



Company Overview

1Q 2020

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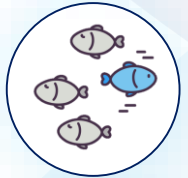


Salarius is a Cancer Focused Biotechnology Company

Developing Treatments for Patients Who Need Them The Most



Drugs that regulate gene expression (“epigenetics”) have shown clinical efficacy plus immuno-oncology potential



Seclidemstat is a novel, oral, reversible LSD1 inhibitor that regulates gene expression and is currently in Phase 1/2 Ewing sarcoma and Phase 1/2 solid tumor clinical trials



Non-Dilutive funding supports low monthly burn rate

- Up to \$18.7M from Cancer Prevention Research Institute of Texas (CPRIT)
- Financial support from the National Pediatric Cancer Foundation



Seclidemstat FDA designations for Ewing sarcoma:

(1) Rare Pediatric Disease Designation, (2) Orphan Drug Designation, and (3) Fast Track Approval



Market expansion with immunotherapy (checkpoint inhibitor combos) and targeted cancers with LSD1 sensitive mutations



Upcoming Development Milestones

Development Milestones	Timing
✓ Rare Pediatric Disease and Orphan Status Designation	2017
✓ Begin Ewing Sarcoma Phase 1/Phase 2 Trial	2H 2018
✓ Begin Advanced Solid Tumor Phase 1/Phase 2 Trial	1H 2019
✓ FDA Fast Track Status	2H 2019
Phase 1 Ewing data readouts	1H 2020 *
Phase 1 AST data readouts	1H 2020 *
ASCO clinical trial updates	1H 2020
Phase 2 Ewing early efficacy data readouts begin	2H 2020 *
Phase 2 AST early efficacy data readouts begin	2H 2020 *
Initiate potential Immunotherapy combo study	2H 2020
Initiate potential expanded Phase 2 Ewing's study (possible registration)	1H 2021
Initiate potential Phase 2 solid tumor study	2H 2021

* Value inflection points



Seasoned Leadership Team



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Chief Executive Officer

Lilly  **Boehringer Ingelheim**



Margaret Dugan, MD
Senior Medical Advisor

 **NOVARTIS**



Bruce McCreedy, PhD
Acting Chief Scientific Officer

 **PRECISION**  **Triangle Pharmaceuticals**




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Chief Business Officer

 **Abbott** 




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Eli Lilly

Development Pipeline

		Indication	Preclinical	Phase 1	Phase 2 ¹	Status
Seclidemstat	Ewing Sarcoma		Dose Escalation and Expansion			<ul style="list-style-type: none"> Phase 1/Phase 2 enrolling up to 50 patients Safety and efficacy data in 2020
	Advanced Solid Tumors		Dose Escalation and Expansion ²			<ul style="list-style-type: none"> Phase 1/Phase 2 enrolling up to 50 patients Safety and efficacy data in 2020
	Immunotherapy		In vitro and In vivo studies ongoing			<ul style="list-style-type: none"> Identifying checkpoint combinations for clinical trials
Identifying opportunities in hematological cancers and select tumor mutations						

1. Expanded Phase 2 in Ewing sarcoma could potentially be a registration study with improvements in response or duration of response compared to the existing standard of care and FDA's agreement

2. Open to all non-Ewing sarcoma solid tumor patients except for primary CNS tumors, enriching patients with sensitive mutations and prostate cancer that can be monitored with prostate specific antigen (PSA)



Seclidemstat

Overview

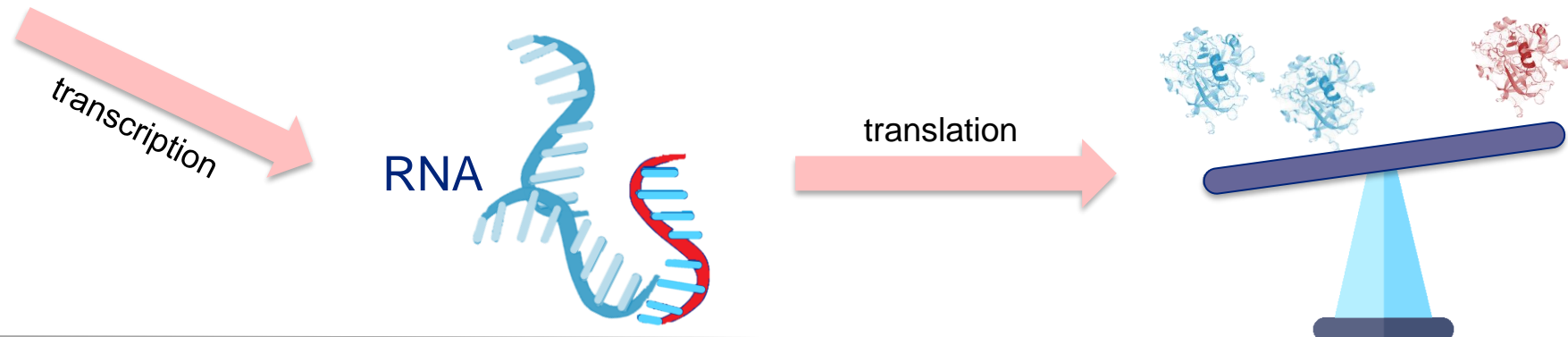


Modulation of Gene Expression (Epigenetics) Plays an Important Role in Regulating Healthy Cells and also Disease Progression

