



ORYZON

A GLOBAL LEADER IN EPIGENETICS

INVESTOR PRESENTATION

MADX: ORY

July 2019

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Company Highlights

- ✓ A **clinical stage** biopharmaceutical company developing innovative therapies in the field of **Epigenetics**
- ✓ Large IP portfolio with technology fully developed in-house
- ✓ MADX: ORY A **publicly traded** company on the **Spanish Stock Exchange**
- ✓ Integrated in the **IBEX Small Cap Index**



BOLSA DE MADRID



- ✓ Raised an aggregate of circa **€65M** (in 2015-2019).
- ✓ **Cash runway** expected till **4Q2020**
- ✓ Loss/Earnings from Operations 1Q2019: **-\$1.0M**
- ✓ 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

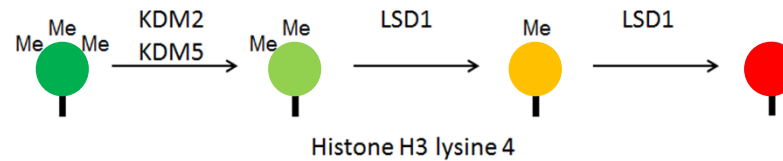
ORYZON GENOMICS SA
BALANCE SHEET DATA (UNAUDITED)¹
(Amounts in thousands US \$)

	March 31st, 2019	March 31st, 2018
Cash and cash equivalents	32.551	37.848
Marketable securities	159	224
Total Assets	73.158	72.720
Deferred revenue	0	0
Total Stockholders' equity	49.240	41.009

¹ Spanish GAAPs

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Oryzon is pioneering epigenetics in CNS and active in oncology



- ✓ 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 important in cancer, CNS, inflammatory and viral diseases
- ✓ LSD1 currently being explored in CNS by Oryzon (3 Phase IIs) and Takeda (Phase I)*. No other players yet
- ✓ In onco/hemonc, other players in LSD1 are Celgene, GSK, Incyte, Salarius, Imago

INDICATION	STUDY	RESEARCH	PRECLINICAL	PHASE I	PHASE IIA	PHASE IIB
VAFIDEMSTAT (ORY-2001) - dual LSD1-MAO B Inhibitor						
Alzheimer's disease (Mild Moderate)	ETHERAL monotherapy					
Multiple Sclerosis (Relapse Remitting & Secondary Progressive)	SATEEN monotherapy					
CNS Basket Trial Aggression	REIMAGINE monotherapy					
IADADEMSTAT (ORY-1001) - selective LSD1 inhibitor						
AML (Elderly Unfit)	ALICE Combo w Aza					
SCLC (First Line Relapsed)	CLEPSIDRA Combo w Platinum/Etoposide					
ORY-3001 - selective LSD1 inhibitor						
Non Oncological	Preclinical finished					
OTHER PROGRAMS						
Undisclosed						

*Takeda is developing its CNS LSD1 inhibitor in Kabuki syndrome and, probably, Autistic Spectrum Disorder (ASD)



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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”

