



Company Overview

3Q 2020

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Mission Statement



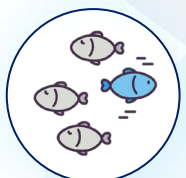
*Developing treatments for patients that
need them the most*



Corporate Overview



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



Lead candidate, 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



Seclidemstat FDA designations for Ewing sarcoma:

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



Non-Dilutive funding in addition to low monthly burn rate

- Up to an aggregate of \$18.7M¹ from Cancer Prevention Research Institute of Texas (CPRIT)
- Financial support from the National Pediatric Cancer Foundation



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




Seasoned Leadership Team




David J. Arthur
Chief Executive Officer

Lilly  **Boehringer Ingelheim**



Nadeem Q. Mirza, MD, MPH
Senior VP Clinical Development

SANOFI  **abbvie**



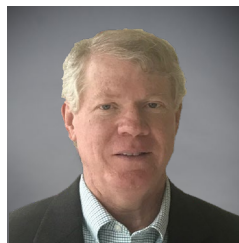
Bruce McCreedy, PhD
Acting Chief Scientific Officer

 **PRECISION**  **Triangle Pharmaceuticals**



Mark Rosenblum
Chief Financial Officer

ADVAXIS
 **Deloitte.**



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VP Chemistry,
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ILEX **APTINYX**



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 **Georgia Tech**

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Danforth Advisors
Histogenics

Tess Burleson, CPA

Translational Genomics Research Institute

Paul Lammers, MD MSc

Triumvira Immunologics
Merck Serono

Bruce McCreedy, PhD

Precision BioSciences
Triangle Pharmaceuticals

William McVicar, PhD

Flex Pharma
Sepracor
Novartis

Arnold Hanish, CPA

Omeros Corporation
Eli Lilly

Recent and Anticipated Milestones

	Development Milestones	Timing
✓	Rare Pediatric Disease and Orphan Status Designation	2017
✓	FDA Fast Track Status	2H 2019
✓	Phase 1 Ewing data (pediatric subcommittee Oncologic Drug Advisory Committee)	1H 2020
✓	Presented at pediatric subcommittee of the Oncologic Drug Advisory Committee	1H 2020
	Additional Phase 1 Ewing data	2H 2020
	Initiate potential hematologic trial	2H 2020
	Initiate potential immunotherapy combo trial	2H 2020
	CPRIT Distribution	2H 2020
	Initiate Ewing-related sarcoma expansion	1H 2021
	Phase 1 Ewing early efficacy data readouts begin	1H 2021
	Phase 1 AST early efficacy data readouts begin	1H 2021
	Potential for Phase 1/2 Ewing and Ewing-related sarcoma readouts	2H 2021
	Initiate potential Phase 1/2 targeted mutation solid tumor study	2H 2021



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
	Advanced Solid Tumors	Dose Escalation and Expansion ²				<ul style="list-style-type: none">Phase 1/Phase 2 enrolling up to 50 patients
	Immunotherapy	In vitro and In vivo studies ongoing				<ul style="list-style-type: none">Identifying combinations and indications for clinical trials
	Hematologic cancers	In vitro and In vivo studies ongoing				<ul style="list-style-type: none">Identifying combinations and indication for clinical trials
Identifying opportunities in 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, potential to enrich for patients with sensitive mutations and prostate cancer that can be monitored with prostate specific antigen



