

Company Overview 1Q 2021

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Mission Statement



Developing treatments for patients that need them the most



Corporate Overview

Salarius's mission is to develop treatments for patients who need them most



Drugs that regulate gene expression ("epigenetics") have shown clinical efficacy plus immunooncology potential



Lead candidate, seclidemstat is a novel, oral, reversible LSD1 inhibitor that regulates gene expression and is currently in Phase 1/2 Ewing and Ewing-related 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
- Original \$18.7M¹ award from Cancer Prevention Research Institute of Texas (CPRIT) with \$4.8M remaining
- Financial support from the National Pediatric Cancer Foundation



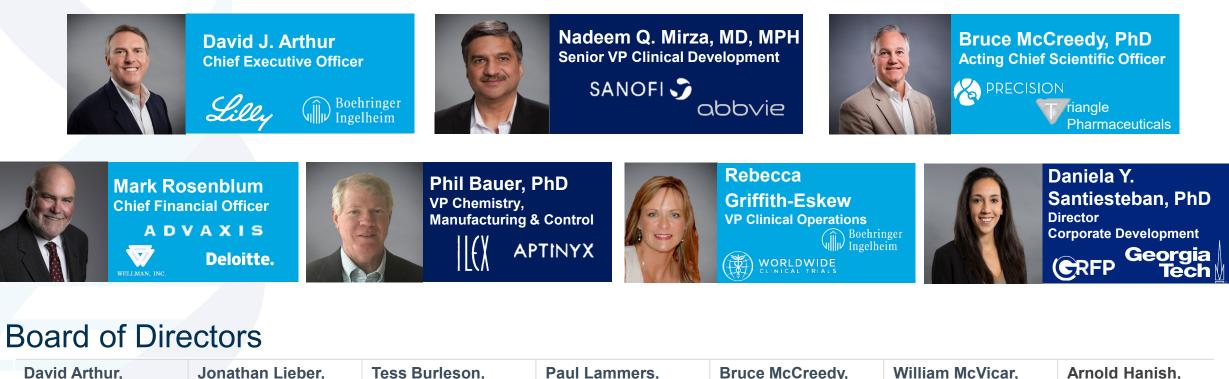
Market expansion in targeted cancers with LSD1 sensitive mutations and immunotherapy (checkpoint inhibitor combos) and hematologic cancers

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¹ As of January 13, 2021, the Company had received \$11.3M from CPRIT and there is up to \$4.8M available subject to certain requirements and spending restrictions.

Seasoned Leadership Team



	David Arthur, MBA	Jonathan Lieber, MBA	Tess Burleson, CPA	Paul Lammers, MD MSc	Bruce McCreedy, PhD	William McVicar, PhD	Arnold Hanish, CPA	
	Salarius Pharmaceuticals	Danforth Advisors	Translational Genomics Research	Triumvira Immunologics	Precision BioSciences	Flex Pharma	Omeros Corporation	
		Histogenics	Institute	Merck Serono	Triangle	Sepracor	Eli Lilly	
					Pharmaceuticals	Novartis		
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Recent and Anticipated Milestones

Development Milestones	Timing
Rare Pediatric Disease, Orphan Status Designation, and Fast Track Designation	2017-2019
Phase 1 Ewing data (pediatric subcommittee Oncologic Drug Advisory Committee)	1H 2020
CPRIT Distribution	2H 2020
Additional Phase 1 Ewing data - RP2D Established (Press release 02/17/21)	1Q2021
Initiate Ewing sarcoma and Ewing-related sarcoma expansion (Press release 02/24/21)	1Q 2021
Initiate potential immunotherapy combo trial	1H2021
Initiate potential hematologic trial	1H2021
Phase 1 Ewing early safety and efficacy data readouts	1H 2021
Phase 1 AST early safety and efficacy data readouts	1H 2021
Potential early readouts from the Ewing and Ewing-related sarcoma Expansion Phase	2H 2021
Full data readouts from completed Ewing and Ewing-related sarcoma Expansion Phase	2022
Early readouts from immunotherapy combo and hematologic trials	2022



