A GLOBAL LEADER IN EPIGENETICS

INVESTOR PRESENTATION

MADX: ORY

March 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€*

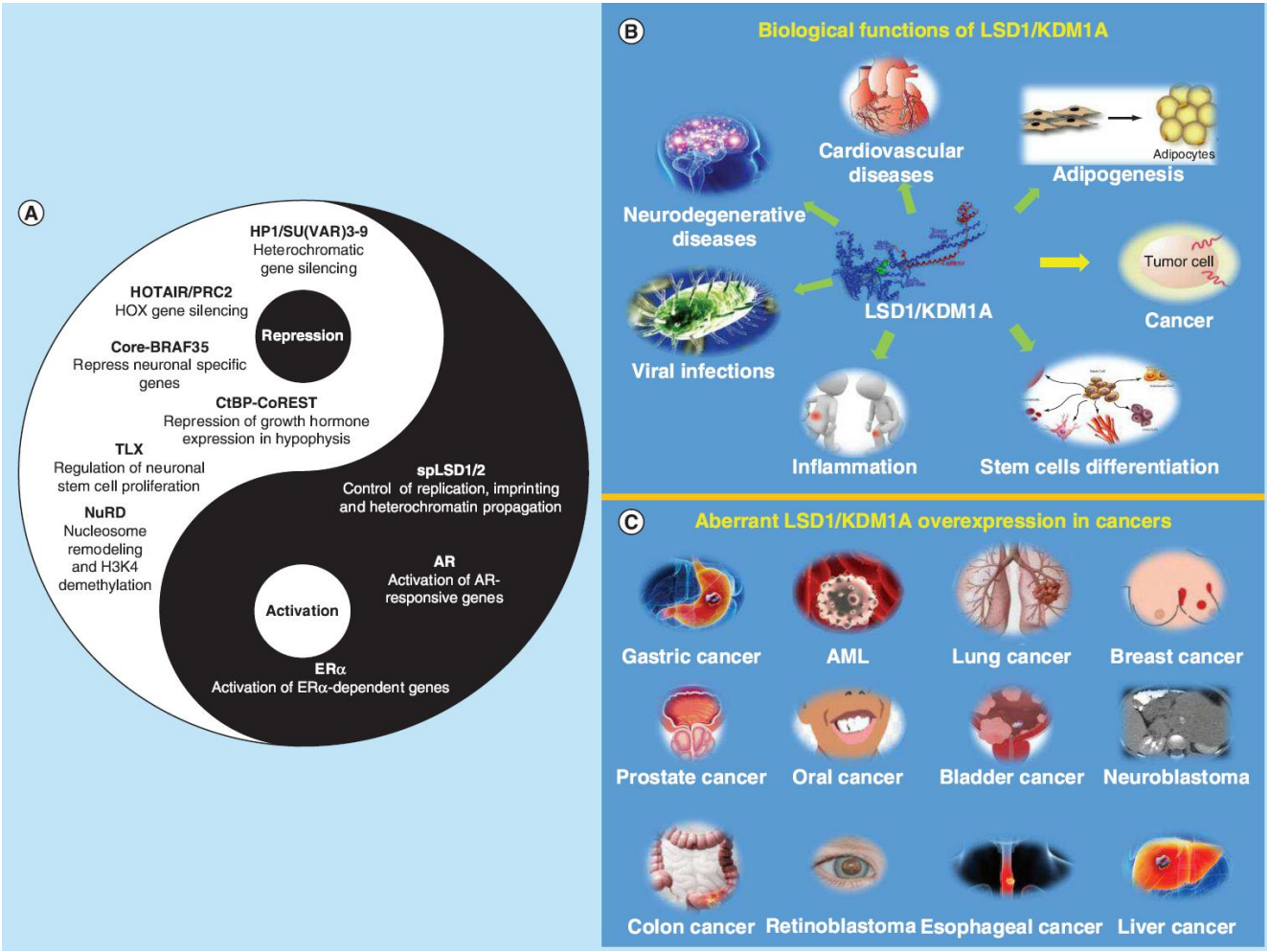
ORYZON

LSD1 in human diseases

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
- 3 Different LSD1 inhibitors in development
- Additional programs on other targets

Vafidemstat (ORY-2001)

A Phase II stage clinical compound

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
- Characterized in 6 and 9 months PC regulatory toxicological studies
- Positive results in 7 different animal models and in i*n-vitro* models
- Superior performance than other LSD1 inhibitors. 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
- Crosses the BBB and human target engagement

In Phase IIa in three different clinical studies

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Vafidemstat (ORY-2001) restores cognition measured by NORT in SAMP8 AD model