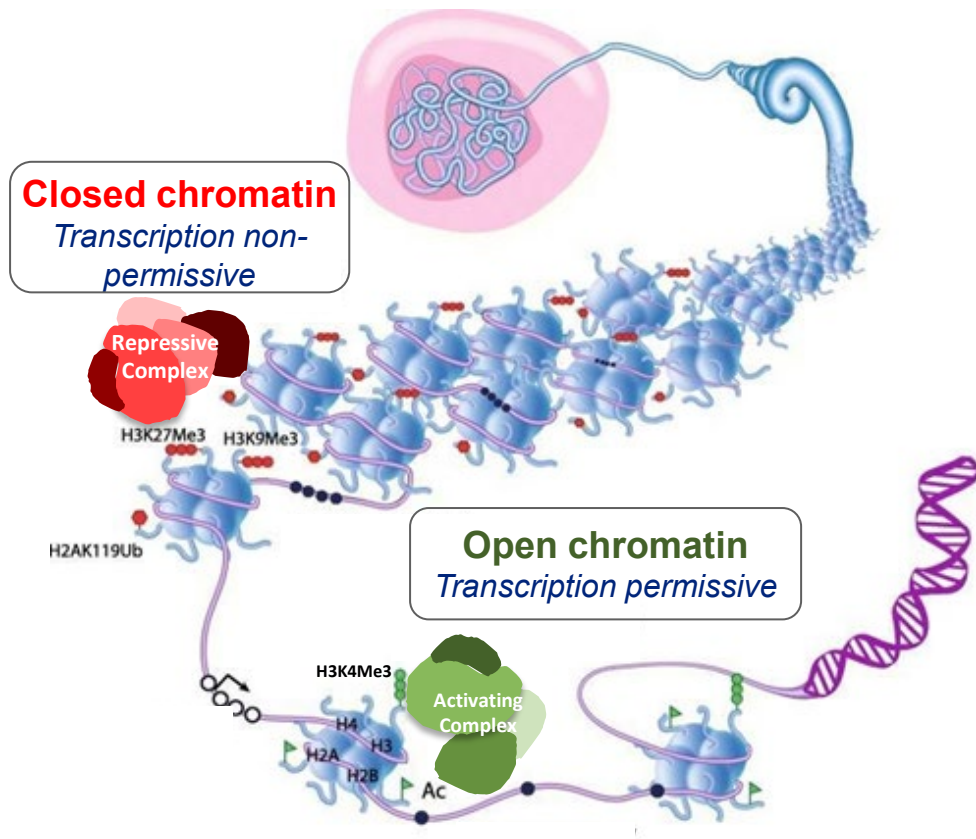
Seclidemstat

Overview

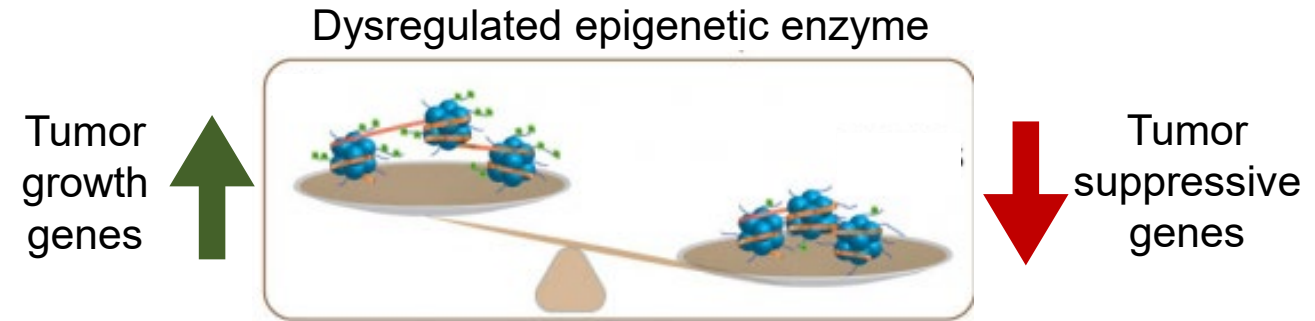


Epigenetic enzymes are attractive targets for cancer therapy

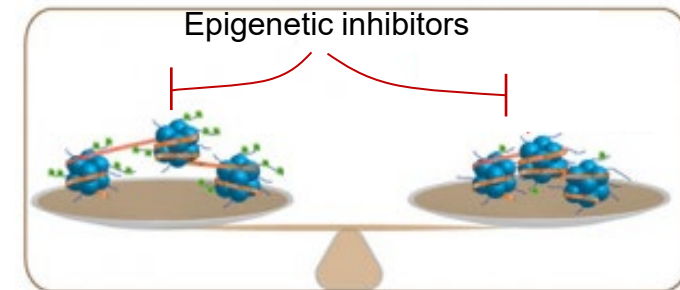
Epigenetic modifying enzymes affect gene expression by manipulating the chromatin structure



Dysregulated epigenetic enzymes can disrupt the transcriptional balance and lead to cancer development



Drugs that correct dysregulated epigenetic enzymes can help treat cancer by restoring to a balanced transcriptional state



Adapted from Holliday, H. Breast Cancer Research 2018

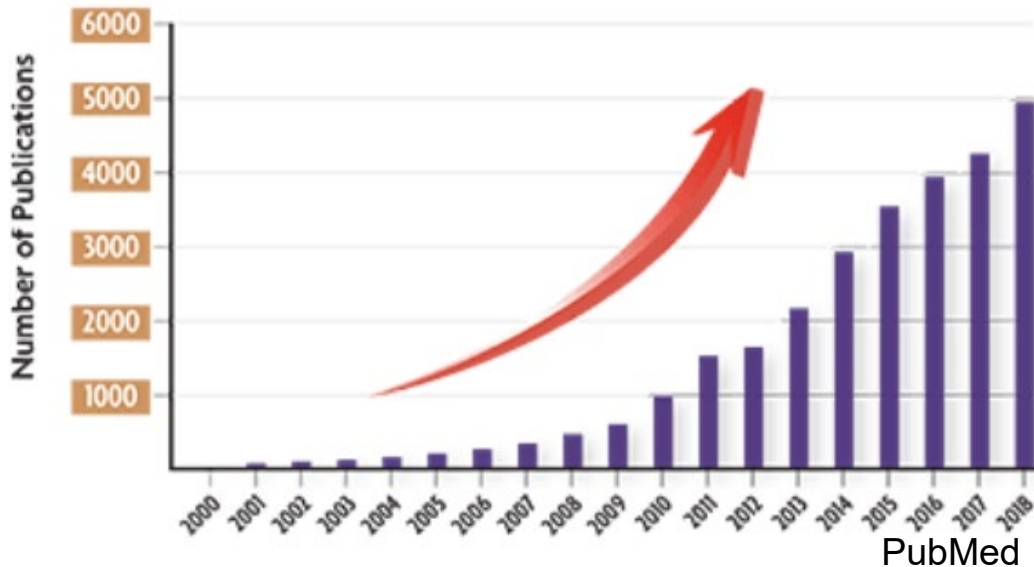
Adapted from Marcin et al. Biomed Intel 2018.