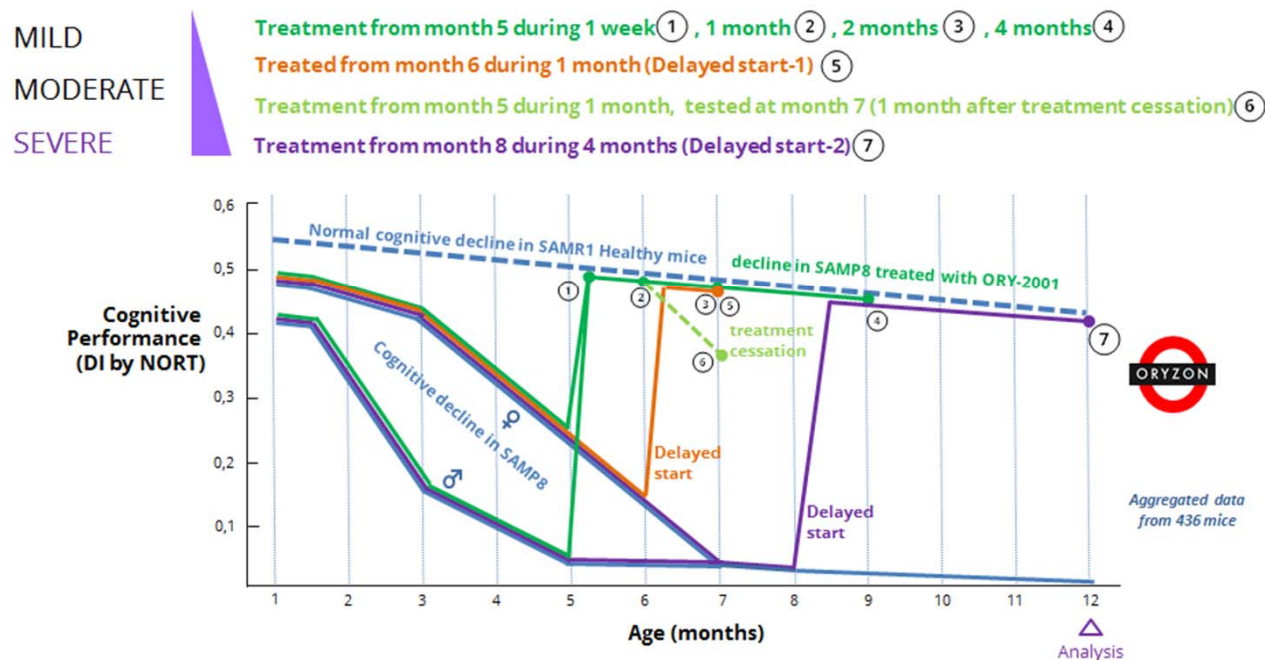
- ✓ LSD1 is the most abundant histone demethylase in the human frontal cortex
- ✓ Vafidemstat is a **small molecule** that selectively inhibits LSD1 and MAO-B
- ✓ **Excellent Pharmacology.** High **oral** bioavailability
- ✓ **Positive** results in **7 different animal models** and in *in-vitro* models
 - ✓ Cognition
 - ✓ Neuroprotection
 - ✓ Neuroinflammation
 - ✓ Social Withdrawal / Apathy
 - ✓ Aggression / Agitation
 - ✓ Others
- ✓ Epigenetic **MoA** that modulates **neuroinflammation** and expression of key **plasticity neuronal genes**
- ✓ Biomarkers identified
- ✓ **Good Safety in humans in Phase I+II trials with +220 participants** so far
- ✓ **BBB penetrance** and (indirect) human brain target engagement established
- ✓ Pharmacologically active in humans

In Phase IIa in three different clinical studies

Vafidemstat, and LSD1 inhibition, improves cognition

- ✓ vafidemstat (ORY-2001) restores memory in the SAMP8 AD model by the NORT model
- ✓ vafidemstat (ORY-2001) improves memory in the R6/1 HD model by the NORT model
- ✓ iadademstat (ORY-1001) improves working memory in the SETD1a +/- schizophrenia model
- ✓ T-448 (TAKEDA) improves memory in the NMDA receptor-hypofunction mice