MILD

MODERATE

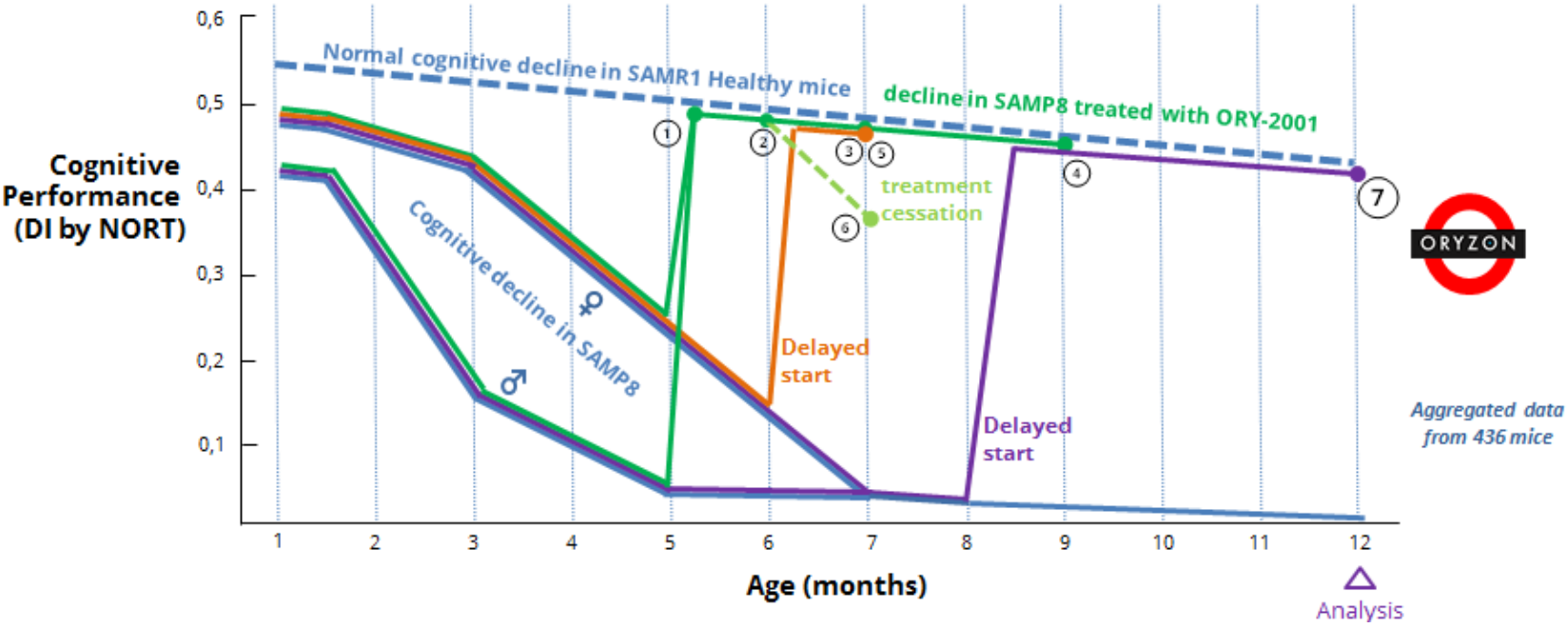
SEVERE

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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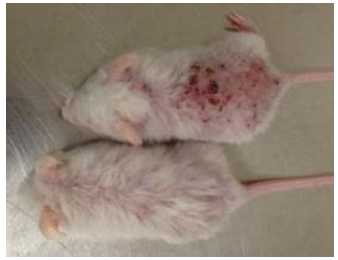
Vafidemstat (ORY-2001) reduces aggression in mice Alzheimer's Disease model



In the cognition tests we noticed that SAMP8 male mice treated with vehicle aggressed cage mates while ORY-2001-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 ORY-2001 are not **aggressive and have normal levels of basal activity (no sedation)**

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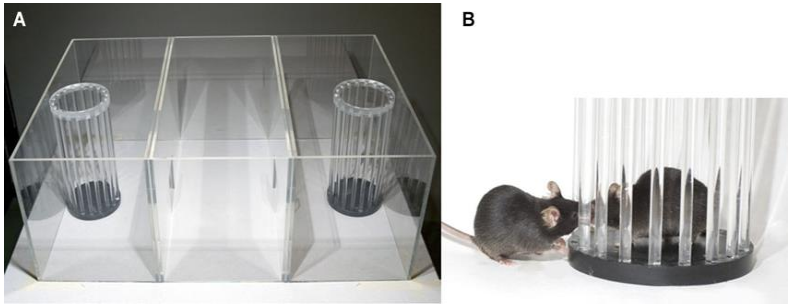
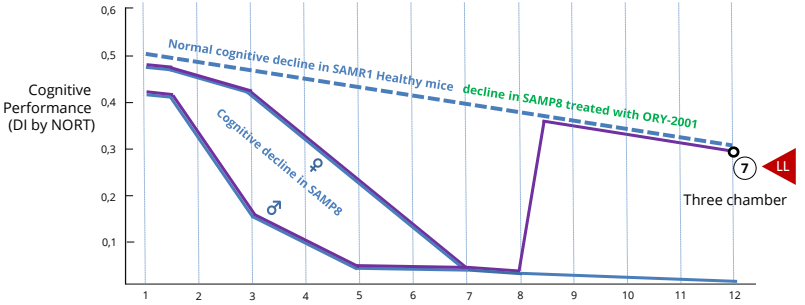
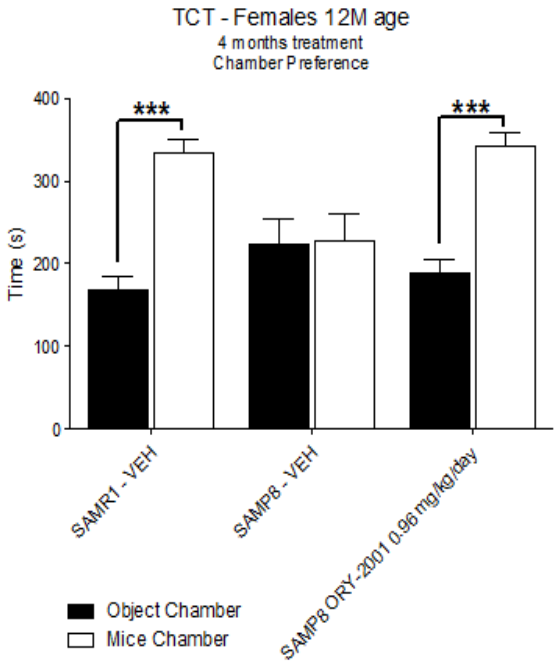
Vafidemstat (ORY-2001) also corrects the lack of sociability of aged SAMP8 mice