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Non Confidential

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
Approved for R/R follicular lymphoma – monotherapy

Market Cap: ~\$1.5B¹



BET inhibitor (CPI-0610)

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

Market Cap: ~\$1.3B¹

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



LSD1 - A Validated Target For Cancer Therapy

Lysine Specific Demethylase 1 (LSD1) affects gene expression through enzymatic activity and scaffolding properties (protein-protein interactions), making it an attractive target for solid tumors and hematological cancers.

LSD1 in Normal Cells and Cancer Cells ¹	
Normal 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 detrimental to cancer cells



Seclidemstat (SP-2577) reversibly inhibits **LSD1**

- Reverses incorrect gene expression, killing or preventing the growth of cancer cells
- Inhibits both the enzymatic and scaffolding activity

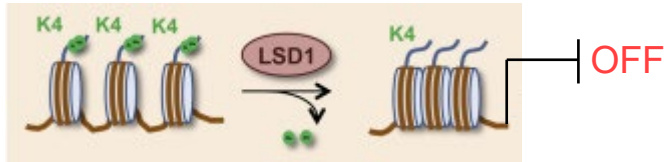


More Comprehensive Inhibition of LSD1 Positively Impacts Therapeutic Activity



Enzymatic activity – Demethylation

Impact: Moderately alter gene expression

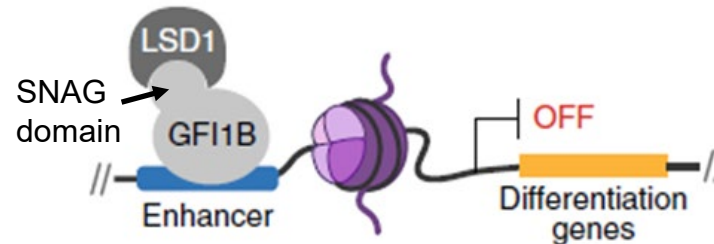


 and competitors



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



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)
		ORY-1001 (RG6016)	Irreversible	AML combo (Ph2b), SCLC combo (Ph2a)
		CC-90011	Reversible	Non-Hodgkin's lymphoma and AST (Ph1), SCLC combo (Ph1b), IO combo (Phase 2)
		IMG-7289	Irreversible	AML and myelodysplastic syndrome (Ph1/2a completed), myelofibrosis (Ph2b), essential thrombocythemia (Ph2a)
Preclinical ²		BEA-17	Reversible	Glioblastoma
		RASP-201	Reversible	AML
		HM9XXX series	Reversible	AML and SCLC

¹Clinicaltrials.gov

²Not an exhaustive list of companies in preclinical stage

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

Preclinical research is shifting to develop reversible LSD1 inhibitors



SPEED TO MARKET

Seclidemstat in Ewing Sarcoma



Ewing Sarcoma - Unmet Need Represents a Meaningful Product Opportunity

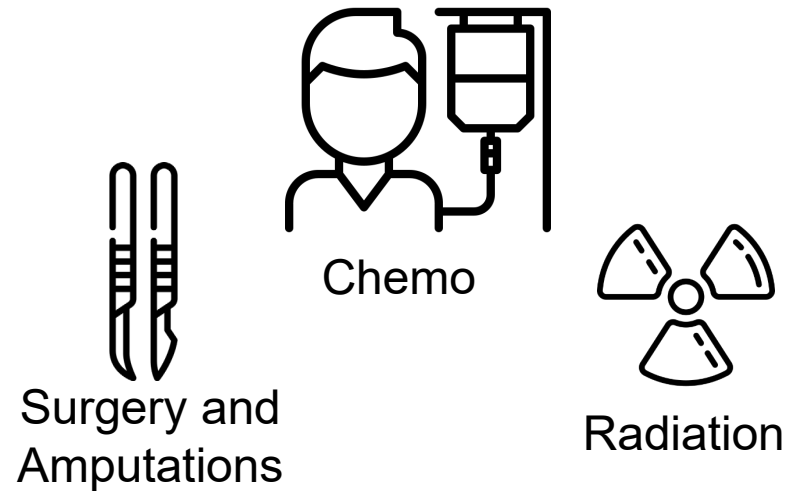
Diagnosis



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

- 75% localized¹
- 25% with metastasis¹

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.