Correct Gene Expression = Healthy Balance of Proteins = Healthy Cells



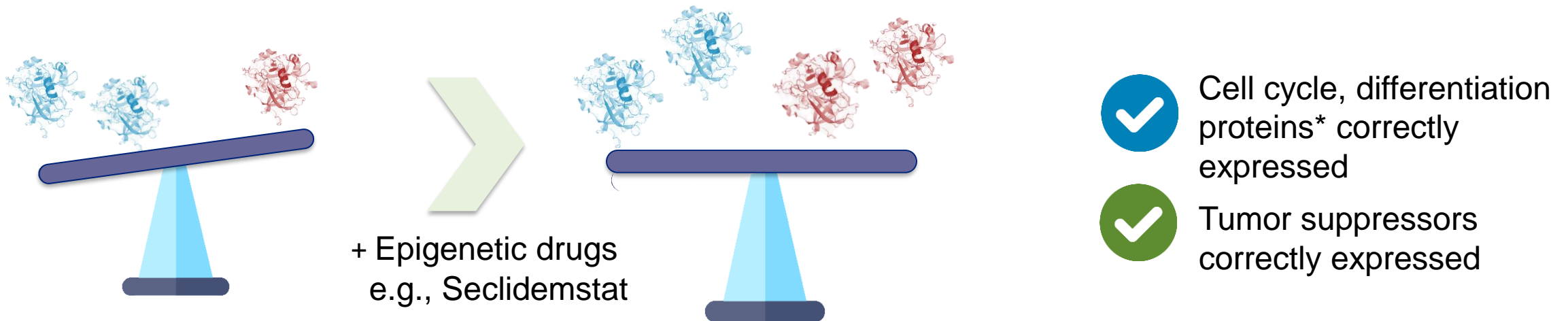
Incorrect Gene Expression = Imbalance of Proteins = Cancer Progression



Targeting Epigenetic Enzymes to Treat Cancer Addresses Dysregulation and Incorrect Gene Expression

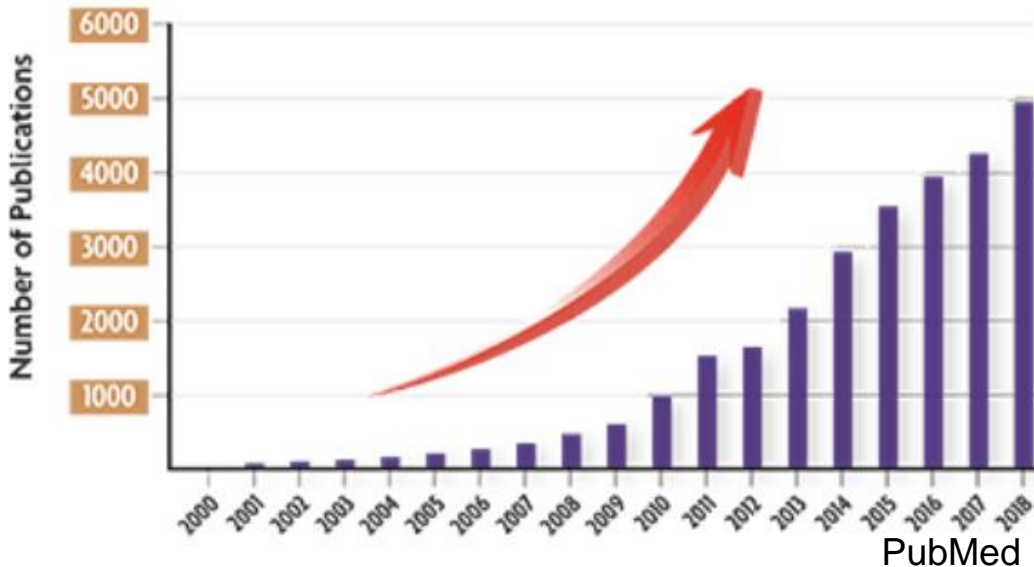


Cancers driven by incorrect modulation of gene expression can be treated with drugs – like **Secclidemstat**, an LSD1 inhibitor- that corrects abnormal epigenetic enzyme activity and restores correct gene expression



Epigenetic Research is Gaining Momentum and Epigenetic Focused Biotechs are Increasing in Valuation

Epigenetics Publications Per Year



Novel epigenetic drugs with clinical proof of concept support billion-dollar valuations



EZH2 inhibitor (tazemetostat)

Approved in epithelioid sarcoma – monotherapy
NDA submitted for follicular lymphoma – monotherapy

