A GLOBAL LEADER IN EPIGENETICS

INVESTOR PRESENTATION

MADX: ORY

April 2019

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ORYZON

Company Highlights

- MADX: ORY A **publicly traded** company on the Spanish Stock Exchange
- Integrated in the **IBEX Small Cap Index**
- A **clinical stage** biopharmaceutical company developing innovative therapies in the field of Epigenetics
- A competitive **EPIGENETIC PLATFORM** validated scientifically and clinically
- Three therapeutic programs in LSD1 in development with multiple indication opportunities
- Large IP portfolio with technology fully developed in-house
- **Raised €50M** (in 2015-2017). Additional **€13M** raised from investors in the US and Europe **in October 2018**
- **Cash runway** expected till **4Q2020**
- Loss/Earnings from Operations 2018: **-3.3M€**
- One of the **MOST LIQUID** companies in the MicroCap group in the Spanish Stock Market
  - 39.1 M Shares outstanding. Fully diluted
  - 350,000 daily volume (Avg Traded Volume in 2018)
  - +88M shares negotiated in 2018 / ≈5 months for share full turnover

IBEX Small Cap

BOLSA DE MADRID

ORYZON GENOMICS SA
BALANCE SHEET DATA (AUDITED)
(Amounts in thousands US $)

	December 31st, 2018	December 31st, 2017
Cash and cash equivalents	39.296 (1)	41.916
Marketable securities	162	256
Total Assets	77.231	73.210
Deferred revenue	0	0
Total Stockholders' equity	51.668	41.294

(1) *34,5 M€*

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EPIGENETIC & LSD1 in human diseases

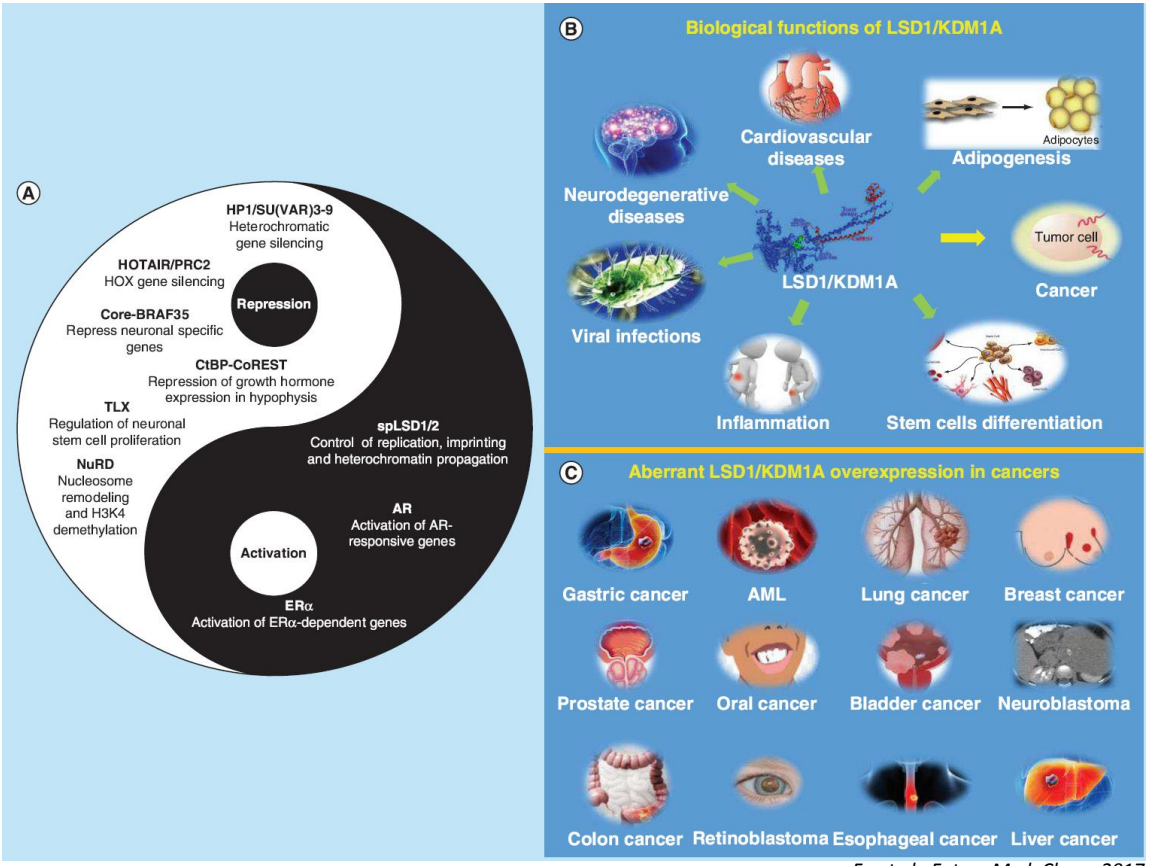
Epigenetic mechanisms regulate the function of chromosomes

Chromatin remodeling enzymes are a central component of the epigenetic regulation

Lysine specific histone demethylase 1 (LSD1), aka KDM1A, removes methyl marks at mono- and dimethyl-H3K4 (histone H3 lysine 4) and H3K9 (histone H3 lysine 9)

LSD1 is involved in different pathologies:

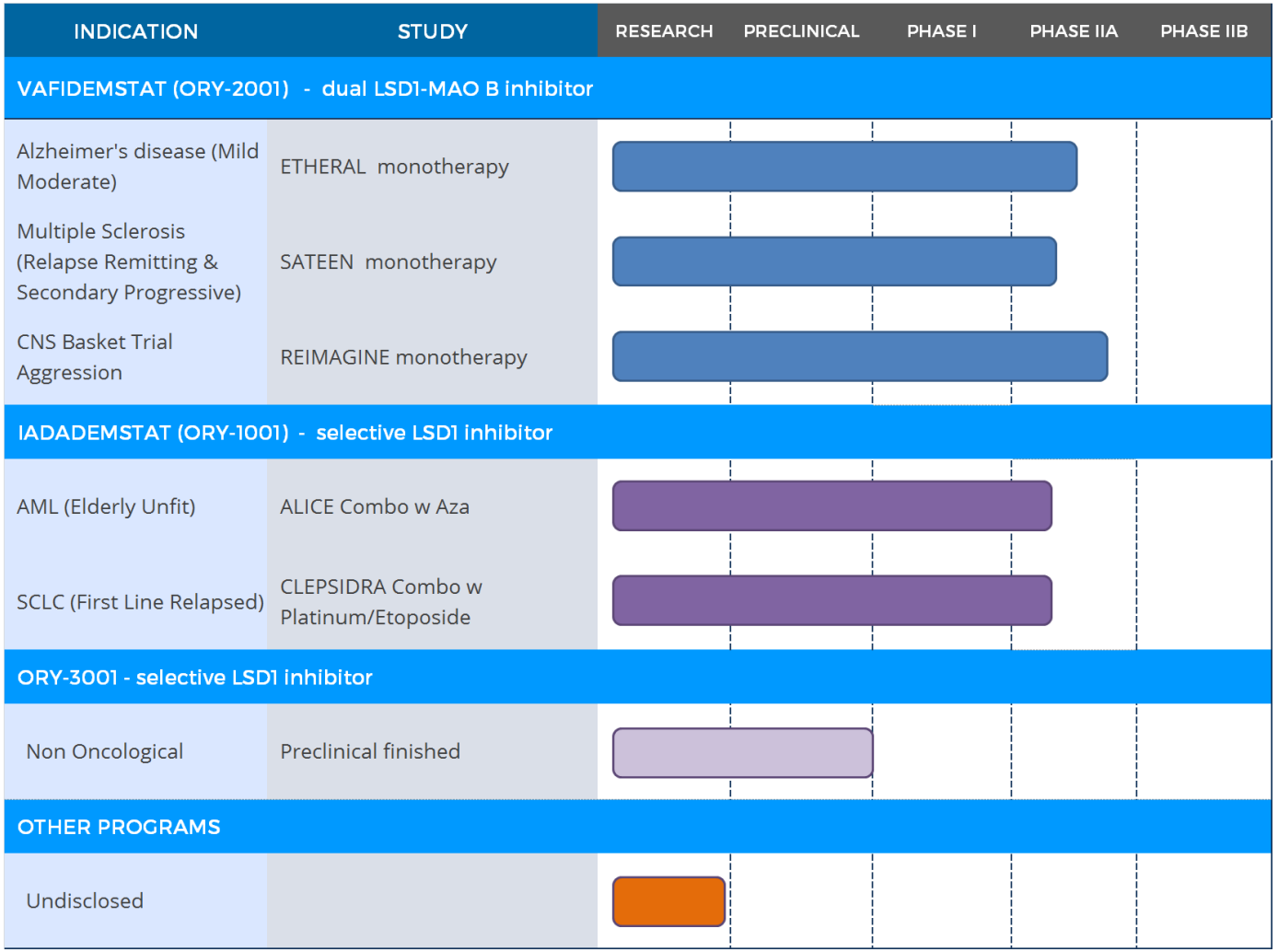
- ✓ Solid tumors
- ✓ HemOnc
- ✓ Hematol. disorders
- ✓ Inflammation
- ✓ Neurodegeneration
- ✓ Psychiatric disorders
- ✓ Viral Infections
- ✓ Others…



Fu et al., Future Med. Chem. 2017 9(11)

Extensive pipeline : 2 programs in clinic with multiple indications each

- ✓ A Productive Epigenetic Platform
- ✓ A strong focus on LSD1



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A GLOBAL LEADER
IN CNS EPIGENETICS

VAFIDEMSTAT a Phase II Clinical Stage Compound with a broad developability in CNS diseases

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Vafidemstat (ORY-2001): a “Neuron-fixer”

- A small molecule that selectively inhibits LSD1 and MAO-B (IC50 s of 100nM in LSD1 / 75 nM in MAOB)
- Covalent binder. Excellent Pharmacology. High oral bioavailability
- Demonstrated target engagement in various animal species
- Characterized in 6 and 9 months PC regulatory toxicological studies
- Positive results in 7 different animal models and in i*n-vitro* models
- Produces positive results in:
  - Cognition
  - Neuroprotection
  - Neuroinflammation
  - Social Withdrawal / Apathy
  - Aggression / Agitation
  - Others
- Biomarkers identified in animals that show promise for use in humans
- Capable of acting in all the processes that manifest in neurodegenerative disease patients
- Safe in humans in a Phase I trial with 106 healthy volunteers
- BBB penetrance and human target engagement established
- Pharmacologically active in humans

In Phase IIa in three different clinical studies

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Vafidemstat restores cognition measured by NORT in SAMP8 AD model

MILD

MODERATE

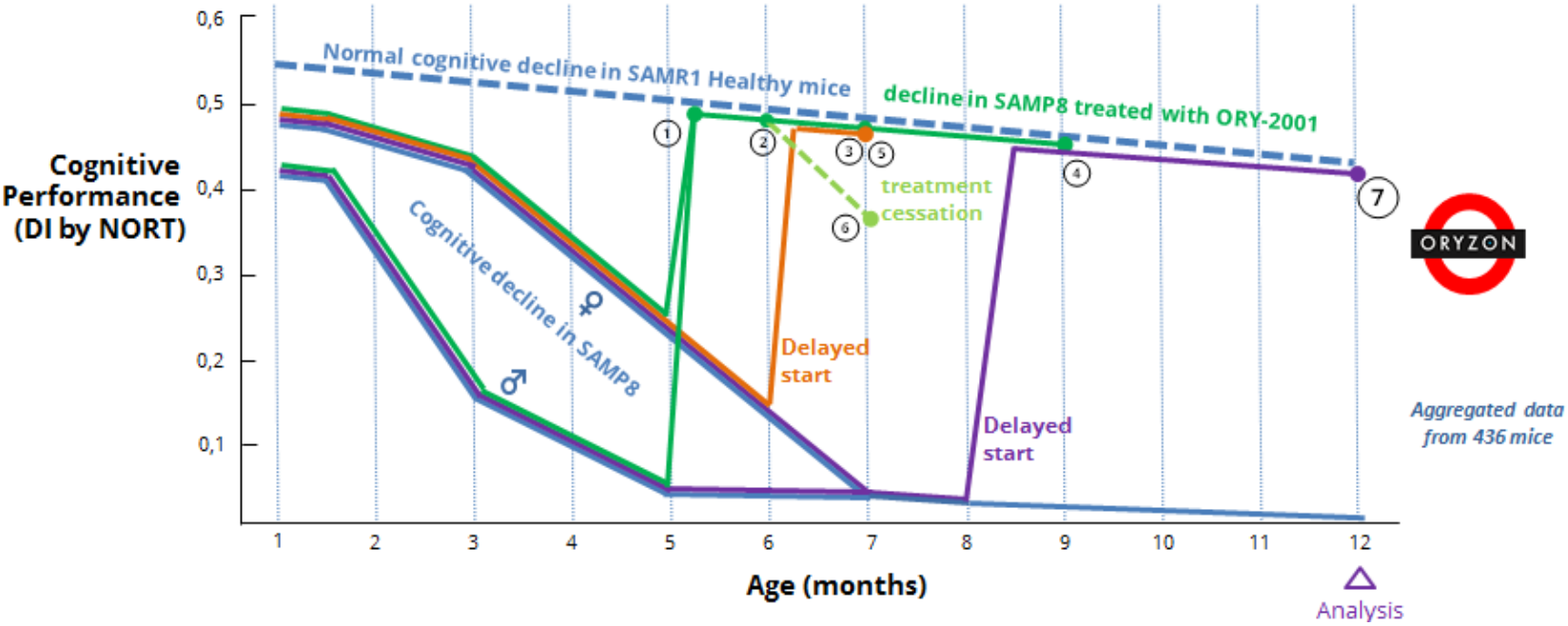
SEVERE

Treatment from month 5 during 1 week (1), 1 month (2), 2 months (3), 4 months (4)