Vafidemstat fully restores memory measured by NORT in SAMP8 AD model



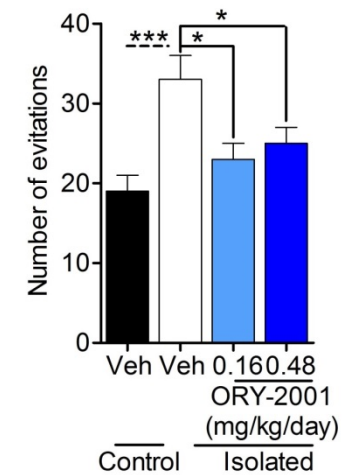
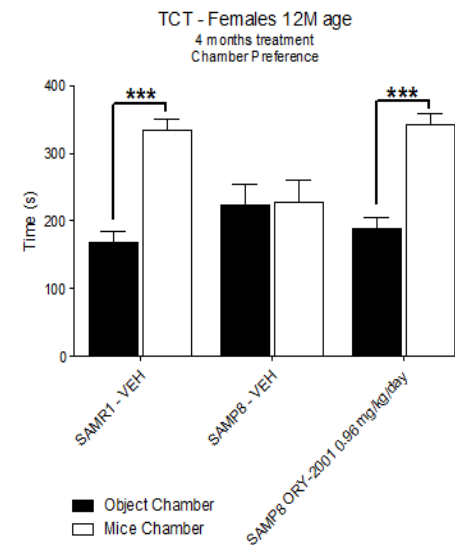
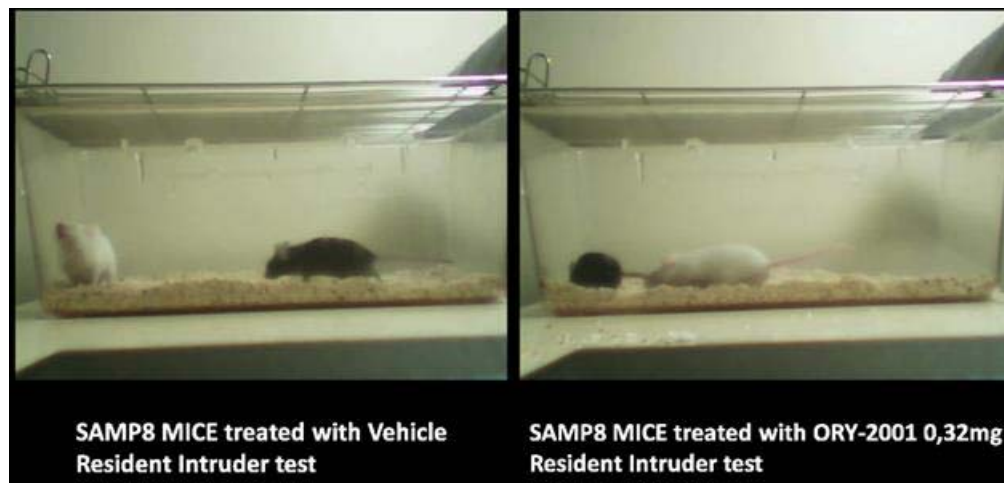
Vafidemstat preclinical results suggestive of Disease modifying potential

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Vafidemstat produces significant behavioral changes

- ✓ vafidemstat **reduces aggression** in the Resident Intruder test in the SAMP8 AD mice model
- ✓ vafidemstat **enhances sociability** in the Three-Chamber test in SAMP8 AD mice
- ✓ vafidemstat **reduces social withdrawal** in the rat isolation model

VIDEO

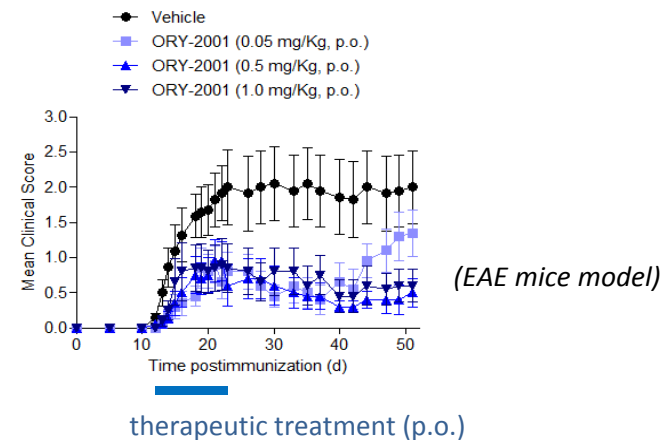
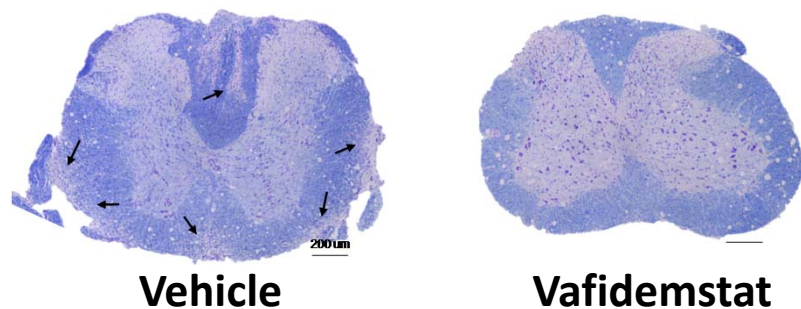