Market Cap: ~\$2.1B¹



BET inhibitor (CPI-0610)

Positive Phase 2 data in combination with existing standard of care in myelofibrosis

Market Cap: ~\$1.4B¹

Other clinical companies include: GSK, Zenith Epigenetics, Resverlogix, 4SC, Viracta, Syndax



LSD1 - A Validated Target For Cancer Therapy

Lysine Specific Demethylase 1 (LSD1) is an epigenetic target for solid tumors and hematological cancers

- Affects gene expression through enzymatic activity and scaffolding properties (protein-protein interactions)

LSD1 in Healthy Cells and Cancer Cells¹

Healthy Cells	<ul style="list-style-type: none">• LSD1 is necessary for stem cell maintenance and cell development processes (e.g., blood cells)
Cancer Cells	<ul style="list-style-type: none">• LSD1 is over expressed• LSD1 acts incorrectly to silence or activate genes leading to disease progression• Validated target: LSD1 CRISPR deletion often kills cancerous cells



Secldemstat (SP-2577) reversible **LSD1** inhibitor

- Reverses incorrect gene expression, killing or preventing the growth of cancer cells
- Inhibits both the enzymatic and scaffolding activity
- Oral tablet
- Strong patent estate – Composition of matter expires 2032

Companies developing LSD1 inhibitors in clinic (Phase 1 or 2):



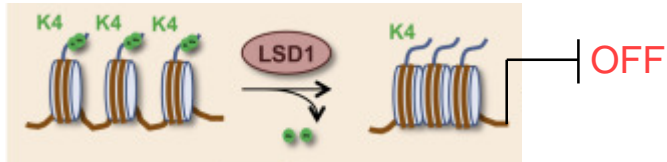
¹Majello, B. *Cancers* 2019.

More Comprehensive Inhibition of LSD1 Positively Impacts Therapeutic Activity



Enzymatic activity – Demethylation

Impact: Moderately alter
gene expression

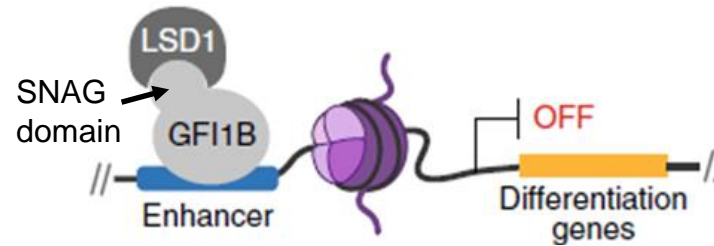


 and competitors



Partial scaffolding* inhibition of LSD1 – protein interaction

Impact: alter gene expression in
cancers (AML, SCLC) driven by
SNAG domain proteins (e.g. GFI1B)



 and competitors



Broader scaffolding inhibition of LSD1 – protein interaction

Impact: Potential efficacy in
broader range of cancer types,
destabilize LSD1 and complexes



- ✓ Differential activity
- ✓ Reduces LSD1 expression
- ✓ Favorable Toxicology Profile

*scaffolding properties – protein to protein interactions



SPEED TO MARKET

Seclidemstat in Ewing Sarcoma



Ewing Sarcoma - Unmet Need Represents a Meaningful Product Opportunity

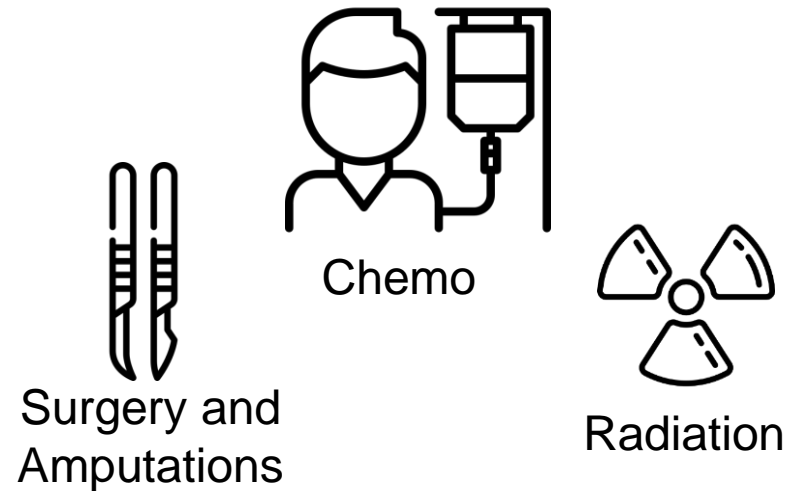
Diagnosis



500 patients diagnosed each year¹
Median age of diagnosis ~15 years

- 75% localized
- 25% with metastasis

Standard of Care



- About 40% of patients are refractory or relapse²
- 70-90% 5-year mortality rate²
- No standardized 2nd line treatment

Salarius' Vision

An effective, non-toxic, oral treatment option:

- Accelerated US approval
- Rapid market uptake
- \$200M+ Global Sales³ (est)
- Possible Priority Review Voucher of \$80M - \$150M

- ✓ Fast Track Designation
- ✓ Orphan Drug Designation
- ✓ Rare Pediatric Drug Designation

³ Represents longer term vision and does not represent estimate of future performance, financial or otherwise. There is no assurance that we will achieve our longer term vision.