Treated from month 6 during 1 month (Delayed start-1) (5)

Treatment from month 5 during 1 month, tested at month 7 (1 month after treatment cessation) (6)

Treatment from month 8 during 4 months (Delayed start-2) (7)



Preclinical results suggestive of Disease modifying potential

(Similar memory restoration results observed with vafidemstat in the R6/1 HD model. Positive effects in memory also described recently in the NMDA receptor-hypofunction mice with T-448, a selective LSD1 inhibitor from Takeda)

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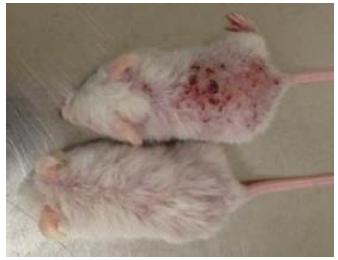
Vafidemstat reduces aggression in mice Alzheimer's Disease model



In the cognition tests we noticed that SAMP8 male mice treated with vehicle aggressed cage mates while vafidemstat-treated animals did not. Later we confirmed this in proper *Resident-intruder* aggression tests.

SAMP8 MICE treated with Vehicle
Resident Intruder test

SAMP8 MICE treated with ORY-2001 0,32mg
Resident Intruder test

SAMP8 animals treated with vafidemstat are not aggressive and have normal levels of basal activity (no sedation)

Vafidemstat also enhances sociability and reduces social withdrawal (data not shown)

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Vafidemstat

CLINICAL DEVELOPMENT

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REIMAGINE Study

- A single center open label exploratory PhIIa basket trial to assess the effect of vafidemstat in reducing aggression in patients with two neurodegenerative and three neuropsychiatric indications
- N=30, with 6 participants per condition
- Single arm of vafidemstat (1.2 mg)
- 8 weeks treatment duration
  - AD
  - DLB
  - BPD
  - ADHD
  - ASD

Global Analysis

3-5 October 2019 Athens, Greece

2019 CINP International Meeting: BREAKTHROUGHS & CONTROVERSIES in MOOD DISORDERS, SCHIZOPHRENIA, ADHD and INSOMNIA

Top Line Data 2019

BPD

EPA 2019 27th EUROPEAN CONGRESS OF PSYCHIATRY
PSYCHIATRY IN TRANSITION TOWARDS NEW MODELS, GOALS & CHALLENGES
Warsaw, Poland 6-9 April 2019 #EPA2019

ADHD

7th World Congress on ADHD
From Child to Adult Disorder
25 – 28 April 2019 | Lisbon, Portugal
www.adhd-congress.org

ASD

32ND ECNP CONGRESS
7-10 SEPTEMBER 2019
COPENHAGEN

Conferences where preliminary data are expected to be presented. Some TBC

EPA 2019
27th EUROPEAN CONGRESS OF PSYCHIATRY
PSYCHIATRY IN TRANSITION
TOWARDS NEW MODELS, GOALS & CHALLENGES
Warsaw, Poland
6-9 April 2019
#EPA2019

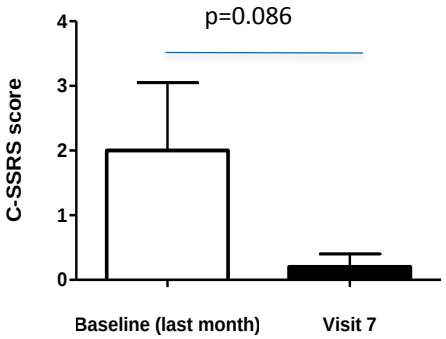
The study has met the primary and secondary endpoints in BPD patients

Borderline Personality Disorder (BPD) patients treated with vafidemstat showed a reduced aggressivity and a better overall performance in the core scales of the disease

Demographic data BPD patients		
n° of patients		6
Sex	Male	0 (0%)
	Female	6 (100%)
Age	Median (years)	37,33
	(Min , Max)	(25/46)
Race	Caucasian	6 (100%)
Weight	Median (Kg)	60,72
	(Min , Max)	(52,7/89,8)
Height	Median (cm)	164,37
	(Min , Max)	(162/172)
BMI	Median	22,51
	(Min , Max)	(19,39/33,39)

Primary endpoint: Safety

- ✓ Vafidemstat was safe and well tolerated by the BPD patients
- ✓ Patients had an overall decrease in the Columbia-Suicide Severity Rating Scale (C-SSRS)



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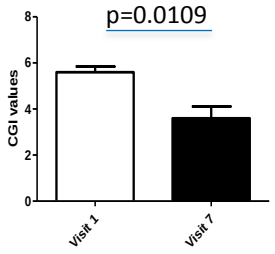
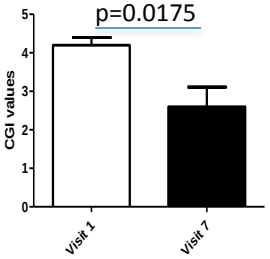
Secondary endpoints: Efficacy

- Vafidemstat produced significant improvements on the Clinical Global Impression (CGI) CGI-S and CGI-I scales
- Vafidemstat also produced significant improvements on the Neuropsychiatric Inventory (NPI), not only at the 4-item agitation/aggression NPI subscale score, but also at the global NPI score (12 items)
- **Remarkably, vafidemstat not only improved aggression but also produced significant improvements on the Borderline Personality Disease Checklist (BPDCL), both on the GLOBAL scale and on the combined score for NON-aggression related domains**

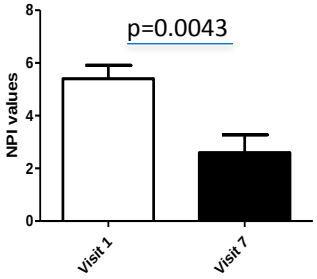
CGI-S



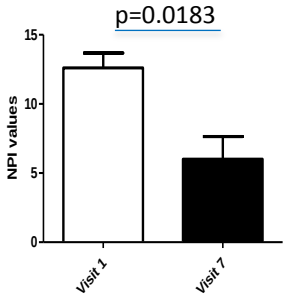
CGI-I



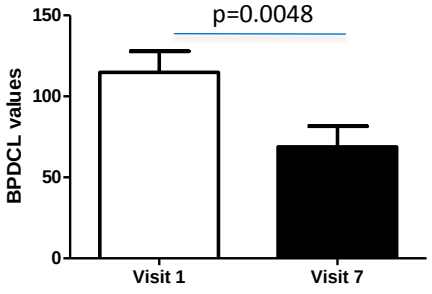
NPI
Agitation/Aggression (4 items)