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Vafidemstat reduces neuroinflammation and confers neuroprotection

- ✓ vafidemstat **improves clinical score in MS models that have a component of chronic and progressive disease**
- ✓ vafidemstat **reduces chronic demyelination** in chronic EAE and TMEV models
- ✓ vafidemstat **inhibits the local neuro-inflammation** in EAE and TMEV models but also blocks the inflammatory infiltration
- ✓ **vafidemstat is neuroprotective**, restoring axonal integrity in TMEV model and also in a glutamate excitotoxicity in vitro model

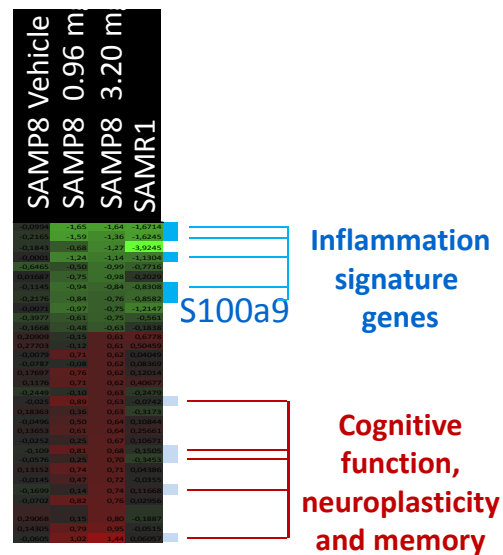
A broad preclinical evidence in different models supports vafidemstat activity in the MS paradigm



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MoA: an upstream epigenetic mechanism producing a dual activity, antiinflammatory and prosynaptic

- ✓ LSD1 **localizes *in vivo* to enhancers and promoters** of confirmed CNS disease risk genes
- ✓ LSD1 **binds to TFs** that control IEG expression and stress in the PFC-amygdala axis, including SRF
- ✓ vafidemstat potentiates the response capacity of IEGs to stress
- ✓ vafidemstat **reduces** the expression of **inflammatory** genes including S100A9 and others
- ✓ vafidemstat **up-regulates** genes associated with:
 - ✓ **Cognition**, notably memory and **executive functioning**
 - ✓ **Neuroplasticity**



Vafidemstat potentially **down-regulated** the expression of a subset of genes related to immune reaction and **inflammation as S100A9** involved in OPC defective remyelination

Genes **up-regulated** in SAMP8 mice by vafidemstat included

Baiap3: involved in retrograde trafficking

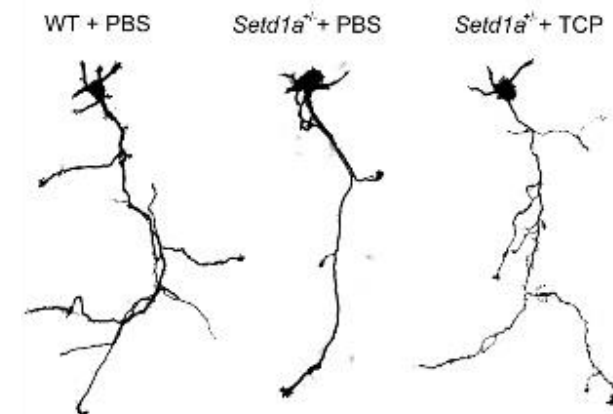
Prph: mutated in Amyotrophic Lateral Sclerosis (ALS),

Fabp7: upregulation in drosophila favors long term memory consolidation

Doc2a: activity-dependent modulator of excitatory synaptic transmission, relevant to memory formation