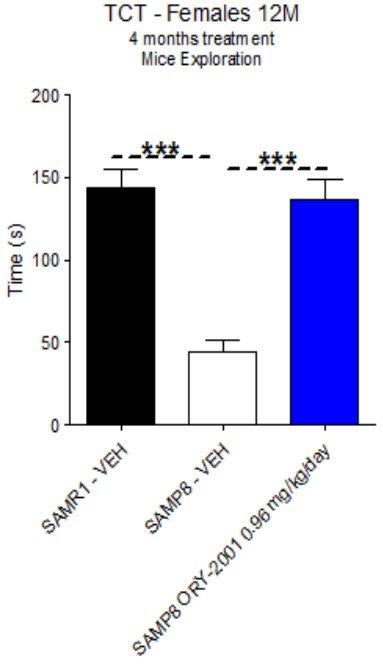
In the delayed start experiment, where treatment was initiated in **8 month** old SAMP8 mice and behavior was evaluated at **12 months** of age, treatment with ORY-2001 restored not only memory but also social interaction /sociability measured on the **Three chamber test Paradigm (TCT)**

TCT is widely used to evaluate drugs as a model for **Autism Spectrum Disorder**





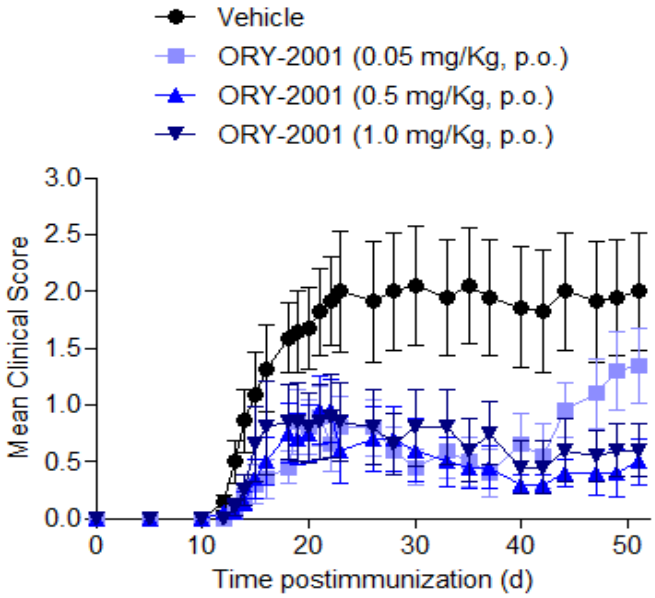




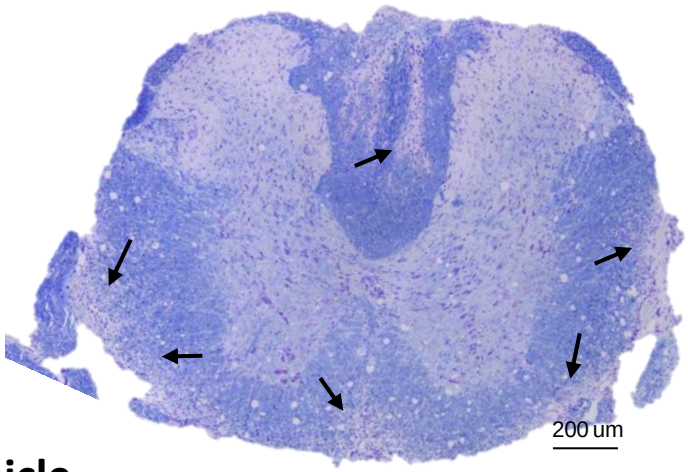
Vafidemstat (ORY-2001) enhances sociability

Vafidemstat (ORY-2001) is effective in the EAE and Thyler's models and reduces neuroinflammation

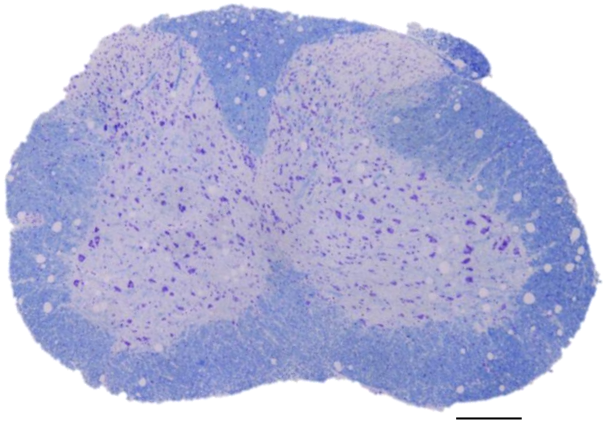
- In specific models of inflammation, ORY-2001 protects the brain and CNS from acute inflammatory stress, as shown in the EAE model where immune infiltration in the spinal cord is significantly reduced, demyelination is avoided and the clinical score is greatly reduced
- ORY-2001 also provides protection in other murine models with induced demyelinating disease
- ORY-2001 reduces microglial activation in Theiler's MS model
- ORY-2001 is neuroprotective, restoring axonal integrity in TMEV model and also in a glutamate excitotoxicity in vitro model



therapeutic treatment (p.o.)