Development Pipeline

	Indication	Preclinical	Phase 1	Phase 2 ¹	Status
	Ewing and Ewing-related Sarcomas	Dose Expansion at RP2D			 Phase 1/Phase 2 enrolling up to 80 patients Recommended Phase 2 Dose (PR2D) established
Seclidemstat	Advanced Solid Tumors	Dose Escalation a Expansion ²	and		 Phase 1/Phase 2 enrolling up to 50 patients
Seclid	Immunotherapy	In vitro and In vivo studies ongoing			 Identifying combinations and indications for clinical trials
	Hematologic cancers	In vitro and In vivo studies ongoing			 Identifying combinations and indication for clinical trials

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

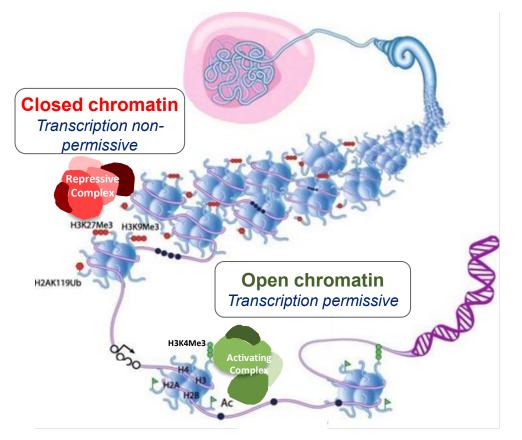
2. Open to all non-Ewing sarcoma solid tumor patients except for primary CNS tumors, potential to enrich for patients with sensitive mutations and prostate cancer that can be monitored with prostate specific antigen

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Seclidemstat Overview

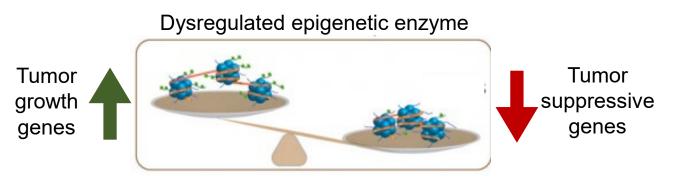
Epigenetic enzymes are attractive targets for cancer therapy

Epigenetic modifying enzymes affect gene expression by manipulating the chromatin structure

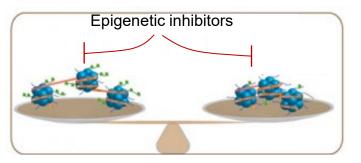


Adapted from Holliday, H. Breast Cancer Research 2018

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



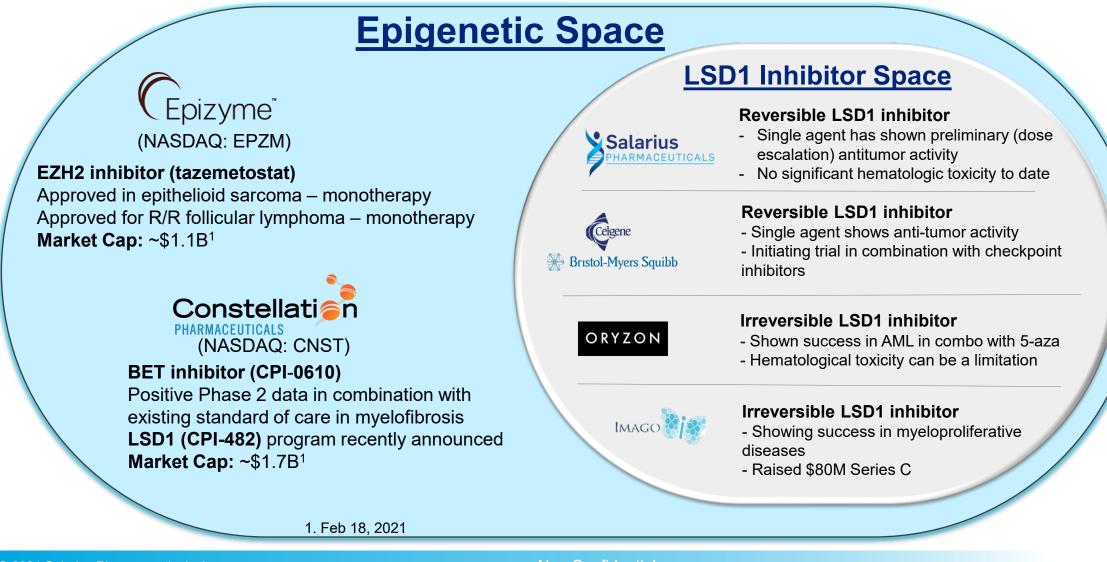
Drugs that correct dysregulated epigenetic enzymes can help treat cancer by restoring to a balanced transcriptional state



Adapted from Marcin et al. Biomed Intel 2018.