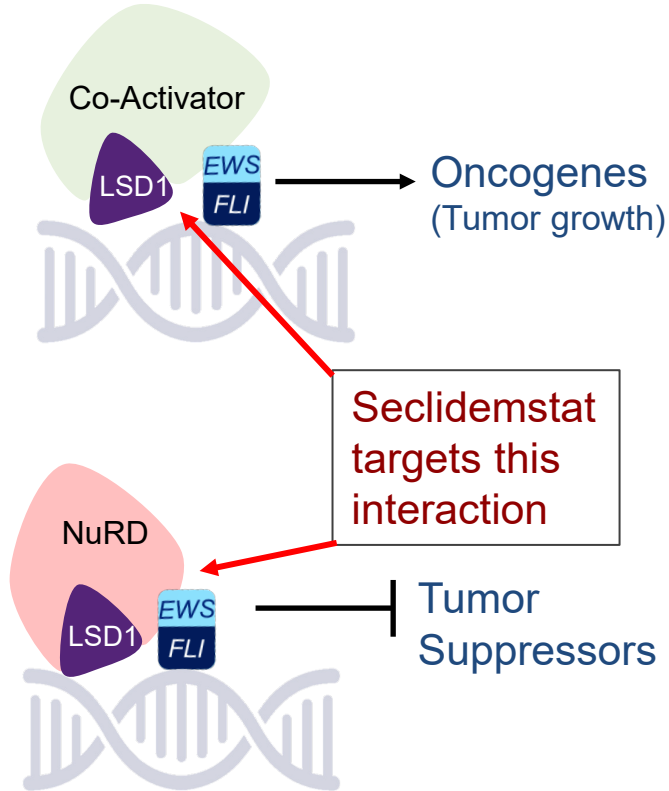
¹ Pishas, K. et al. (2016)

² Van Mater, et al. Oncotargets (2019)

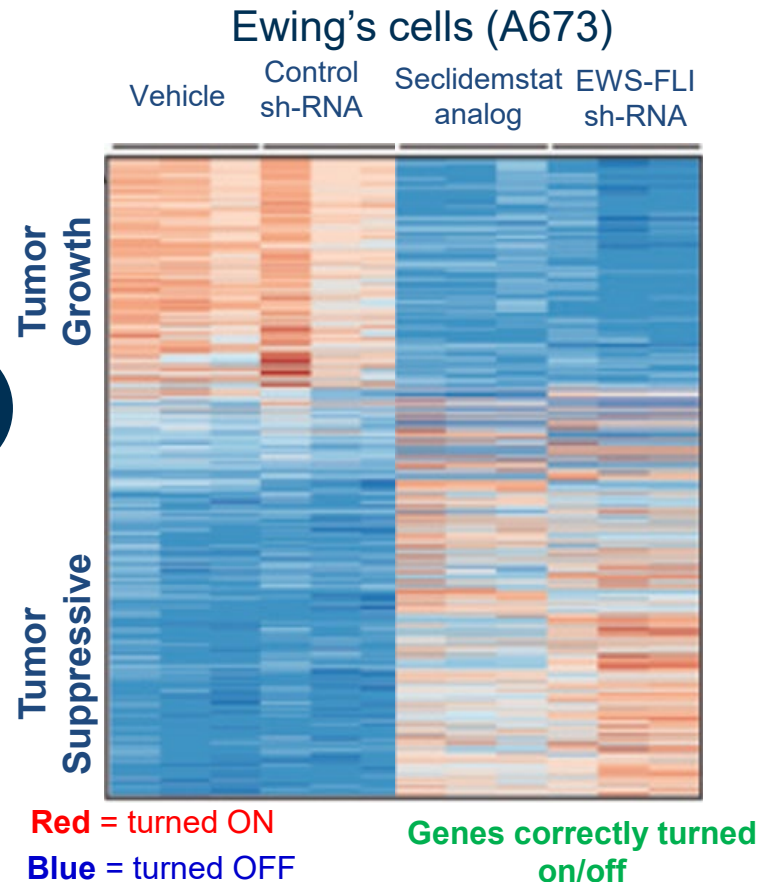
Targeting The Root Cause Of Ewing Sarcoma Via LSD1 Inhibition

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

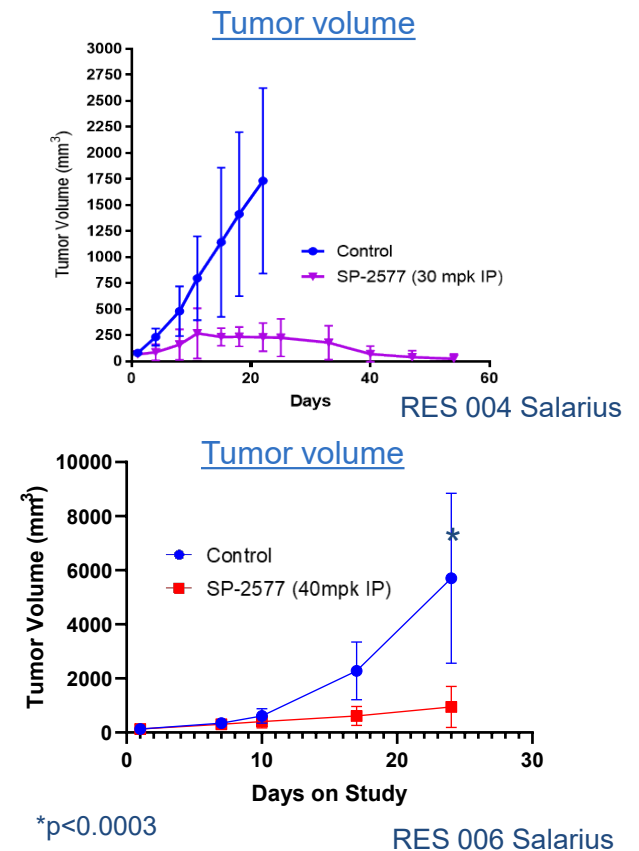
Incorrect transcription factor leads to gene dysregulation