Vehicle



ORY-2001

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Vafidemstat (ORY-2001)

CLINICAL DEVELOPMENT

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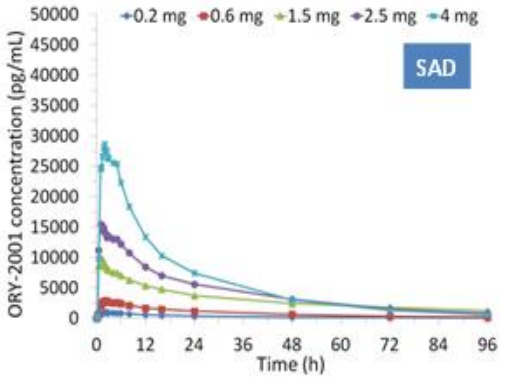
Vafidemstat (ORY-2001) Phase I: Safety and hematology

- **Safe and well tolerated in a +100 healthy volunteers Phase I study**
- **No hematological impact at the planned doses**
- **Efficiently crossed the BBB:**
  - ORY-2001 concentrations measured in CSF at 2, 6 and 12 h after a single oral 2 mg or 4 mg dose
  - CSF levels comparable to corresponding unbound plasma concentrations (CSF/plasma$_u$ ratio ≈ 0.7-0.9)



- **ORY-2001 efficiently inhibits the brain human LSD1**
- **PK Oral PK T1/2 ≈ 22h allowing once daily oral**
- **PK/PD data allow to select Phase II doses**
- **ORY-2001 has been already administered to many patients in the ongoing Phase IIs with no safety issues so far**

Vafidemstat (ORY-2001) is in Phase II in humans in AD and MS where we expect to have the first read outs in 2H2019

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ETHERAL: Epigenetic THERapy in ALzheimer's Disease

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

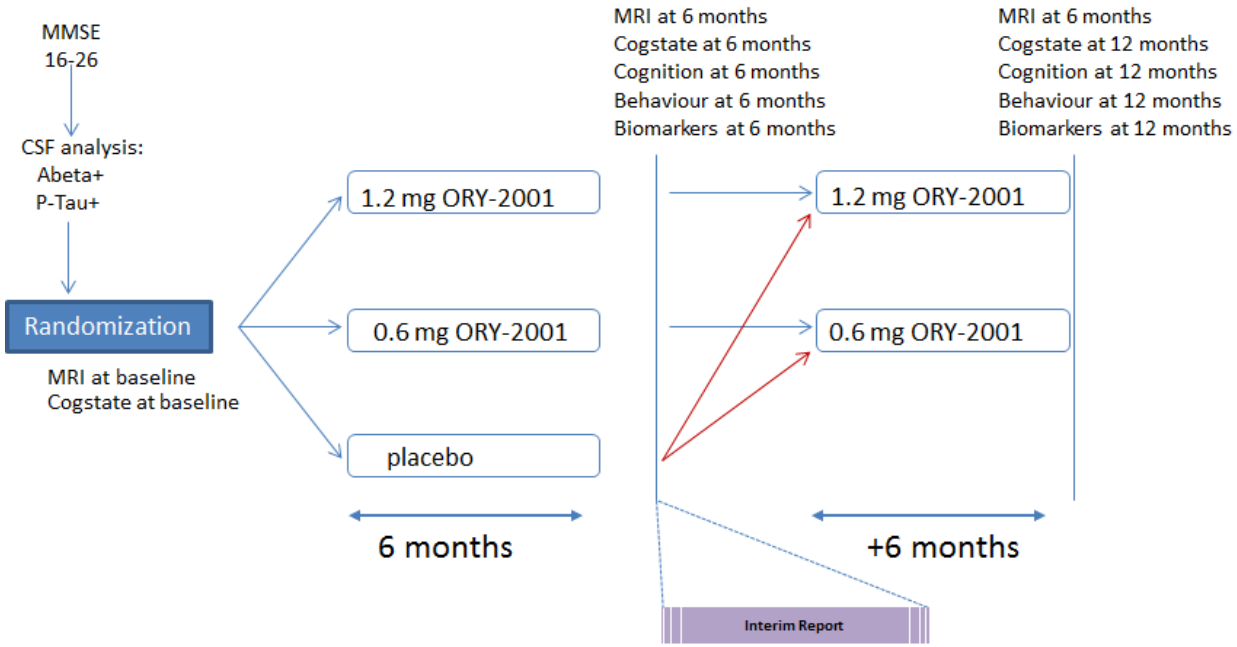
CLINICAL STUDY PROTOCOL

A multicentre, multinational, randomised, double-blind, placebo-controlled, 3-arm, 24-week parallel-group study to evaluate the safety, tolerability and preliminary efficacy of ORY-2001 in patients with mild-moderate Alzheimer's Disease. ETHERAL Study