Kremen2 and Rspo1, regulators of the WNT pathway

LSD1 inhibition rescues the axon branching deficits in the *Setd1a*^{+/-} mice



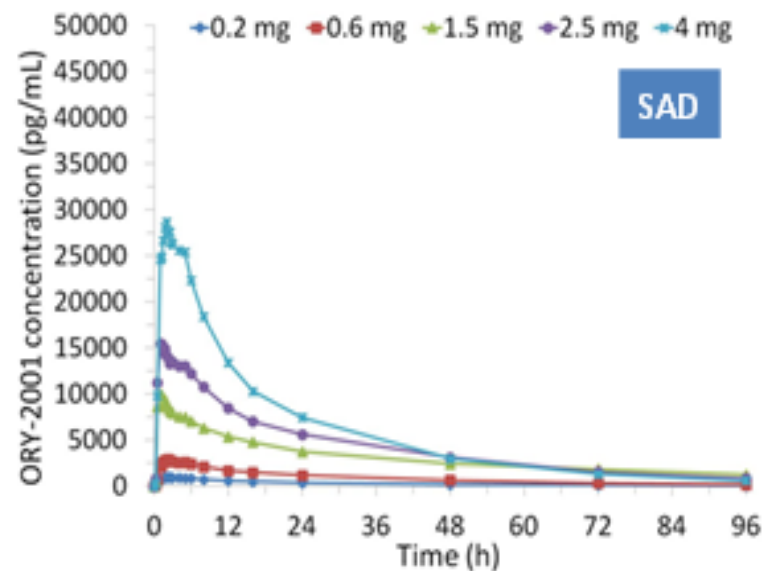
In vitro axon branching rescue assays ORY-1001 was 1000-fold more potent than TCP

Mukai et al 2019 <http://dx.doi.org/10.1101/529701>
Recapitulation and reversal of schizophrenia-related phenotypes in *Setd1a*-deficient mice

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Vafidemstat : Safety demonstrated in a Phase I study

- ✓ **Safe and well tolerated** in a +100 healthy volunteers Phase I (MAD+SAD) study
- ✓ No hematological impact at the planned doses
- ✓ Efficiently **crossed the BBB (70-90%)**
- ✓ Vafidemstat efficiently inhibits the brain human LSD1 in vitro
- ✓ Oral PK. **Half Life of 22h** allowing once daily oral
- ✓ PK/PD data allowed to select Phase II doses
- ✓ Vafidemstat has been already administered to **+220 volunteers and patients**
- ✓ **Phase IIs with no safety signals till now. Longest exposure to date: 15 months**



Vafidemstat: REIMAGINE - a Basket trial in aggression

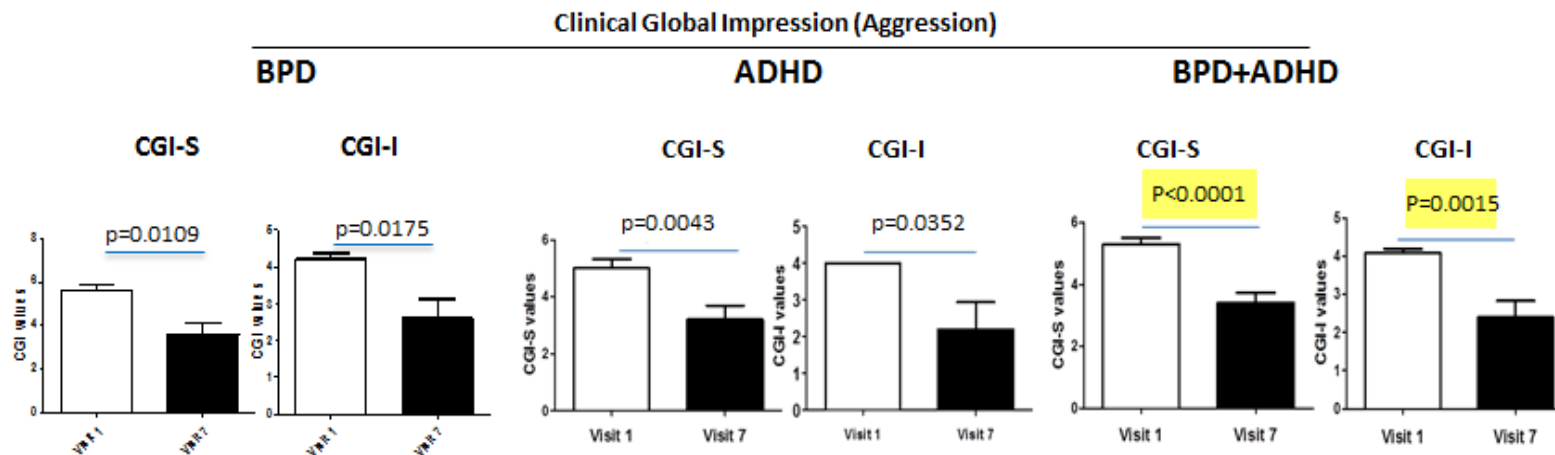
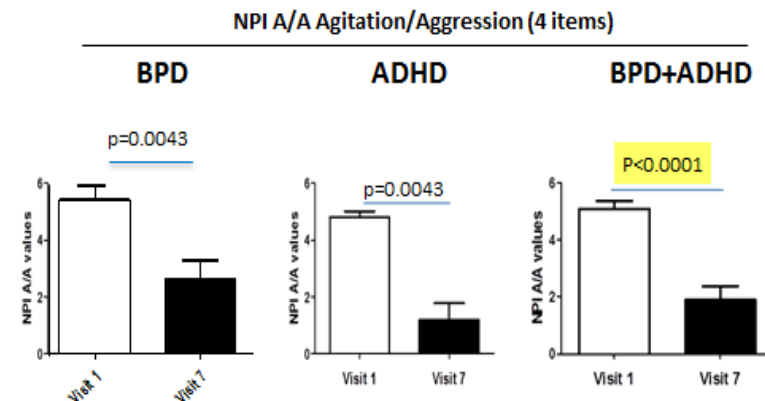
REIMAGINE: A Phase II Basket trial in Aggression with vafidemstat