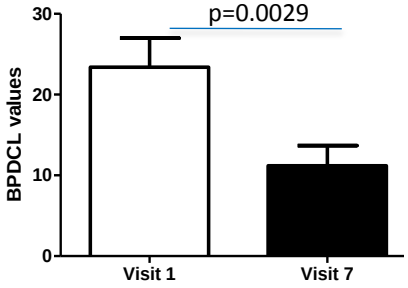
Total NPI
(12 items)



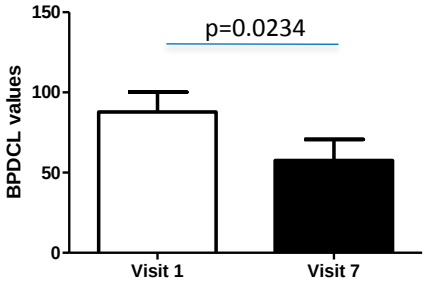
BPDCL
(Total Score)



BPDCL
Aggression-related combined score
(3 domains)



BPDCL
Non-Aggression-related combined score
(6 domains)



Vafidemstat may be a therapeutic option for BPD

- ✓ BPD prevalence ranges between 0.5%-1.4%[1] of the total population (≤ 9.1M in US+EU5)
- ✓ The treatment of BPD is largely based on psychotherapeutic interventions. It represents a significant unmet medical need: No drugs currently approved for this condition
  - ✓ Anxiety & depression are usually treated with common antidepressants but do not seem to have a strong effect on other features of the disorder. Some anxiolytic (benzodiazepines) may worsen the clinical presentation.
  - ✓ Antipsychotic agents (Risperdal®, Seroquel® etc) have shown some effect to reduce anxiety, paranoid thinking, anger/hostility, and impulsivity in patients with BPD, but sedation, weight gain[2] and other side effects are a significant hurdle for long term treatment and adherence.
- ✓ Vafidemstat reduces aggression and social withdrawal while enhances sociability and restores memory in animals
- ✓ In BPD patients, it not only improves aggression but produces an overall improvement of the core features of the disease, with no sedation and no weight gain
- ✓ Vafidemstat may be a disease modifying therapeutic option for BPD

1 BMC Psychiatry. 2016; 16: 249.
2 Neuropsychiatr Dis Treat. 2017; 13: 2231–2241.

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Alzheimer's, the huge need

- **45 million** people affected worldwide
- The Global cost of AD is $**605 billion/year**
- No therapeutic options so far
- The recent failures of BACE-i and mAb's against Abeta (Aducanumab, Crenezumab and others) have finally convinced the industry about the need to look for other MoAs
- AMBAR study (Grifols) has demonstrated statistical improvement in ADAS-Cog, language and verbal scales and QoL after 14 months in plasmapheresis vs placebo in moderate AD, demonstrating therapeutic feasibility in this target population

Vadifemstat proposition in AD

- Vafidemstat is safe and highly brain-penetrant in humans
- We have demonstrated indirectly brain target engagement in humans
- In preclinical models we see positive effects on memory, aggression, sociability and apathy, all core features in Mild and Moderate AD patients
- We have identified biomarkers that may be surrogate pharmacological biomarkers
- Vafidemstat is pharmacologically active in humans
- **The drug may provide clinical improvement in AD in both domains, symptomatic and disease modifier**

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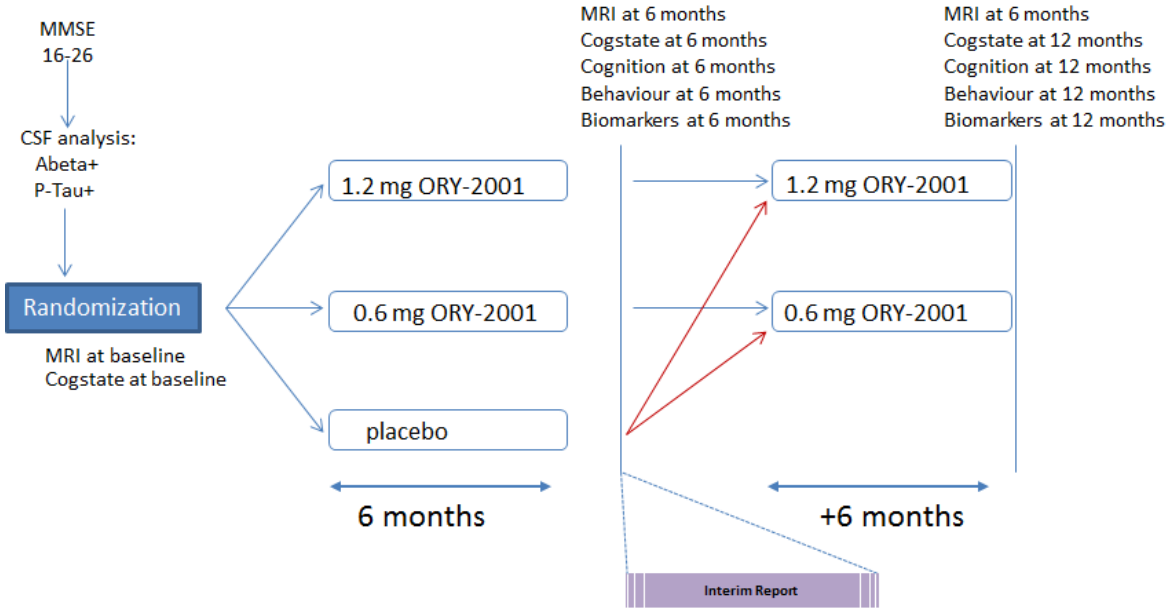
ETHERAL: **E**pigenetic **THER**apy in **AL**zheimer's Disease

An ambitious Phase IIa study to provide useful information to design future Phase II/III studies

- ✓ **150 Mild to Moderate AD** patients
- ✓ Primary Objective: Safety & Tolerability
- ✓ Secondary Objectives :
  - ✓ Cognition/Agitation/Apathy/QoL
  - ✓ Volumetric MRI
- ✓ **Biomarker guided study** with several CSF inflammatory Biomarkers

- ✓ 125 patients in EU. 17 sites
- ✓ Spain, France & UK actively recruiting
- ✓ **80 randomized** as per mid March