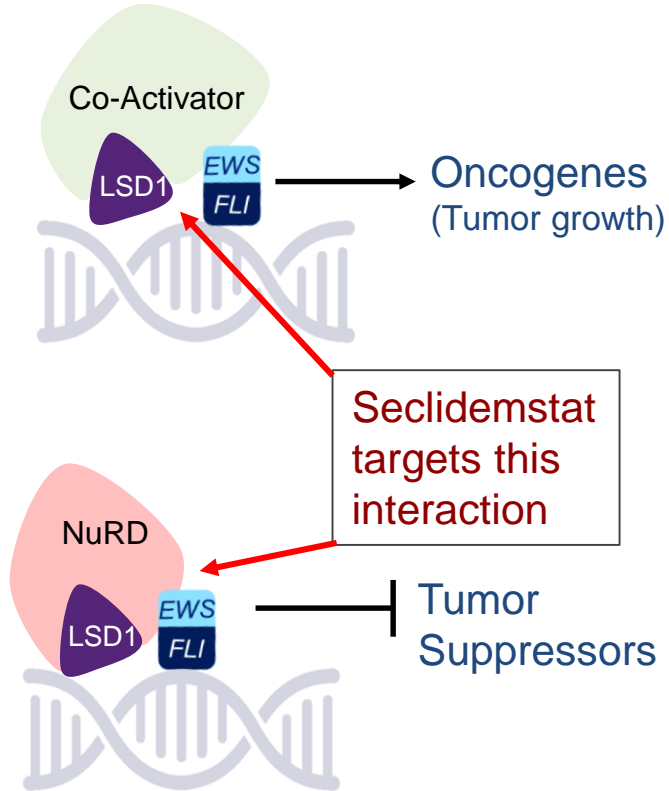
¹ Pishas, K. et al. (2016)

² Van Mater, et al. Oncotargets (2019)

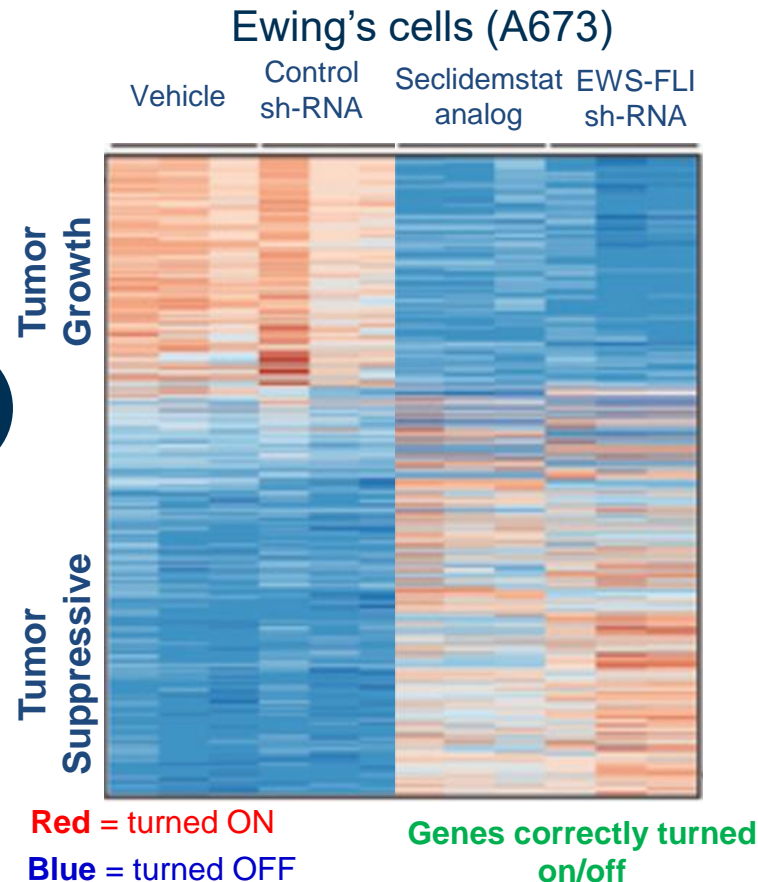
Targeting The Root Cause Of Ewing Sarcoma Via LSD1 Inhibition

Ewing sarcoma is driven by an easily diagnosed chromosomal translocation, i.e., EWS-FLI