- **Mild to Moderate AD** patients
- Nº of patients: **150**
- 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

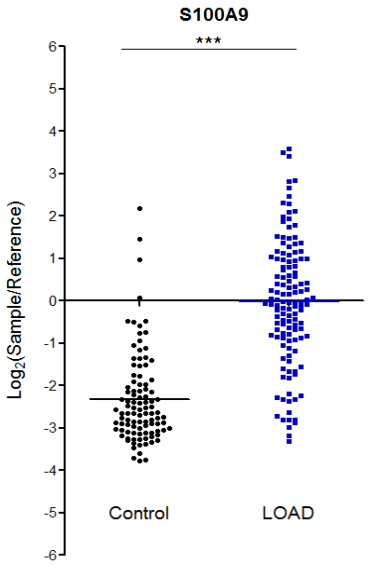


Vafidemstat (ORY-2001) ETHERAL Phase IIa: Biomarker strategy

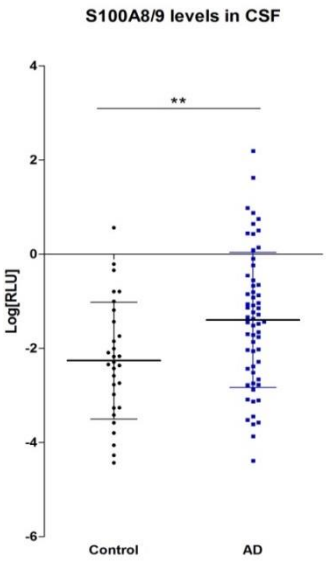
S100A9 has been characterized as one of the TOP10 up-regulated genes in LOAD dataset

- ✓ S100A9 PROTEIN levels are significantly increased in CSF from AD patients compared to age-matched controls
- ✓ S100A9 CSF PROTEIN levels will be 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
  - ✓ ORY-2001 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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Vafidemstat (ORY-2001): REIMAGINE: A Basket trial in aggression

ORY-2001 REIMAGINE Study

Vall d'Hebron Institut de Recerca VHIR

- A single center open label exploratory basket trial to assess the effect of ORY-2001 in reducing aggression in patients with two neurodegenerative and three neuropsychiatric indications
- N=30, with 6 participants per condition
- Single arm of ORY-2001 (1.2 mg)
- 8 weeks treatment duration
  - AD
  - DLB
  - BPD
  - ADHD
  - ASD
- Approved September 2018
- FPI 4Q 2018
- Expected LPO 1Q 2019

Top Line Data 2-4Q2019

Conferences where preliminary data are expected to be presented

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Vafidemstat (ORY-2001): REIMAGINE: A Basket trial in aggression

REIMAGINE the first proof of concept for Vafidemstat in human patients.

Borderline Personality Disorder (BPD) patients treated with Vafidemstat showed a reduced aggressivity and a better overall performance in the global BPDCL

Complete data on this cohort will be presented at the Warsaw EPA 2019 Conference

- ✓ Vafidemstat was safe and well tolerated by the BPD patients
- ✓ Patients had an overall decrease in the Columbia-Suicide Severity Rating Scale
- ✓ Vafidemstat produced significant improvements in the Clinical Global Impression (CGI)
- ✓ Vafidemstat also produced significant improvements in the Neuropsychiatric Inventory, not only at the 4-item agitation/aggression NPI subscale score, but also at the global NPI score (12 items)
- ✓ Remarkably, Vafidemstat also produced significant improvements on the Borderline Personality Disease Checklist (BPDCL) both on the global scale and in the subset of domains related with agitation/aggression
- ✓ BPD prevalence ranges between 0.5%-1.4% (*) and it represents a significant unmet medical need

* BMC Psychiatry. 2016; 16: 249.

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IN EPIGENETICS

Iadademstat (ORY-1001)

A Phase II stage clinical compound

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Iadademstat (ORY-1001): the most advanced 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.
- MoA identified in Leukemia, SCLC and medulloblatoma
- 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 LSD1 drug to enter into clinical trials and still Best in Class
- Produced positive results in an Acute Leukemia Phase I/IIa trial (manuscript submitted)
- 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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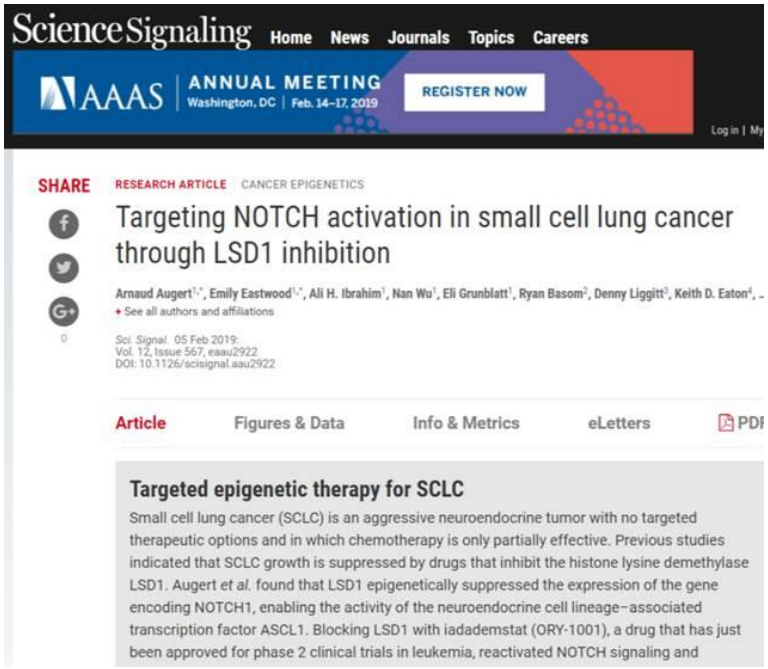
https://doi.org/10.1016/j.ccell.2018.02.002