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 2H2020

Dose expansion (after MTD is established)

- ~20 patients at Recommended Phase 2 Dose
- Safety and early efficacy data in 1H2021

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

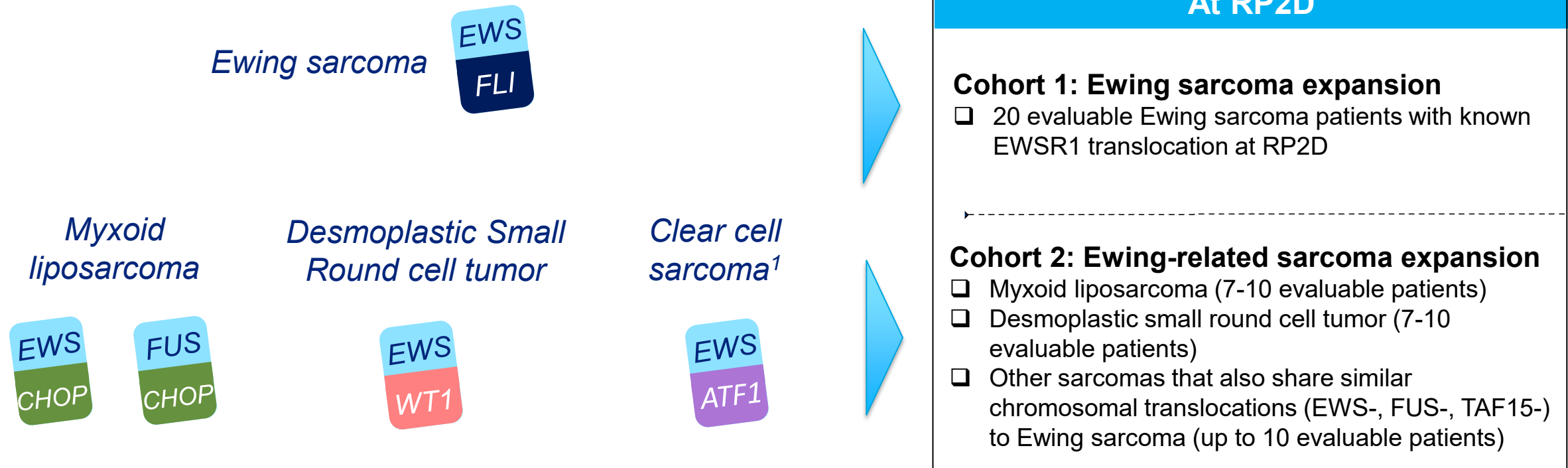


Early clinical data presented at pediatric ODAC meeting in June 2020



Salarius Plans To Expand Ewing Sarcoma Trial To Include Ewing-related Sarcomas

- Preclinical activity and early clinical observations in sarcomas driven by FET family* gene rearrangements suggest seclidemstat may be a potential treatment option
 - Ongoing Ewing sarcoma trial amended to include these Ewing-related sarcomas at recommended phase 2 dose (RP2D)



* FET family includes EWS, FUS and TAF15 gene rearrangements/mutations.

Phase 1a Ewing Safety Data And Preliminary Drug Activity Observed In Patient's Target Lesions As Assessed By Investigator

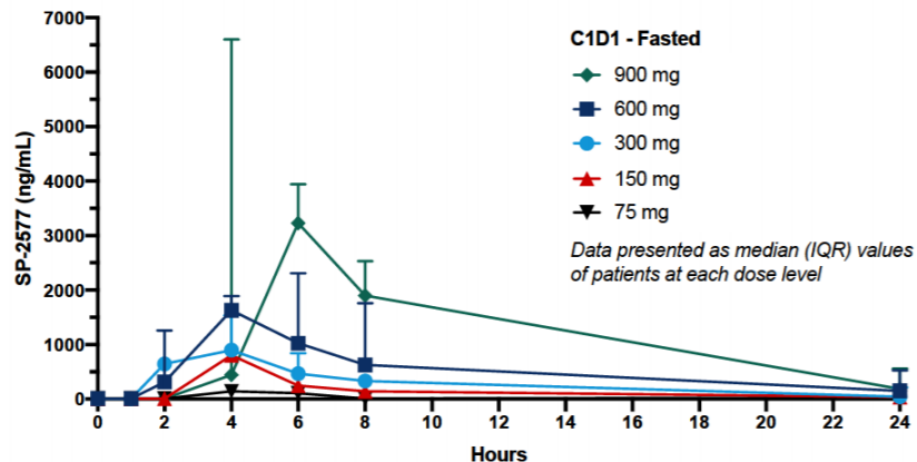
Early dose escalation results

Patients enrolled¹: 21 patients

- No treatment related deaths or study discontinuations due to treatment-related adverse events
- Dose-limiting toxicities have not prevented dose escalation