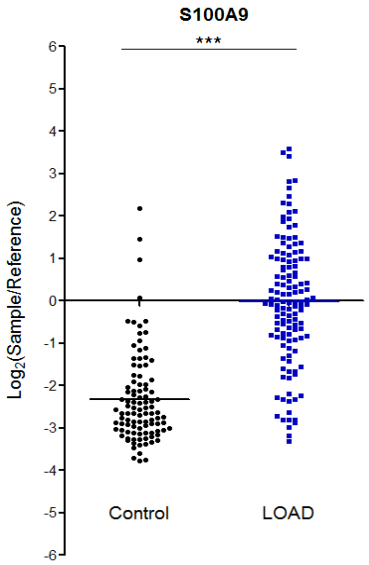
- ✓ A Twin study in US: around 25 patients
- ✓ IND approved
- ✓ FPI expected 1H2019



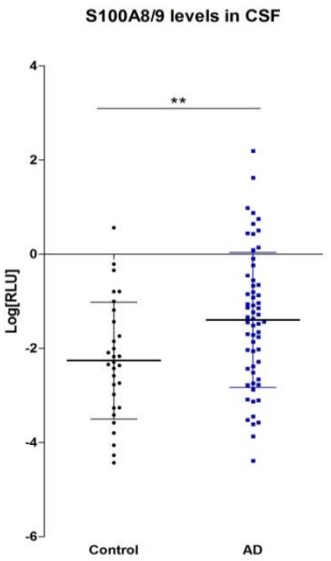
S100A9 has been characterized as one of the TOP10 up-regulated genes in LOAD dataset

- S100A9 PROTEIN levels are significantly increased in CSF from AD patients compared to age-matched controls
- S100A9 CSF PROTEIN levels are monitored in ETHERAL AD trial
  - S100A9 and inflammation have a correlation with the disease
  - Inflammation plays a mechanistic role in the progression of the disease
  - Vafidemstat reduces S100A9 in animals

Human PFC (RNA)



Human CSF (protein)



S100A9 CSF levels will be monitored in Phase II studies
S100A9 has the potential to be a surrogate biomarker for drug activity
S100A9 data might be part of a rationale for a fast track

Changes in S100A9 in patient's CSF may have important clinical development implications

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SATEEN A pilot study in MS to see a proof of biological activity

SAfety, **T**olerability and **E**fficacy in an **E**PIGE**N**ETIC approach to treat Multiple Sclerosis

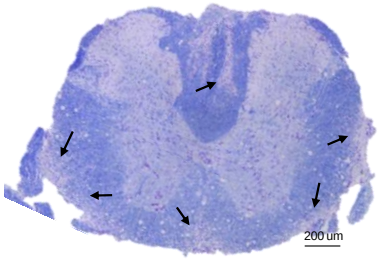
Randomised, double-blind, placebo-controlled, 3-arm, 36 weeks parallel-group study to evaluate the safety and tolerability of vafidemstat (ORY-2001) in patients with Relapsing-Remitting Multiple Sclerosis (RRMS) and Secondary Progressive Multiple Sclerosis (SPMS)

Spain only; 9 sites; 24 patients (RR & SP)

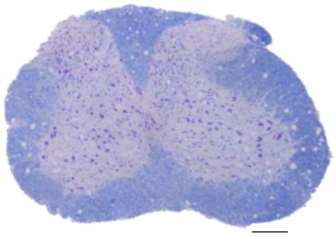
Active recruitment ongoing

Excellent safety. One patient is +1year on treatment

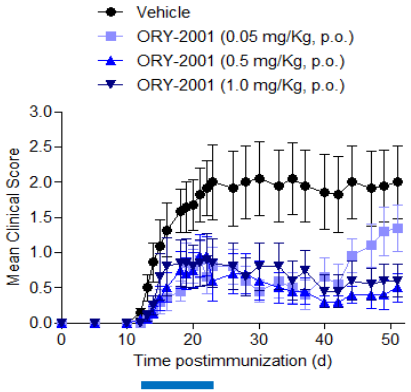
A broad preclinical evidence in different models supports vafidemstat activity in the MS paradigm



Vehicle



Vafidemstat



therapeutic treatment (p.o.)

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Iadademstat (ORY-1001)

A Phase II stage clinical compound

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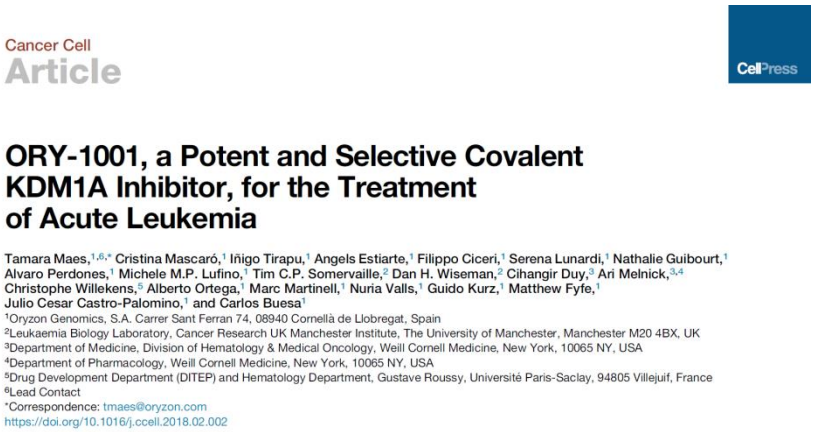
Iadademstat (ORY-1001): the most advanced selective LSD1 inhibitor in clinic

- ✓ LSD1 is involved in different cancers. High levels of LSD1 often correlate with more aggressive forms of cancer and/or bad prognosis
- ✓ Iadademstat is a small molecule that selectively inhibits LSD1. Preclinical in-vivo positive results in xenografts of AML, SCLC and in PDX of SCLC
- ✓ First LSD1i drug to enter into clinical trials and still Best in Class
- ✓ Produced positive results in an Acute Leukemia Phase I/IIa trial
- ✓ Identified Biomarkers to stratify SCLC patients
- ✓ Phase IIa ongoing in SCLC (CLEPSIDRA)
- ✓ Phase IIa ongoing in AML (ALICE)
- ✓ Preclinical / Biomarkers and new combos under constant investigation



Cancer Cell
Article

CellPress

ORY-1001, a Potent and Selective Covalent KDM1A Inhibitor, for the Treatment of Acute Leukemia

Tamara Maes,[1,6,*] Cristina Mascaró,[1] Iñigo Tirapu,[1] Angels Estiarte,[1] Filippo Ciceri,[1] Serena Lunardi,[1] Nathalie Guibourt,[1] Alvaro Perdones,[1] Michele M.P. Lufino,[1] Tim C.P. Somervaille,[2] Dan H. Wiseman,[2] Cihangir Duy,[3] Ari Melnick,[3,4] Christophe Willekens,[5] Alberto Ortega,[1] Marc Martinell,[1] Nuria Valls,[1] Guido Kurz,[1] Matthew Fyfe,[1] Julio Cesar Castro-Palomino,[1] and Carlos Buesa[1]