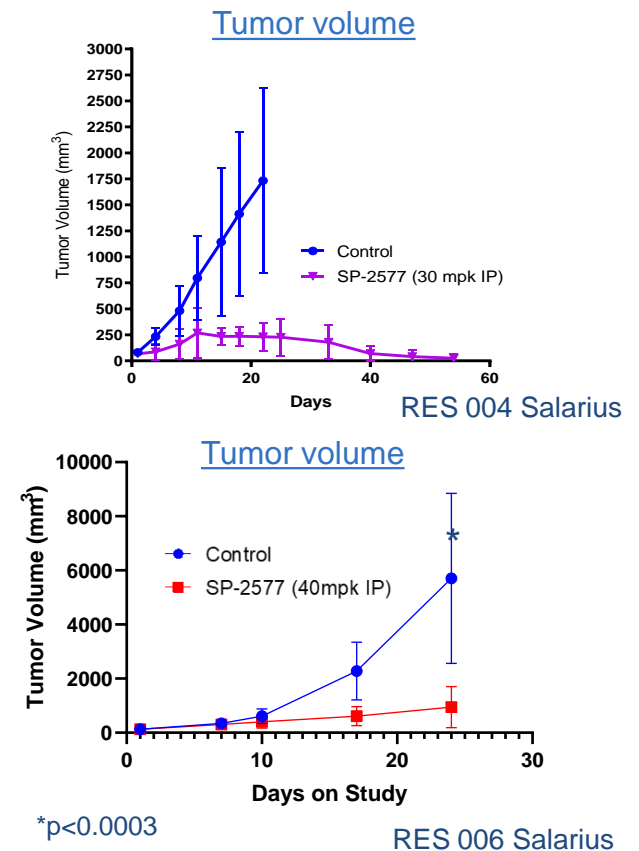
Incorrect transcription factor leads to gene dysregulation



Seclidemstat corrects gene expression



Potent anti-tumor activity in SKNMC (Ewing sarcoma cells) *in vivo* studies



Ewing Sarcoma Phase 1/2: Safety and Efficacy Data in 2020

Open-label dose escalation / dose expansion trial design

Dose escalation (ongoing)

- Dose escalation in cohort 6
- Maximum Tolerated Dose (MTD) expected in 1H2020

Dose expansion (after MTD is established)

- ~20 patients at MTD
- Safety and early efficacy data in 2H2020

Primary objective: Safety, PK

Secondary objectives: Anti-tumor assessment

Exploratory: Hemoglobin F, cfDNA, CTCs

CURRENTLY ENROLLING AT 8 CLINICAL SITES



Plasma PK is dose proportional



Targeting ASCO 2020 for trial update





MARKET EXPANSION

Secclidemstat in Advanced Solid Tumors

Select Tumor Mutations

Immunotherapy

LSD1 Overexpression Increases With Disease Progression And Correlates With Poor Patient Prognosis – Secclidemstat Reduces LSD1 Activity

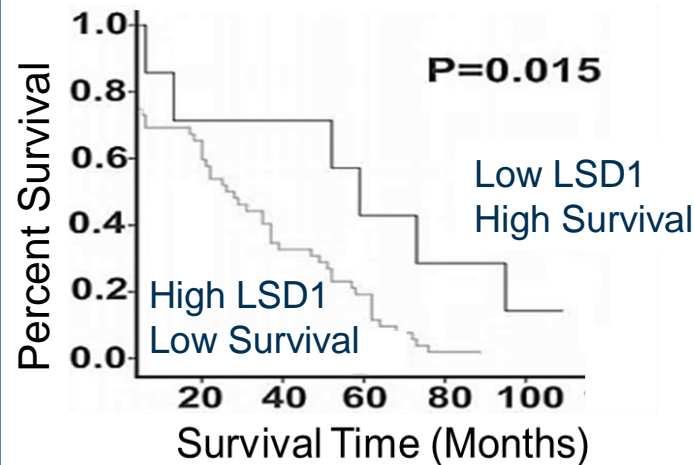


Increased LSD1 expression correlates with solid tumor progression

- High LSD1 expression in ~30% of primary prostate tumors, but >90% of advanced castration resistant prostate cancer¹
- LSD1 expression associated with shorter survival in Triple Negative Breast cancer

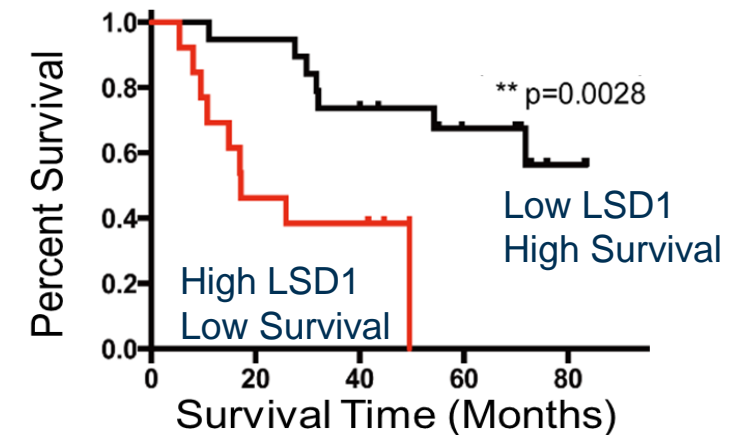
¹ Sehrawat, A. et. al., 2018

Castration Resistant Prostate Cancer



Kashyap, V., et al. (2013).