Pharmacokinetics:

- At dose levels 900 mg BID and above cohorts achieving drug levels of preclinical efficacious concentrations
- 5-8 hour half-life supports BID dosing

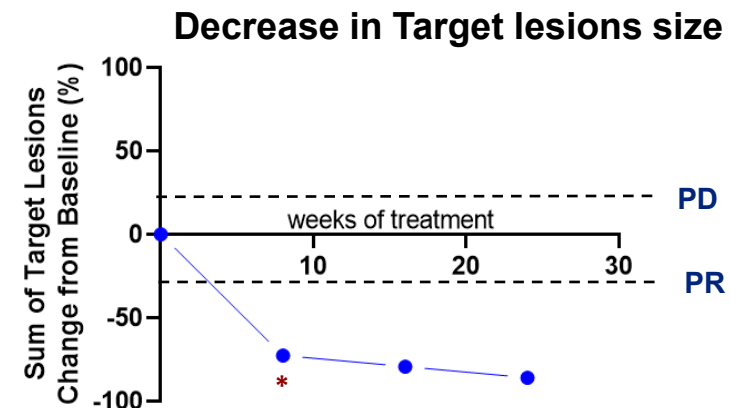


Preliminary drug activity in target lesions of refractory Ewing's patient

- Feb 2016: 30 year-old male diagnosed and treated with standard VDC/IE chemotherapy
- July 2017: Presented with bone lesion and treated with standard I/T chemotherapy
- Feb 2019: External beam radiation treatment
- Sep 2019: Enrolled in SP-2577 study at 600 mg BID dose cohort.

Prospectively defined target lesions decreased 86% in size after 6 months of treatment

- Partial Response (PR) of target lesions
- At cycle 2 non-target lesions increased resulting in overall assessment of Progressive Disease (PD) per RECIST 1.1.
- Patient continued treatment for additional 4 cycles (total of 6 cycles) due to response in target lesions and clinical benefit as determined by Investigator.



* PD in non-target lesions at 8 weeks, patient continued therapy

¹ As of May 1, 2020

MARKET EXPANSION

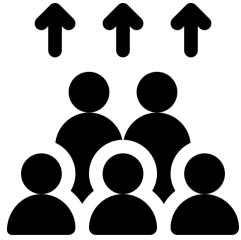
Secclidemstat in Advanced Solid Tumors

Select Tumor Mutations

Immunotherapy



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

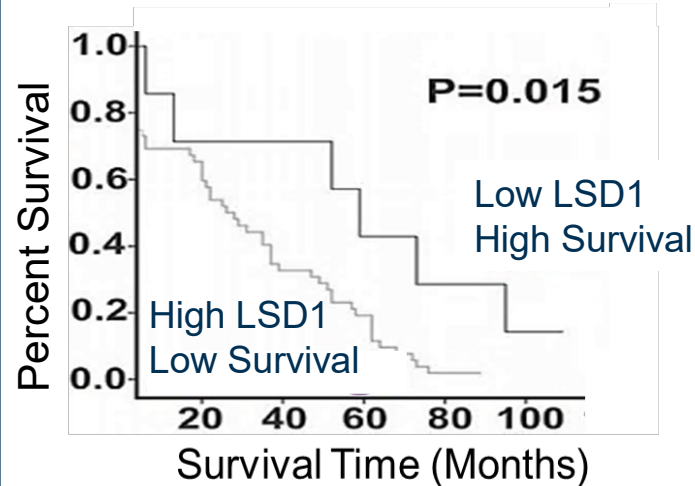


Increased LSD1 expression correlates with solid tumor progression

- 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

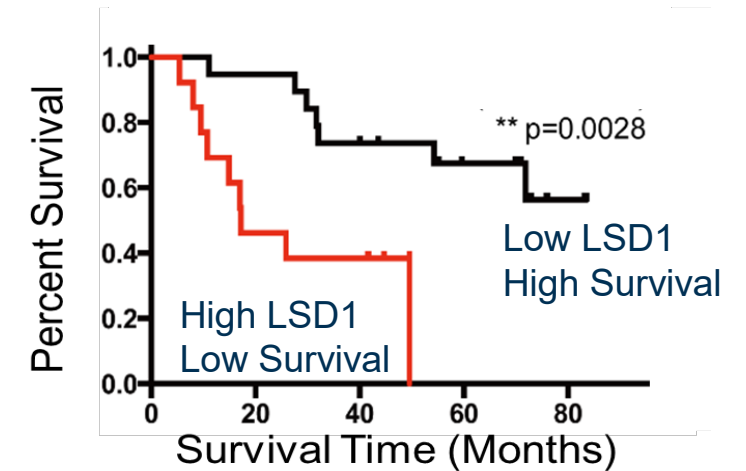
¹ Sehrawat, A. et. al., 2018

Castration Resistant Prostate Cancer



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

Triple Negative Breast Cancer (TNBC)