Study type	Interventional	single-center
Allocation	Single-arm	
Masking	Open Label	
Treatment	vafidemstat 1.2 mg/day	
Duration	8 weeks + 4 weeks of follow up	
Cohorts to be recruited		
Alzheimer's disease	12 patients	Starting
Borderline Personality Disorder	6 patients	Done
Attention Deficit and Hyperactivity disorder	6 patients	Done
Autism Spectrum Disorder	6 patients	Under analysis
Primary End Point	Safety	
Secondary End Points	Aggression / Agitation measured by CGI-S Aggression / Agitation measured by CGI-I Aggression / Agitation measured by NPI A/A 4 items Psychiatric status measured by NPI Global assessment (12 items) Change of BPD symptomatology measured by BPD Check List (BPDCL) Change of ADHD symptomatology measured by ADHD-RS Change of ASD symptomatology measured by ASD rating scale	<i>when appropriate to the cohort</i> <i>when appropriate to the cohort</i> <i>when appropriate to the cohort</i>

Borderline Personality Disorder (BPD) and Attention Deficit and Hyperactivity Disorder (ADHD) patients treated with vafidemstat showed a reduced aggressivity

Secondary endpoints: Efficacy

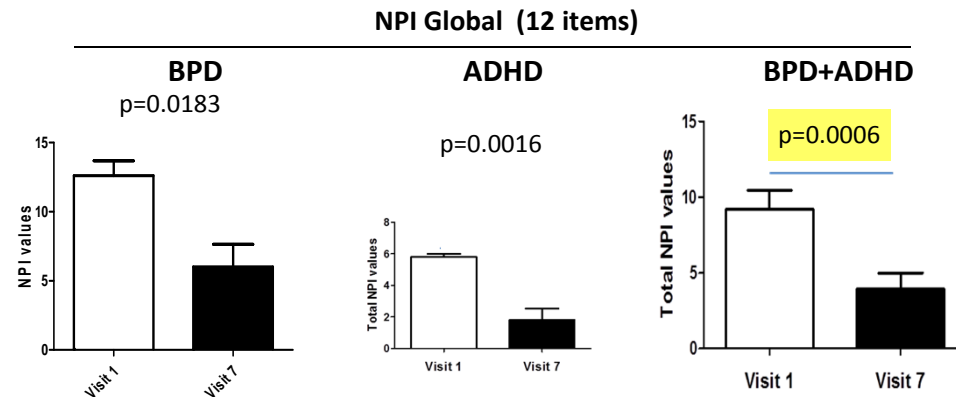
- ✓ Significant improvements on the Neuropsychiatric Inventory (NPI) 4-item agitation/aggression score
- ✓ Significant improvements in aggression evaluated using the Clinical Global Impression (CGI) CGI-S and CGI-I scales