Triple Negative Breast Cancer (TNBC)



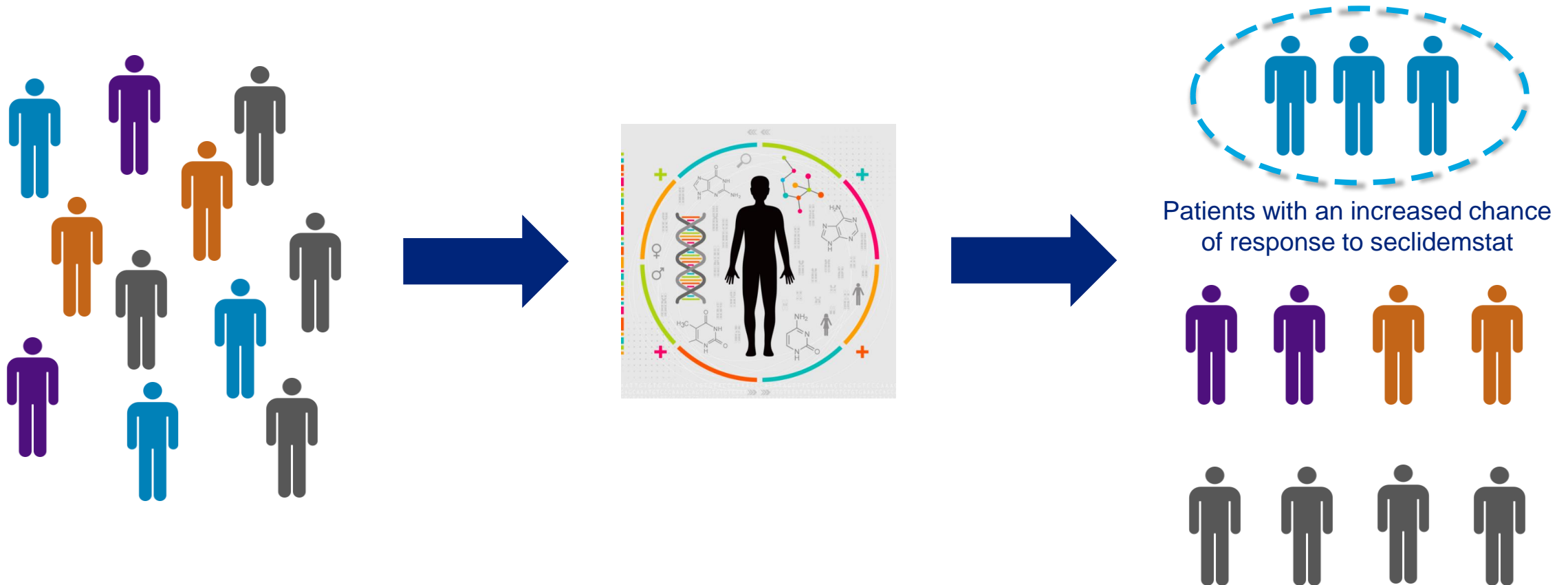
Nagasawa, S. et al (2015)

Ongoing Phase 1 Advanced Solid Tumor Study sites: Honor Health, Phoenix AZ and Sarcoma Oncology Center, Santa Monica CA



Increasing Probability Of Success Via Identification Of Sensitizing Mutations

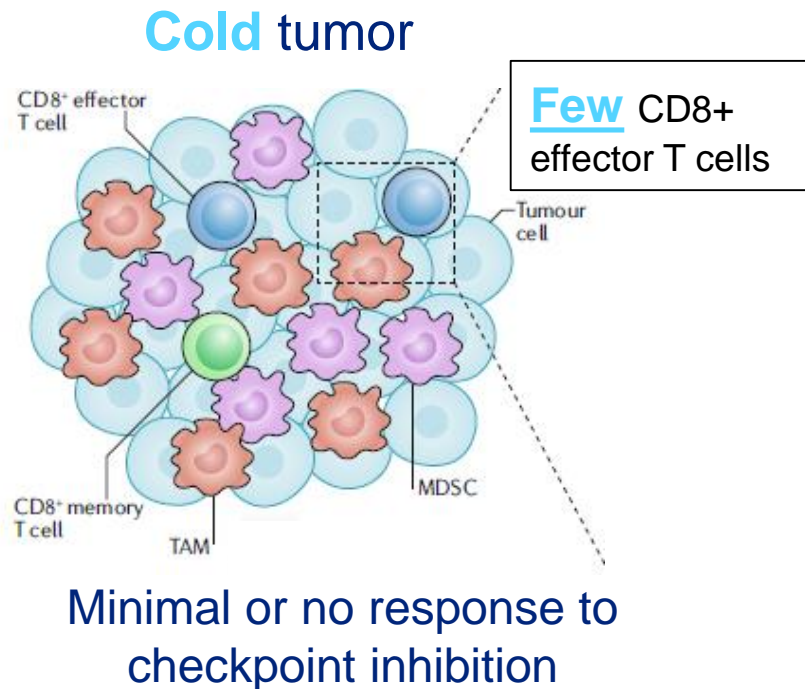
Genetic screens (e.g., Foundation Medicine) can help identify patients with an increased chance of response to secnidemstat