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Epigenetic Space Is Gaining Momentum And Epigenetic Focused Biotechs Are Increasing In Valuation



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 Cells1Normal
Cells• LSD1 is necessary for stem cell
maintenance and cell development
processes (e.g., blood cells)

- Cancer 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



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Cells

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More Comprehensive Inhibition of LSD1 Positively Impacts Therapeutic Activity

Degree of LSD1 inhibition

Enzymatic activity – Demethylation

Impact: Moderately alter gene expression

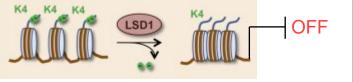
Partial scaffolding* inhibition of LSD1 – protein interaction

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

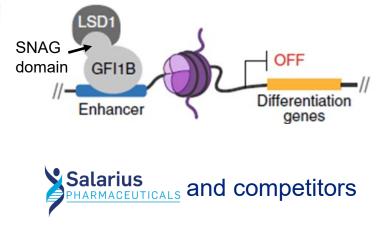


of LSD1 – protein interaction

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



Salarius PHARMACEUTICALS and competitors



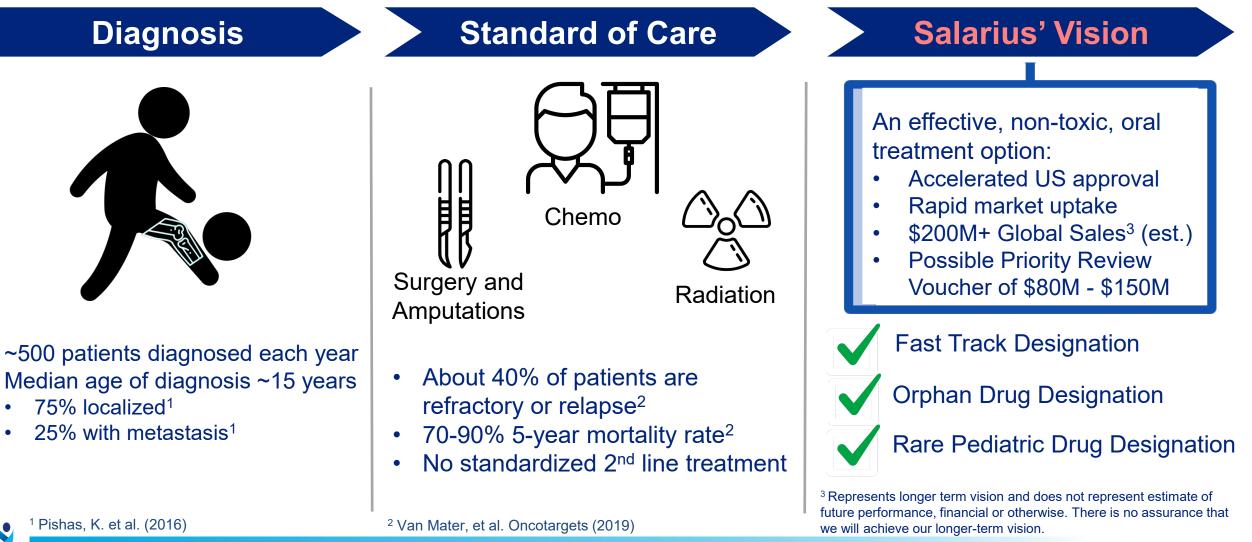


*scaffolding properties – protein to protein interactions

SPEED TO MARKET

