.6% (56)
<b>Overall Response Rate (CR + Cri)</b>	<b>13.3% (6)</b>	<b>31.0% (13)</b>	<b>17.1% (38)</b>	<b>27.7% (123)</b>
Median Overall Survival (months)	<b>5.2</b>	<b>8.0</b>	<b>6.5</b>	<b>5.6</b>
Median Event-Free Survival (months)	2.3	5.6	2.8	3.3
Median Relapse-Free Survival (months)	10.0	18.5	18.7	13.1
Febrile Neutropenia (CTCAE grades 3-5)	15.6% (7)	54.8% (23)	28.4% (63)	58.7% (258)
Infections and Infestations (CTCAE grades 3-5)	22.2% (10)	47.6% (20)	38.3% (85)	57.4% (255)

# BI Phase 3 Post Hoc Analysis Triggered Enhanced BI Trial at MDACC



## Phase 3 Post Hoc Analysis

- Clinical responses across all risk groups, including high risk (complex cytogenetics; p17/TP53)
- Inconsistent antibiotic prophylaxis: febrile neutropenia, infections, including grade 5 infections
- Infections especially increased in patients with low body surface area (BSA) due to Volasertib fixed dosing\*

**Enhanced BI Trial\*\***  
(FDA-cleared)

Enhanced  
Phase 2  
Antibiotics  
BSA-dosing

**Prophylactic Antibiotics** to reproduce Ph2 profile  
**BSA-Dosing** to further increase benefits



# Notable's Phase 2 Trial Overview

# Notable's Phase 2 Further Enhanced By PMP Patient Selection

## Key Inclusion Criteria

- Confirmed AML
- Ineligible for intensive chemo
- 1-3 failed treatments

**Part 1**  
Antibiotics  
BSA-Dosing

**Part 2**  
Antibiotics  
BSA-Dosing

**Selection by PMP-Platform:**  
Enroll the Most Volasertib-Sensitive Patients

## Goal Part 1:

### Prophylactic Antibiotics/BSA-Dosing Tolerability Data

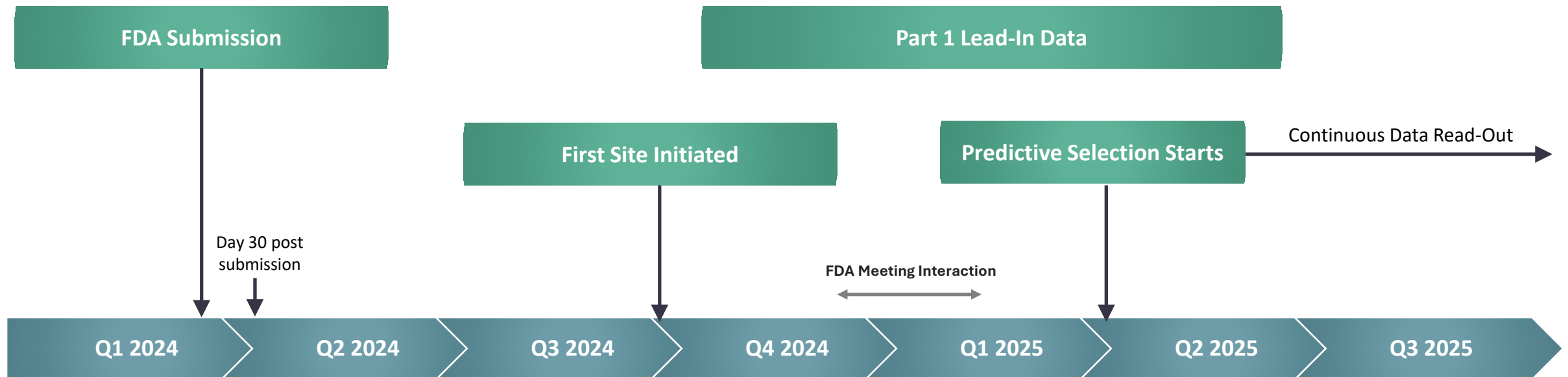
- Volasertib 170mg/m<sup>2</sup> (Day 1 of 28d cycle)
- Can be adjusted based on clinical profile
- In combination with Decitabine 20mg/m<sup>2</sup>, D1-5

## Goal Part 2:

### Enrich Volasertib-Responsive Population at Least Two-Fold

- Prepare Phase 3 trial

# Volasertib Phase 2 Trial: Anticipated Near-Term Milestones





# Corporate Summary and Intellectual Property



# Notable Business Model is Scalable

## Predict Clinical Responders Through the Notable Platform. Propel Advanced-Stage Drugs over the Finish Line

### Platform

#### Biology and Technology

- Identifies patients most likely to respond to a treatment (no need for genetic markers, e.g. next generation sequencing)
- Measures multi-dimensional biological response of cells to drugs in proprietary bioassay (flow cytometry)
- Computational algorithms integrate these data to accurately predict patient response

#### Validated and Scalable

- Robotic automation enables virtuous learning cycles and optimization via machine learning
- 97% of predicted responders clinically responded to their actual treatment across 4 validation trials
- Massive, continually growing data repository drives expansion across drugs and diseases

### Business Model

#### From Shelf to Leadership

- Focus on indications with high unmet need (low response rates)
- Target, screen, and in-license advanced-stage shelved drugs or co-develop undervalued drug opportunities
- De-risk and fast-track remaining development in predicted responders

#### Volasertib: Lead Clinical Program

- In-licensed from Oncoheroes/Boehringer Ingelheim (BI)
- Initial focus on predicted responders with relapsed/refractory AML
- First Phase 2 data expected in 4Q 2024 (enhancements vs. BI trials)
- Continuous safety and efficacy readouts in 2025 (in platform-predicted responders)

# Intellectual Property Built on Three Pillars

## Volasertib

- **In-licensed BI portfolio**
  - 19 issued patents across API, formulation, method of use, method of manufacture
  - API Loss of Exclusivity = 2027
  - Patent Term Extension strategy: Use on critical Method of Use family, expiring 2035

## Predictive Medicine Platform

- **Protected via trade secrets**
  - Parsing of knowledge across scientific, engineering and data teams
  - Drug-specific method filings protect as above

## Volasertib + PMP

- **Notable additional filings**
  - CDX + VOLA novel method patents would extend to 2044+

# Cash Position and Stock Information

- NASDAQ: NTBL (launched on Oct 17, 2023, following reverse merger with VBLT)
- Office and laboratories in Foster City, California
- \$4.1 mm cash and cash equivalents (June 30, 2024)
  - \$3.2 mm cash and cash equivalents (Aug. 9, 2024)
- 9.7 mm shares outstanding (Aug. 14, 2024)
  - 0.1mm warrants\*
  - No debt



Thank you!