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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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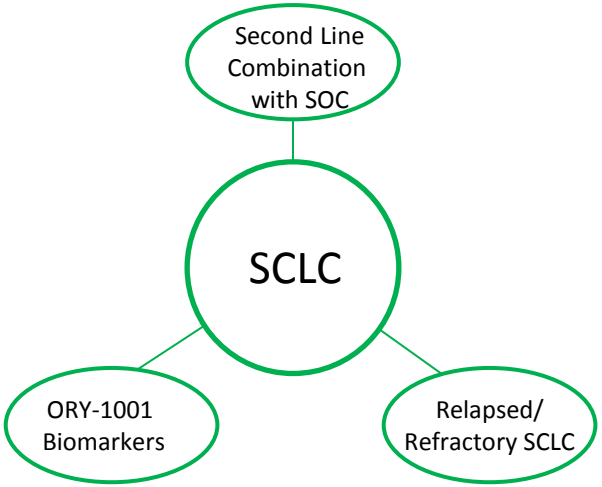
Iadademstat a flexible CDP for a Large Market Opportunity

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

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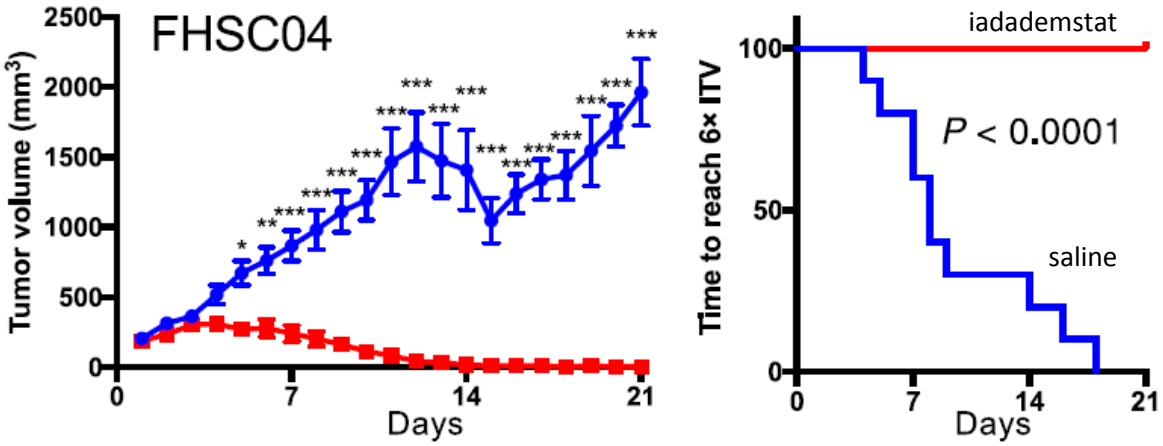
Iadademstat opportunity in SCLC

- 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 is the best and first in class LSD1 inhibitor in clinic development
- 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 (ORY-1001): 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: 3 more patients enrolled as per 2nd week of February

➡ 2019 ASCO ANNUAL MEETING

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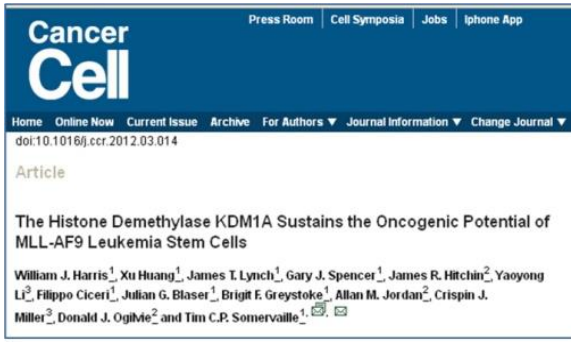
Iadademstat (ORY-1001) MoA: a potent differentiating agent to treat Acute Leukemias

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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doi:10.1016/j.ccr.2012.03.014

Article

The Histone Demethylase KDM1A Sustains the Oncogenic Potential of MLL-AF9 Leukemia Stem Cells

William J. Harris[1], Xu Huang[1], James T. Lynch[1], Gary J. Spencer[1], James R. Hitchin[2], Yaoyong Li[3], Filippo Ciceri[1], Julian G. Blaser[1], Brigit F. Greystoke[1], Allan M. Jordan[2], Crispin J. Miller[3], Donald J. Ogilvie[2] and Tim C.P. Somervaille[1],


nature medicine

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NATURE MEDICINE | LETTER

Inhibition of the LSD1 (KDM1A) demethylase reactivates the all-*trans*-retinoic acid differentiation pathway in acute myeloid leukemia