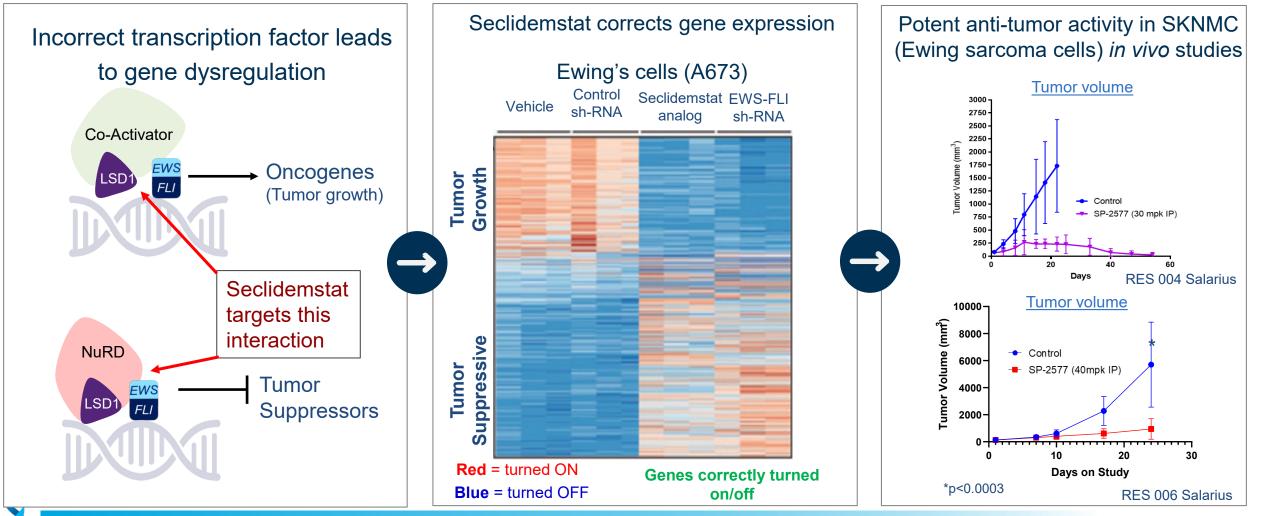
Seclidemstat in Ewing Sarcoma and Ewing-related Sarcomas

Ewing Sarcoma - Unmet Need Represents a Meaningful Product Opportunity



Targeting The Root Cause Of Ewing Sarcoma Via LSD1 Inhibition

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



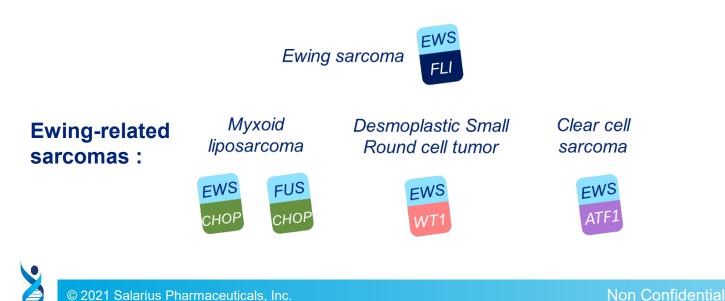
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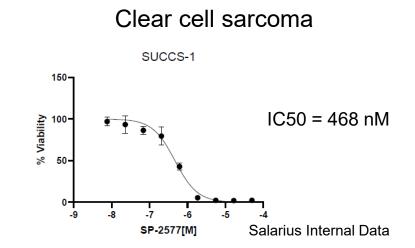
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Sankar et al. Clinical cancer research 20.17 (2014)

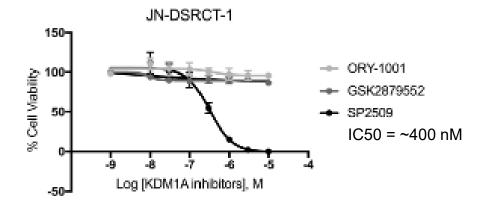
Seclidemstat's mechanism of action results in anti-proliferative activity in Ewing-related (FET-translocated) sarcomas

- Salarius's ongoing Ewing sarcoma trial amended to include Ewing-related sarcomas at the RP2D supported by preclinical and clinical data
 - <u>Clinical data</u>: FET-sarcoma patients¹ treated at doses below the RP2D have a median time to progression above a commonly used benchmark for assessing single agent activity in soft tissue sarcomas





Desmoplastic Small Round Cell Tumor



Romo-Morales A et al. Pediatr Blood Cancer. 2019.