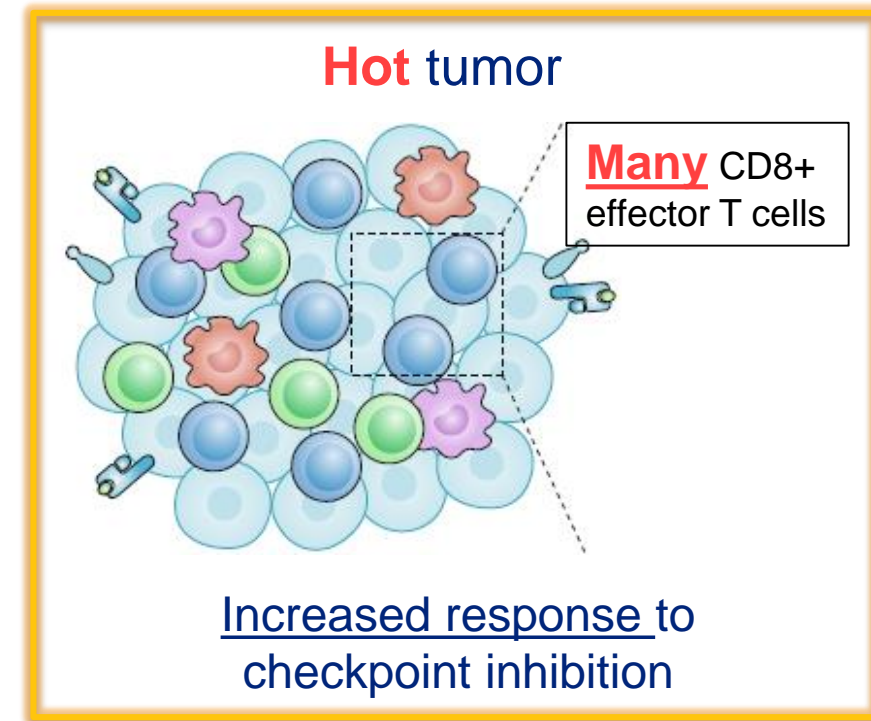
Exploring Additional Opportunities: LSD1 Inhibition Turns Cold Tumors Hot And Increases Efficacy Of Checkpoint Inhibitors

Sensitizing cancers resistant to checkpoint inhibitors (CI) increases patients available for treatment

- ~\$15B CI market¹ with ~70% patients² resistant to CI treatment (cold tumors)
- LSD1 inhibition turns cold tumors hot by increasing CD8+ effector T cells within the tumor
- Expands CI market into patients currently resistant to CI treatment



LSD1 inhibition



LSD1 Inhibition Sensitizes Triple Negative Breast Cancer to Checkpoint Blockade *in vivo*

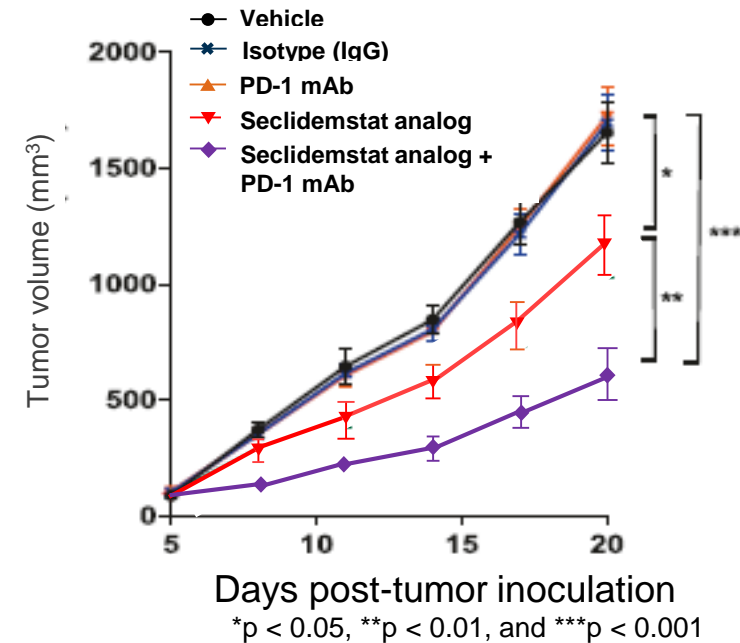
Oncogene

Inhibition of histone lysine-specific demethylase 1 elicits breast tumor immunity and enhances antitumor efficacy of immune checkpoint blockade

- **LSD1 inhibition** (Seclidemstat analog) drives increased immune cell infiltration, and sensitizes resistant tumors to checkpoint inhibition
- “Cold” tumors turn “Hot” and then respond to checkpoint inhibition
- **Increased response by ~65%**

Qin, Ye, et al. *Oncogene* (2018).