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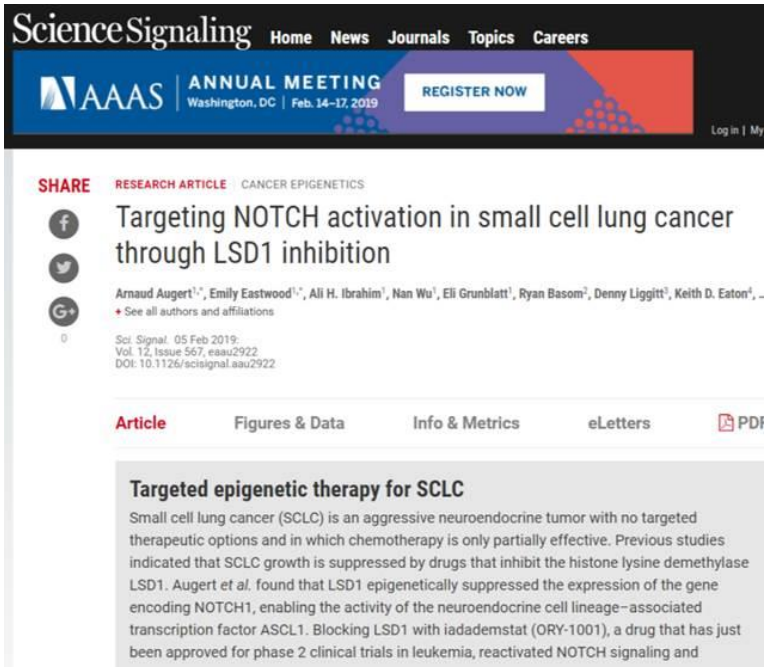
https://doi.org/10.1016/j.ccell.2018.02.002



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RESEARCH ARTICLE | CANCER EPIGENETICS

Targeting NOTCH activation in small cell lung cancer through LSD1 inhibition

Arnaud Augert[1,*], Emily Eastwood[1,*], Ali H. Ibrahim[1], Nan Wu[1], Eli Grunblatt[1], Ryan Basom[2], Denny Liggitt[3], Keith D. Eaton[4], ...
+ See all authors and affiliations

Sci. Signal. 05 Feb 2019:
Vol. 12, Issue 567, eaau2922
DOI: 10.1126/scisignal.aau2922

Article Figures & Data Info & Metrics eLetters PDF

Targeted epigenetic therapy for SCLC

Small cell lung cancer (SCLC) is an aggressive neuroendocrine tumor with no targeted therapeutic options and in which chemotherapy is only partially effective. Previous studies indicated that SCLC growth is suppressed by drugs that inhibit the histone lysine demethylase LSD1. Augert *et al.* found that LSD1 epigenetically suppressed the expression of the gene encoding NOTCH1, enabling the activity of the neuroendocrine cell lineage–associated transcription factor ASCL1. Blocking LSD1 with iadademstat (ORY-1001), a drug that has just been approved for phase 2 clinical trials in leukemia, reactivated NOTCH signaling and

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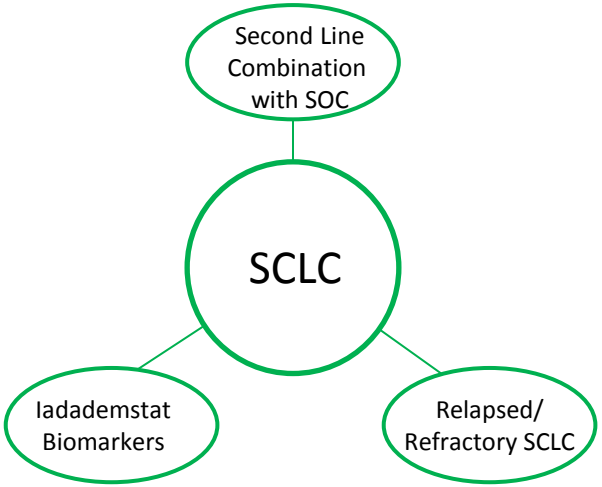
Iadademstat a flexible CDP for a Large Market Opportunity

MoA well characterized in SCLC, AML and Medulloblastoma



Small Cell Lung Cancer is the main indication under exploration

POTENTIAL IADADEMSTAT ONCOLOGICAL INDICATIONS:

Solid Tumors

Small Cell Lung Cancer
Prostate cancer
Colorectal cancer
Bladder cancer
Some breast cancers

HemONC

AML
MDS
Myelofibrosis
Non Hodgkin Lymphoma

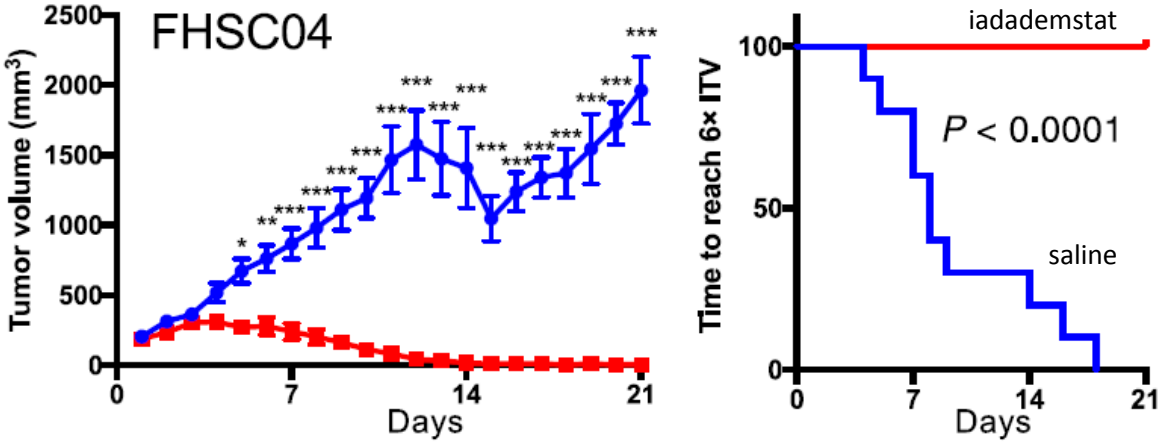
Brain Tumors

Medulloblastoma
Glioblastoma

ORYZON

Iadademstat opportunity in SCLC

- LSD1 is a target well characterized in SCLC and validated in preclinical models. LSD1 inhibitors are effective in vitro and in-vivo xenograft models of SCLC
- Iadademstat produces complete and durable tumor regression in different chemoresistant PDX models
- Characterized MoA (induction of Notch and repression of ASCL1)
- Identified and patented Biomarkers that are differential in sensitive cell lines
- Characterization of Biomarkers in tumors and plasma from patients
- Phase II clinical trial ongoing in second line SCLC patients using these biomarkers to stratify patients and identify super-responders