1. As of December 30, 2020 a small subset of FET-rearranged sarcomas have enrolled in Salarius's AST Trial

Ewing Sarcoma and Ewing-Related Sarcomas Phase 1/2 Trial

Open-label dose escalation / dose expansion trial design

Dose escalation (completed 1Q2021)

- Seclidemstat has a manageable safety profile
- RP2D established

Dose expansion amended to reach more sarcoma patients (initiating 1Q2021)

- **Arm 1**: Up to 30 Ewing sarcoma patients treated in combination with Topotecan/Cyclophosphamide
- Arm 2: Up to 30 Ewing-related sarcoma patients treated with single agent seclidemstat

Primary objective: Safety, Tolerability Secondary objectives: Anti-tumor assessment Exploratory: Hemoglobin F, cfDNA, CTCs





Drug exposure at RP2D is above concentration that showed activity in preclinical models



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

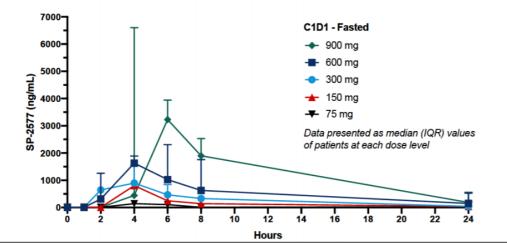
Early dose escalation results

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

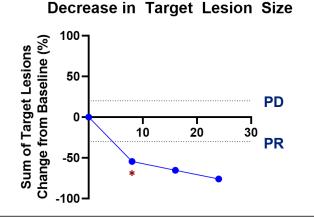


Preliminary drug activity in target lesions of refractory Ewing's patient

- 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 76% 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

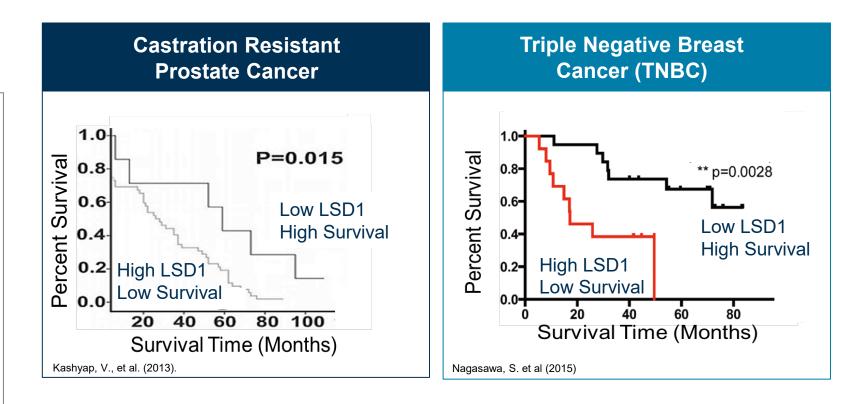
MARKET EXPANSION

Seclidemstat in Advanced Solid Tumors Select Tumor Mutations Immunotherapy LSD1 Overexpression Increases With Disease Progression And Correlates With Poor Patient Prognosis – Seclidemstat 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



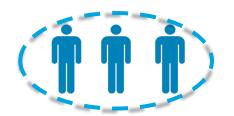
Ongoing Phase 1 Advanced Solid Tumor Study sites: Honor Health, Phoenix AZ and Sarcoma Oncology Center, Santa Monica CA



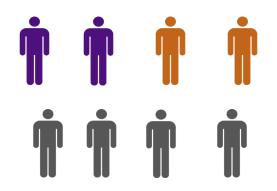
¹ Sehrawat, A. et. al., 2018

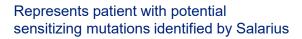
Seclidemstat Expansion Strategy Built Upon Patient Targeting, Increasing Immuno-oncology Response & Hematological Cancers

Patient Targeting



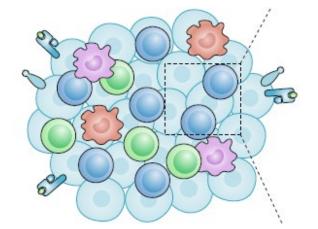
Potential enrollment to target patients with an increased chance of response to seclidemstat