Syngeneic Breast Tumor Model (EMT-6)



Combination of Possibilities Presents Significant Market Opportunity for Seclidemstat

SPEED TO MARKET

Ewing Sarcoma

500 patients
diagnosed/year



Status: Phase 1/2 clinical trial

- ✓ Orphan Drug Status
- ✓ Rare Pediatric Disease Designation (Priority Review Voucher)
- ✓ Fast Track Designation
- Potential for accelerated approval, priority review

\$80M-\$150M

Possible Pediatric Priority
Review Voucher (est)

\$200M+

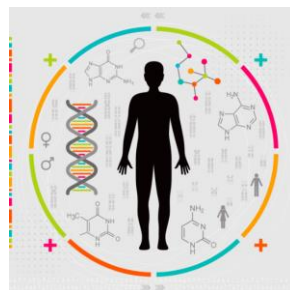
Global Sales per year (est)¹

EXPANDING INTO LARGER MARKETS

ADVANCED SOLID TUMORS

Status: Phase 1 clinical trial

Ongoing work to identify **SELECT TUMOR MUTATIONS**
that may increase patient response to LSD1 inhibition (e.g. SWI/SNF)



Market Potential in Solid Tumors^{2,3,4,5,6}

\$1B+

About 25% of solid tumors (e.g., breast, ovarian, prostate, lung) have mutations in that may sensitize to seclidemstat⁶

POTENTIAL TO ENTER INTO IMMUNOTHERAPY

- Sensitizing resistant cancers to checkpoint Inhibitors
- **Status:** Preclinical

\$1B+ Market Potential⁷








COMPETITIVE LANDSCAPE

Seclidemstat's differentiation



LSD1 Competitive Landscape Highlights Seclidemstat's Differentiation

	Company	Drug Name	Binding Mechanism	Indications and Phase
In clinic ¹		SP-2577 (Seclidemstat)	Reversible	Ewing sarcoma (Ph1/2), Advanced Solid Tumors (Ph1/2)
		INCB59872	Irreversible	Advanced malignancies (AML, SCLC) (Ph1/2), Ewing sarcoma (Ph1b)
		ORY-1001 (RG6016)	Irreversible	AML (Ph2b), SCLC (Ph2a)
		CC-90011	Reversible	Non-Hodgkin's lymphoma and AST (Ph1), SCLC (Ph1)
		IMG-7289	Irreversible	AML and myelodysplastic syndrome (Ph1/2a completed), myelofibrosis (Ph2b)

¹Clinicaltrials.gov

Seclidemstat's differentiated binding mechanism and binding location shows potential **increased therapeutic activity** and **safety***

Preclinical ²		BEA-17	Reversible	Glioblastoma
		RASP-201	Reversible	AML
		HM9XXX series	Reversible	AML and SCLC

²Not an exhaustive list of companies in preclinical stage

Preclinical research is shifting to develop reversible LSD1 inhibitors



Salarius Investment Opportunity: An Early- Clinical Stage Focused Biotech With Several Value-driving Inflection Points Occurring In 2020



Lead compound is in the growing epigenetic therapy space

- Attractive price for investors interested in this growing therapeutic area



Extensive non-dilutive funding supports low quarterly burn rate

- Up to \$18.7M from CPRIT
- Financial support from NPCF



Recipient of FDA designations that facilitates rapid product development

- Orphan Drug Designation
- Rare Pediatric Disease Designation
- Fast Track Designation

Salarius has worked to establish itself for a newsworthy 2020:



Readouts from two ongoing clinical trials is expected to include safety, pharmacokinetic, and early efficacy data (value inflection points)





Thank you!

Appendix A: Additional Sources

- Combination of Possibilities Presents Significant Market Opportunity for Seclidemstat

¹ Represents longer term vision and does not represent estimate of future performance, financial or otherwise. There is no assurance that we will achieve our longer term vision.

² Cancer of the Ovary – Cancer Stat Facts, The National Cancer Institute: Surveillance, Epidemiology and End Results Program

<https://seer.cancer.gov/statfacts/html/ovary.html>.

³ GlobalData: Prostate Cancer: Global Drug Forecast and Market Analysis to 2028

⁴ GlobalData and Epidemiology Market Size Database, TNBC

⁵ GlobalData: Opportunity Analyzer: Ovarian Cancer - Opportunity Analysis and Forecast to 2025

⁶ Morel, D., et al. Ann of Oncology 2017

⁷ <https://www.forbes.com/sites/greatspeculations/2019/03/12/how-much-can-mercks-share-price-grow-if-keytruda-gets-10-share-of-oncology-drug-market/#77edba677e18>