Tino Schenk, Weihsu Claire Chen, Stefanie Göllner, Louise Howell, Liqing Jin, Katja Hebestreit, Hans-Ulrich Klein, Andreea C Popescu, Alan Burnett, Ken Mills, Robert A Casero Jr, Laurence Marton, Patrick Woster, Mark D Minden, Martin Dugas, Jean C Y Wang, John E Dick, Carsten Müller-Tidow, Kevin Petrie & Arthur Zelent

Affiliations | Contributions | Corresponding author

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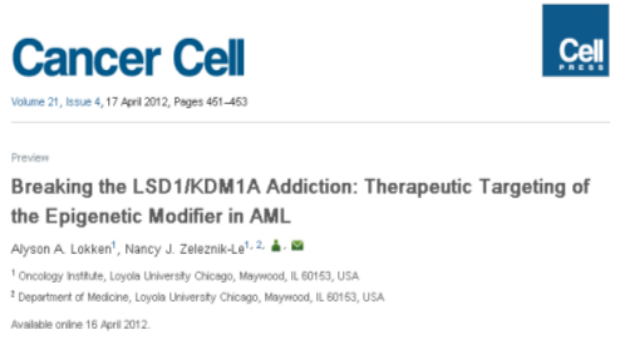
Cancer Cell

Cell

Volume 21, Issue 4, 17 April 2012, Pages 451–453

Preview

Breaking the LSD1/KDM1A Addiction: Therapeutic Targeting of the Epigenetic Modifier in AML

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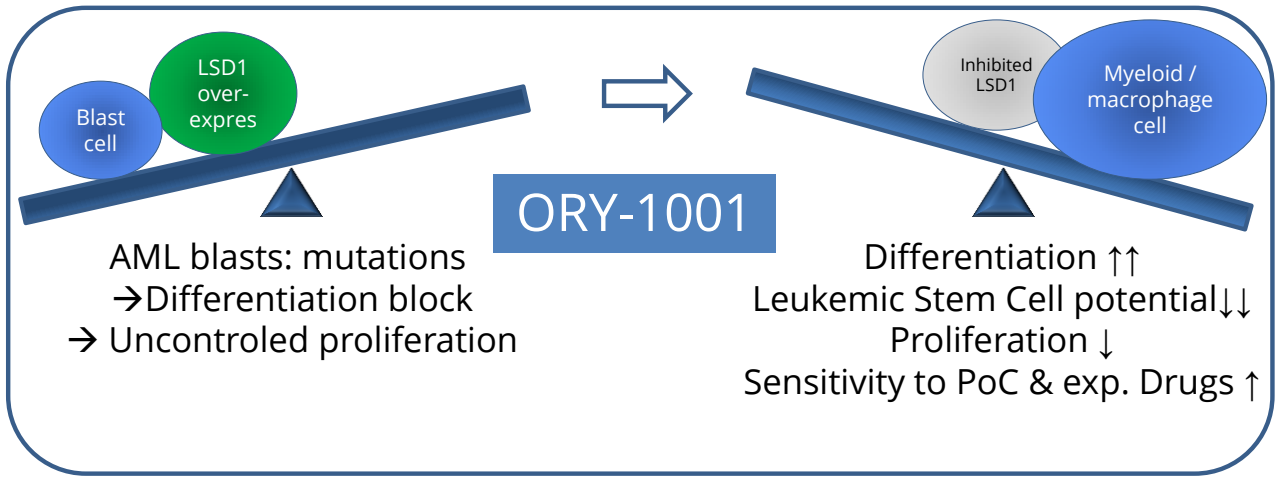

ORYZON

Phase I/IIa previous data (manuscript submitted)

- ✓ 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: 2nd cohort started by February

EHA EUROPEAN HEMATOLOGY ASSOCIATION

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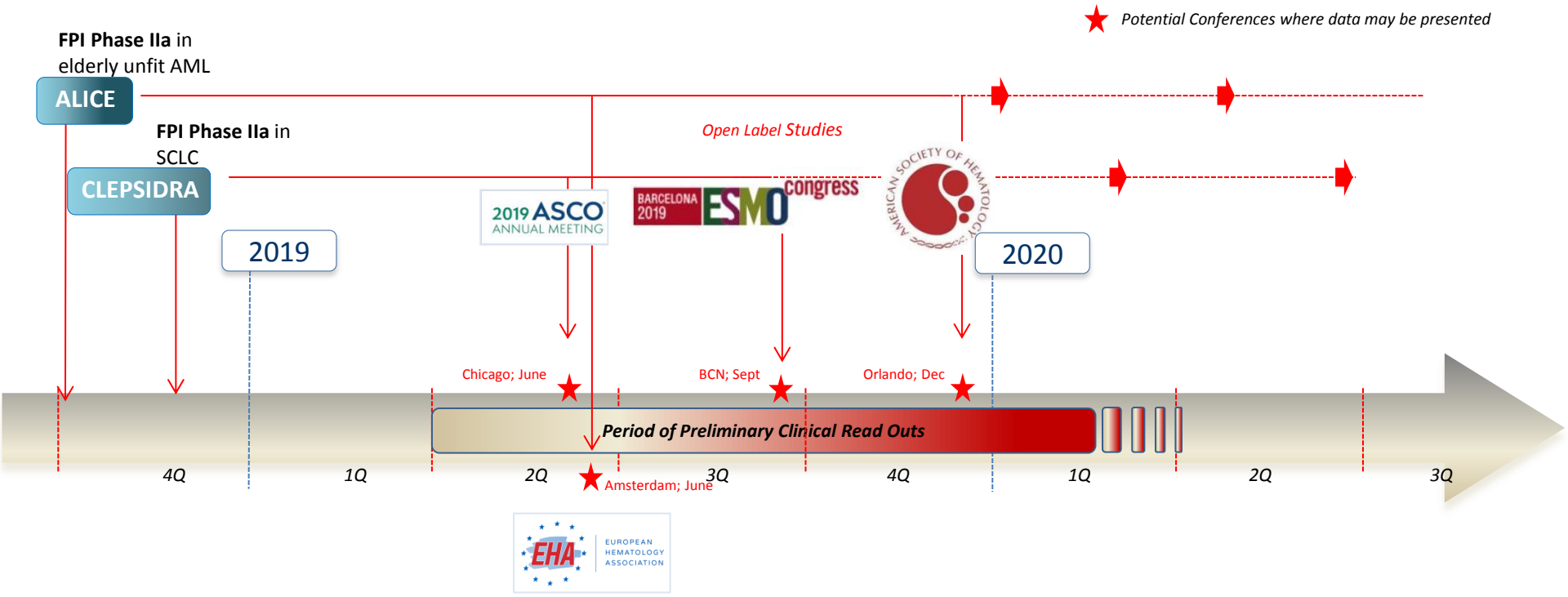
Recent & Anticipated Oryzon main catalysts