Increase Response to Checkpoint Inhibitors

LSD1 inhibition can turn **cold** tumors to **hot** tumors

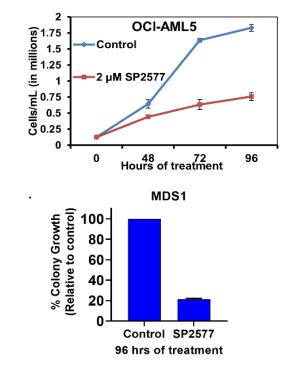


May help increase patient response to IO therapies

Topper, M.J., et al. Nature Reviews (2019)

Hematologic Cancers

Seclidemstat (SP-2577) inhibits Acute Myeloid Leukemia (AML) and Myelodysplastic Syndrome (MDS) cell growth



Combination of Possibilities Presents Significant Market Opportunity for Seclidemstat

SPEED TO MARKET

Ewing and Ewing related sarcomas 500 to 2000 patients diagnosed/year



Potential for accelerated approval, priority review

\$80M-\$150M

Possible Pediatric Priority Review Voucher (est.)

\$400M+ Global Sales per year (est)¹ EXPANDING INTO LARGER MARKETS

POTENTIAL TO IDENTIFY SELECT PATIENT

Ongoing work to identify genetic backgrounds that may increase patient response to LSD1 inhibition



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

\$1B+

POTENTIAL TO ENTER INTO IMMUNOTHERAPY

Sensitizing resistant cancers to checkpoint Inhibitors

\$1B+ Market Potential⁷

POTENTIAL TO ENTER INTO HEMATOLOGIC CANCERS

Hematologic cancers with clinical evidence for LSD1i

\$1B+ Market Potential⁸

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



- Lead compound, seclidemstat, is in the growing epigenetic therapy space
 - Clinical data suggests seclidemstat has a manageable safety profile and has demonstrated anti-tumor activity in patients with advanced disease



- Extensive non-dilutive funding coupled with low quarterly burn rate
 - Original \$18.7M¹ Award from CPRIT
 Received financial support from NPCF



- Recipient of FDA designations that facilitates rapid product development
 - Orphan Drug Designation
 Rare Pediatric Disease Designation
 Fast Track Designation

Salarius anticipates several value-inflection announcements in the upcoming months:



Safety, pharmacokinetic, and early efficacy data from our two ongoing clinical trials to be presented at an upcoming scientific conference

Announcement of additional seclidemstat clinical trials in attractive indications

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LSD1 Competitive Landscape Highlights Seclidemstat's Differentiation

	Company	Drug Name	Binding Mechanism	Indications and Phase		
	Salarius PHARMACEUTICALS	SP-2577 (Seclidemstat)	Reversible	Ewing sarcoma (Ph1/2), Advanced Solid Tumors (Ph1/2)	Seclidemstat's differentiated binding	
lic ¹	ORYZON	ORY-1001 (RG6016)	Irreversible	AML combo (Ph2b), SCLC combo (Ph2a)	mechanism (reversibility) and binding location shows potential	
In clinic ¹	(Celgene (BMS)	CC-90011	Reversible	Non-Hodgkin's lymphoma and AST (Ph1), SCLC combo (Ph1b), IO combo (Ph 2), Prostate (Ph1), AML (Ph1/2)		
		IMG-7289	Irreversible	Myelofibrosis (Ph2b), essential thrombocythemia (Ph2a), Polycythemia vera (Phase 2a)	increased therapeutic activity and safety*	
				¹ Clinicaltrials.gov		
	BE/(CTICA ⁻	BEA-17	Reversible	Glioblastoma, IO		
Preclinic ²	RASNA THERAPEUTICS	RASP-201	Reversible	AML	Preclinical research is	
Prec	Hanmi	HM9XXX series	Reversible	AML and SCLC	shifting to develop reversible LSD1 inhibitor	
		CPI-482	Irreversible	Myeloproliferative neoplasms	L	
				² Not an exhaustive list of companies in preclinical stage		
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GlaxoSmithKline and Incyte previously had clinical LSD1 programs (irreversible) that have since been terminated

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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.

²Cancer 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