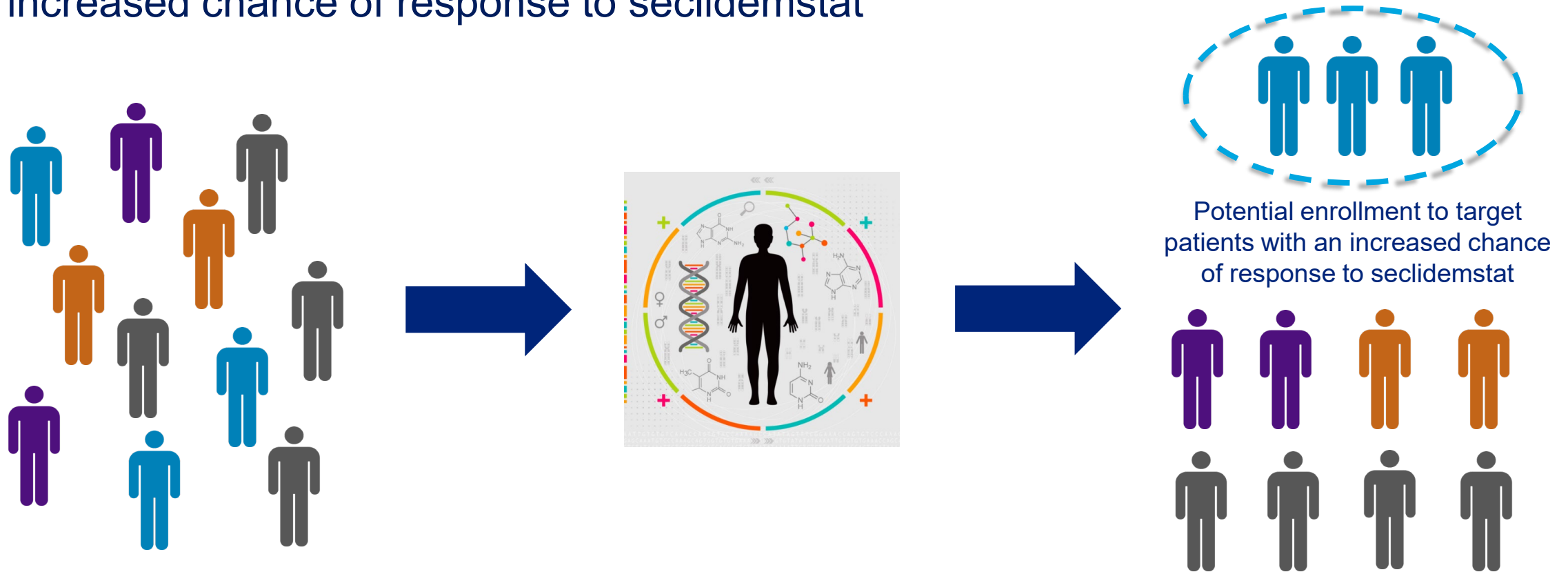
Nagasawa, S. et al (2015)

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 Known Sensitizing Mutations

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



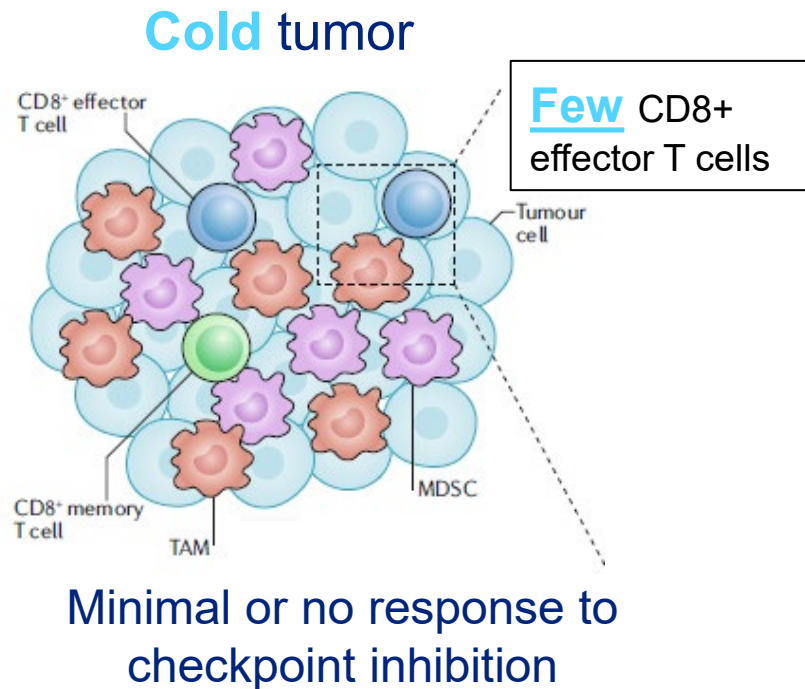
 Represents patient with potential sensitizing mutations identified by Saliarius