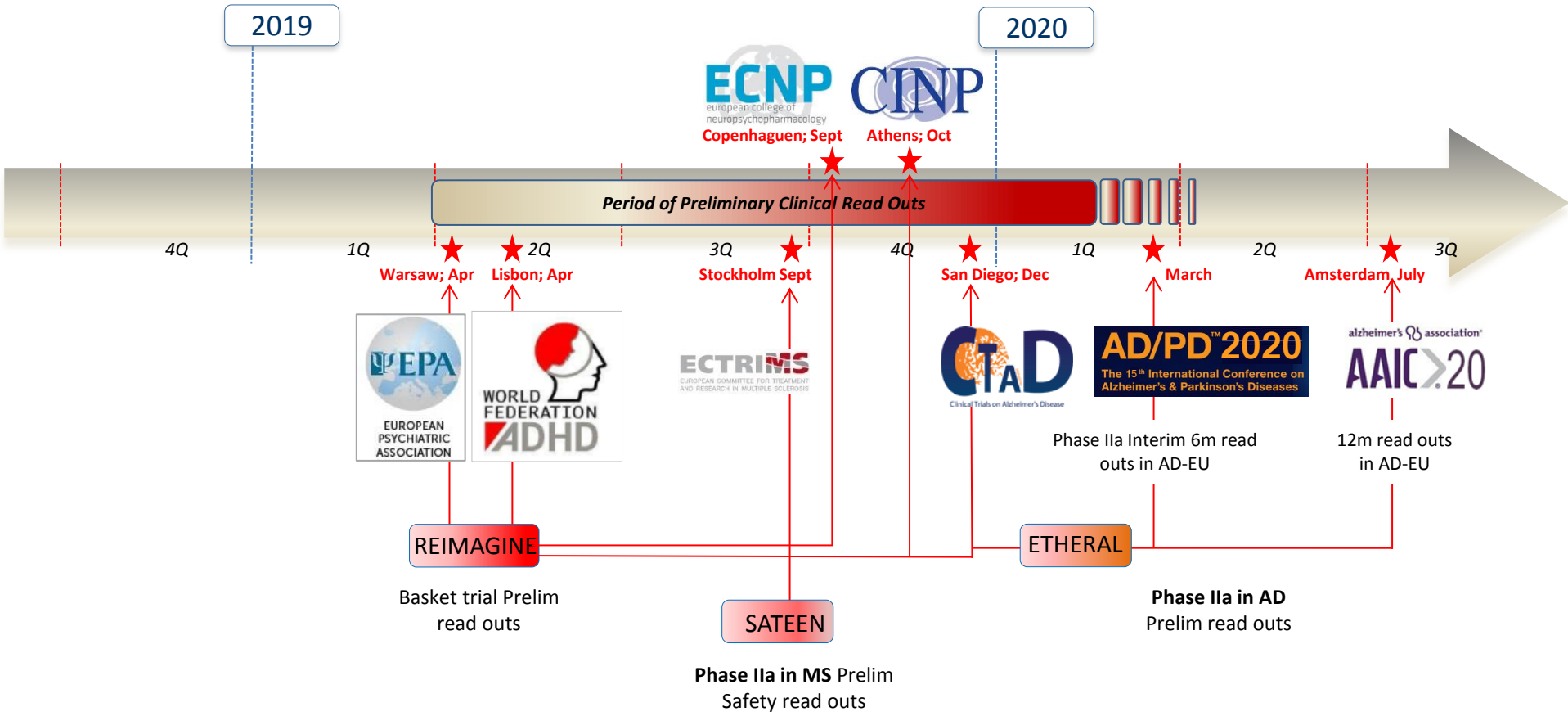
IADADEMSTAT (ORY-1001): lead CANCER asset



Recent & Anticipated Oryzon main catalysts

VAFIDEMSTAT (ORY-2001): lead CNS asset

★ *Conferences where preliminary data are expected to be presented*



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A GLOBAL LEADER
IN CNS EPIGENETICS

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