Iadademstat: SCLC Current Clinical Development Plan

CLEPSIDRA: A **C**ombination trial of **L**SD1 and **E**top-**P**latinum in **S**mall Cell Lung Cancer in **biomarker-ID** **R**elapsed p**A**tients

A Phase IIa study to assess the safety, tolerability, dose finding and efficacy of iadademstat (ORY-1001) in combination with platinum-etoposide chemotherapy in patients with relapsed, extensive-stage disease small cell lung cancer who are positive to candidate predictive biomarkers

- ✓ Single arm
- ✓ Open label; 4 sites in Spain
- ✓ Up to 36 patients to be enrolled
- ✓ **Primary end point**: Safety and tolerability of the combo with platinum-etoposide therapy
- ✓ **Secondary endpoints:** RECIST responses; time to responses; duration of response; and overall survival

Preliminary Results

- ✓ Patient 1 already completed the first two cycles of combo iada+SoC and has started cycle 3.
- ✓ Satisfactory and dynamic recruitment pace

Clinical Preliminary Reports to be presented at several Medical Conferences to be announced in 2019-2020

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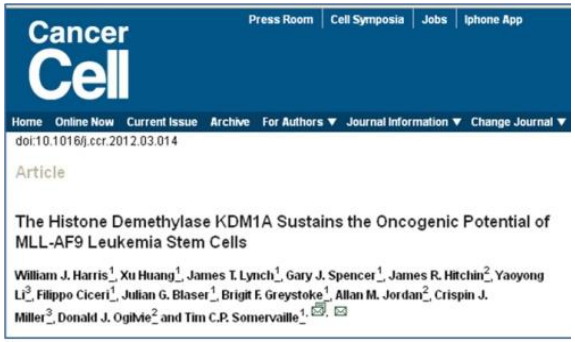
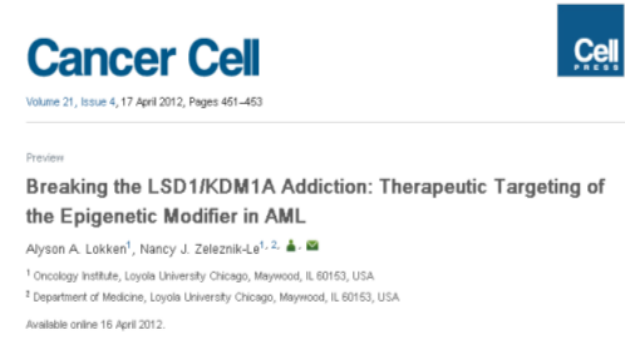
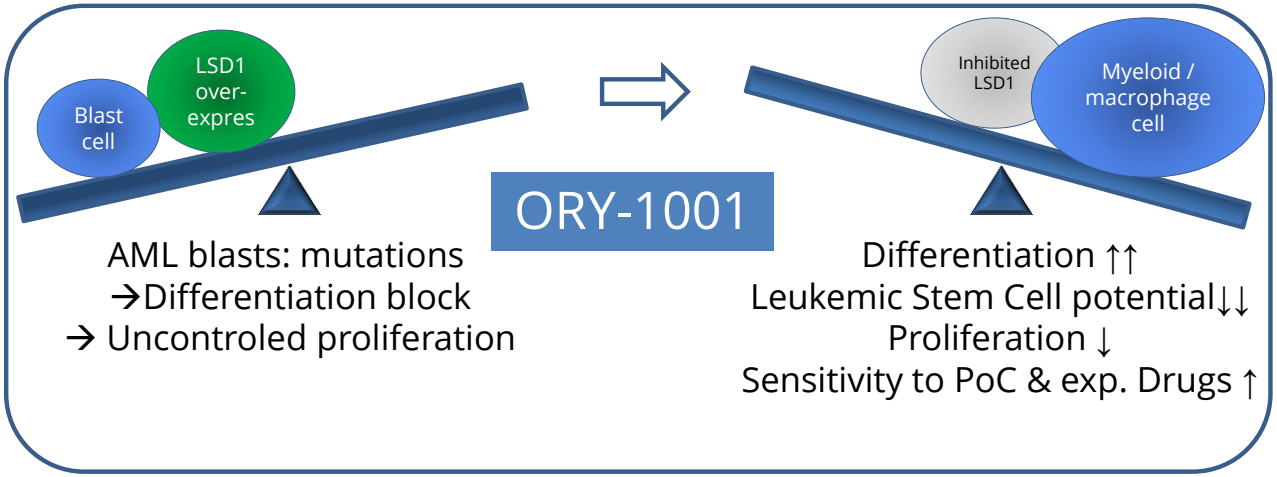
Iadademstat MoA: a potent differentiating agent to treat Acute Leukemias

LSD1 is a target for HEMATOLOGICAL CANCERS, and in particular, for a subset of acute myeloid leukemia: *mixed lineage leukemia* MLL-AML

- ✓ Oryzon's LSD1 inhibitors block progression of leukemia into the circulation in mice with experimentally initiated MLL-AF9 AML
- ✓ Oryzon's LSD1 inhibitors target Leukemia Stem Cells but spare normal HSPCs







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Phase I/IIa previous data

- ✓ Safe and very well tolerated and therefore a meaningful candidate for combination with other agents
- ✓ PD Biomarkers identified in different subsets of leukemia
- ✓ Antileukemic activity observed in 29% of patients (12/41), including one CRi as Proof of Biological concept

ALICE: An **A**ML trial with **L**SD1**i** in **C**ombination with azacitidine in the **E**lderly

A Phase IIa study to evaluate the safety, tolerability, dose finding and efficacy of iadademstat (ORY-1001) in combination with azacitidine in older patients with AML in first line therapy

- ✓ Single arm & Open label. Up to 36 patients to be enrolled
- ✓ **Primary end point**: Safety and tolerability of the combo with hypomethylating agent Azacitidine
- ✓ **Secondary endpoints:** Responses; time to responses; duration of response; and overall survival

Preliminary Results

- ✓ 3 patients have already gone through the first cycle; good tolerability
- ✓ Satisfactory and dynamic recruitment pace

Clinical Preliminary Reports to be presented at several Medical Conferences to be announced in 2019-2020