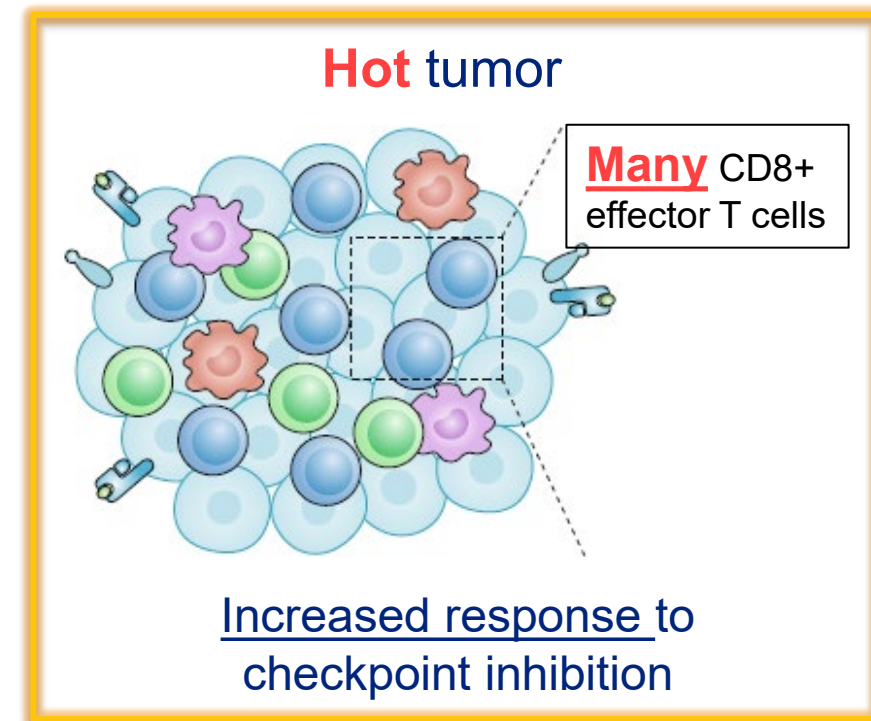
LSD1 Inhibition Turns Cold Tumors Hot And Increases Efficacy Of Checkpoint Inhibitors

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

- ~\$15B CPI 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 CPI market into patients currently resistant to CPI treatment



LSD1 inhibition



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

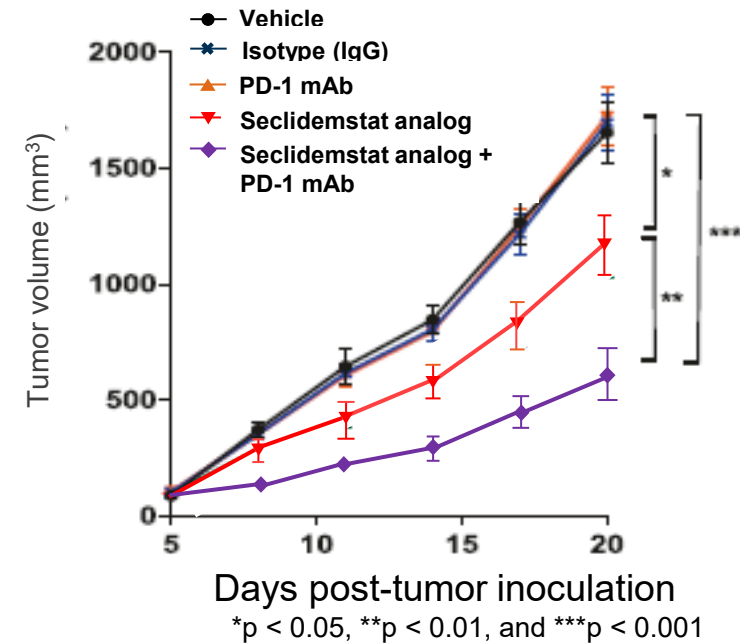
Oncogene

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

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

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) may
have mutations that sensitize to seclidemstat⁶

POTENTIAL TO ENTER INTO IMMUNOTHERAPY and HEMATOLOGIC CANCERS

Sensitizing resistant cancers
to checkpoint Inhibitors

\$1B+ Market Potential⁷

Hematologic cancers with
clinical evidence for LSD1i

\$1B+ Market Potential⁸



Salarius Investment Opportunity: Clinical Stage Biotech With Several Value-driving Inflection Points Occurring In 2020/2021



Lead compound is in the growing epigenetic therapy space

- Attractive price for investors interested in this growing therapeutic area



Extensive non-dilutive funding coupled with low quarterly burn rate

- Up to \$18.7M¹ 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 is positioned for a newsworthy 2020 and 2021:



Two ongoing clinical trials are expected to readout safety, pharmacokinetic, and early efficacy data. Potential to initiate additional trials.





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>

⁸ Hematological Malignancies. Apr 2020. Brand Essence Market Research.



Appendix B: US Intellectual Property Portfolio

- Composition of matter: #8,987,335
- Composition of matter: #9,266,838
- Methods of Use: #9,642,857
- Methods of Use: #9,555,024