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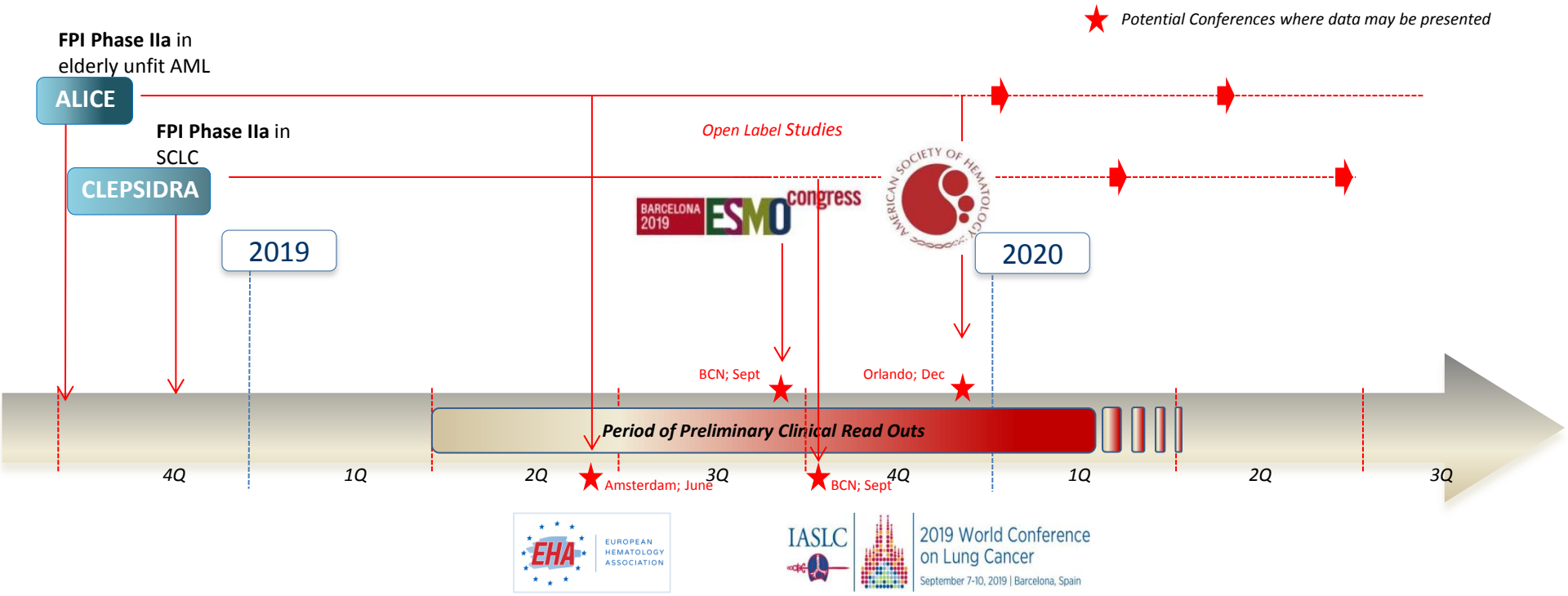
Recent & Anticipated Oryzon main catalysts

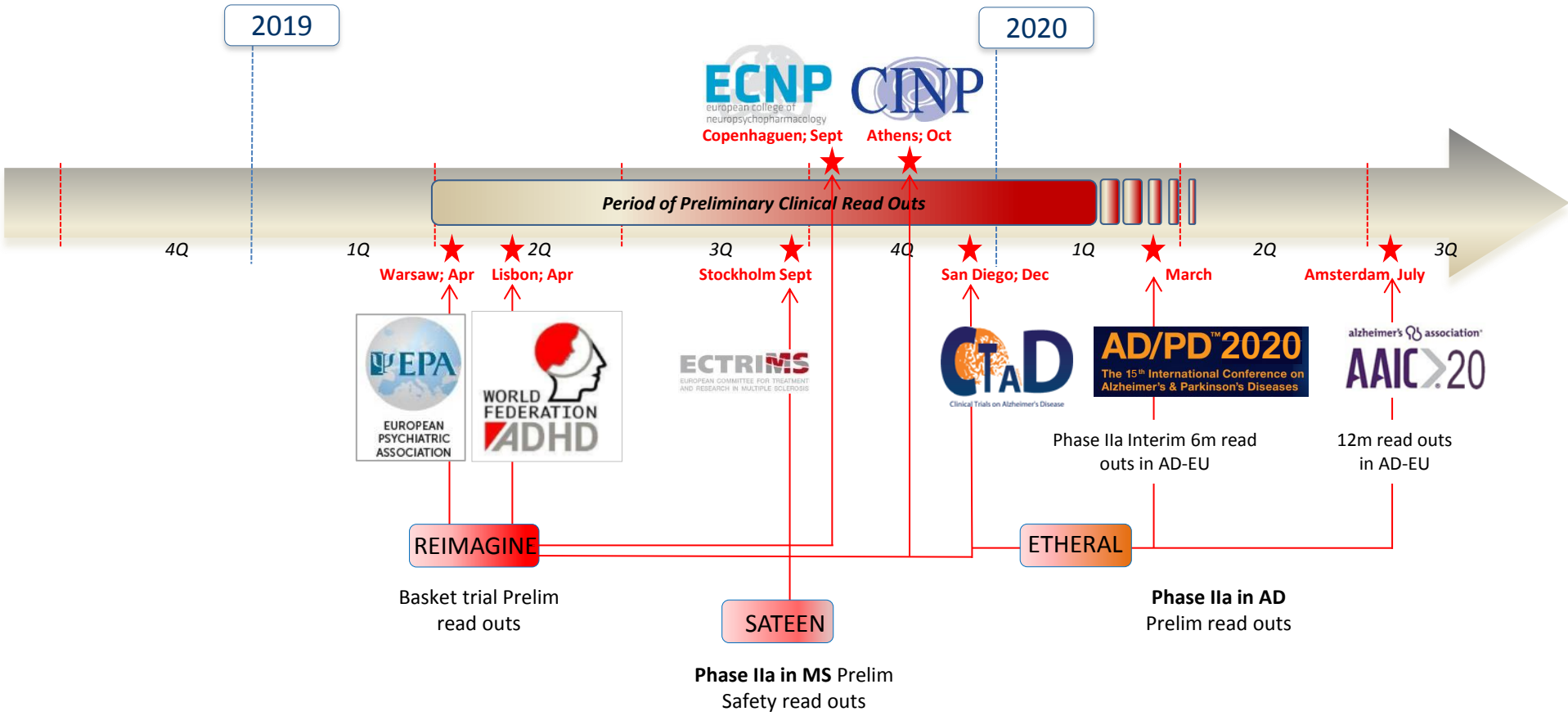
IADADEMSTAT (ORY-1001): lead CANCER asset



Recent & Anticipated Oryzon main catalysts

VAFIDEMSTAT (ORY-2001): lead CNS asset

★ *Potential Conferences where data may be presented*



ORYZON
A GLOBAL LEADER
IN CNS EPIGENETICS

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