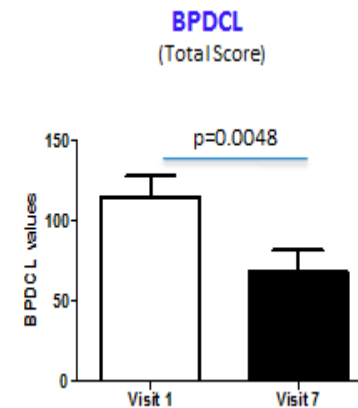
REIMAGINE the first proof of concept for vafidemstat in human patients

The significant improvements in the NPI global score and overall specific scales for BPD and ADHD suggest that vafidemstat has a **broader psychiatric effect beyond aggression**

- ✓ Vafidemstat also produced significant improvements on the global NPI score (12 items) in BPD and ADHD patients



- ✓ Remarkably, vafidemstat not only improved aggression but also produced significant improvements on the GLOBAL Borderline Personality Disease Checklist (BPDCL) scale



Next steps: Vafidemstat, a meaningful therapeutic option for BPD

"I find myself able now to control my negative emotions and my frustration"

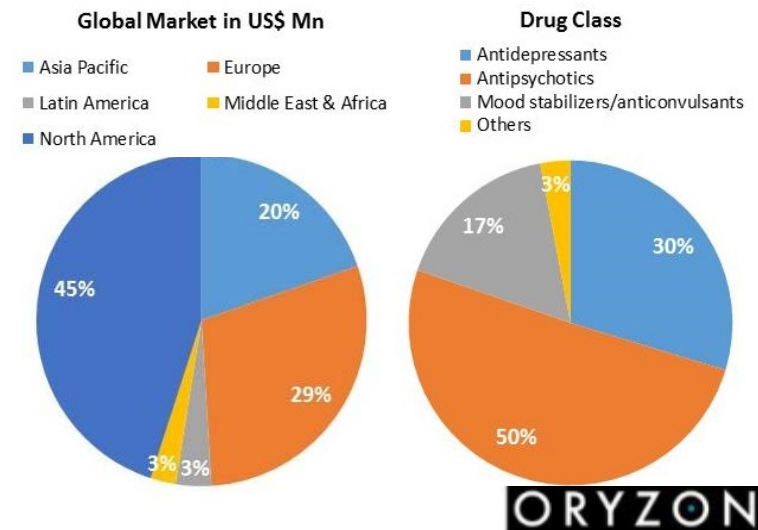
Patient with severe borderline personality disorder during treatment with vafidemstat. Testimony to her psychiatrist Dr. Marc Ferrer



The company recognizes a significant development potential for vafidemstat in psychiatric indications

- ✓ Vafidemstat may be a **disease modifying therapeutic option for BPD**: reduces aggression and produces an overall improvement of the core features of the disease, with **no sedation and no weight gain**.
- ✓ BPD prevalence ranges between 0.5%-1.4% of the total population ($\leq 9.1\text{M}$ in US+EU5)
- ✓ The treatment of BPD is now based on psychotherapeutic interventions. No drugs currently approved for this condition.
- ✓ A **significant unmet medical need**
- ✓ Global BPD Market, 2018-2027 (US\$), **\$2,6B expected in 2027**.

The company is preparing an additional Phase II/III trial in BPD and considering a Phase IIb in adult aggressive ADHD



Vafidemstat : a new therapeutic option for Alzheimer's disease

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 the amyloid drugs have moved the industry to look for other MoAs

Vafidemstat proposition in AD

- ✓ Vafidemstat is **safe and highly brain-penetrant** in humans
- ✓ Brain target engagement in humans established (indirectly)
- ✓ Positive **effects** in different preclinical models on **memory, aggression, sociability and apathy**, all core features in Mild and Moderate AD patients
- ✓ Biomarkers identified that may be surrogate pharmacological biomarkers
- ✓ Vafidemstat is **pharmacologically active in BPD and ADHD patients**.
- ✓ Data on aggressiveness in AD to come in a few months.
- ✓ **Vafidemstat may also provide clinical benefit in AD either as a single or multi-symptomatic drug or as a disease modifier**

ETHERAL: Epigenetic THERapy in Alzheimer's Disease

Besides aggression, vafidemstat may provide also further benefits

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

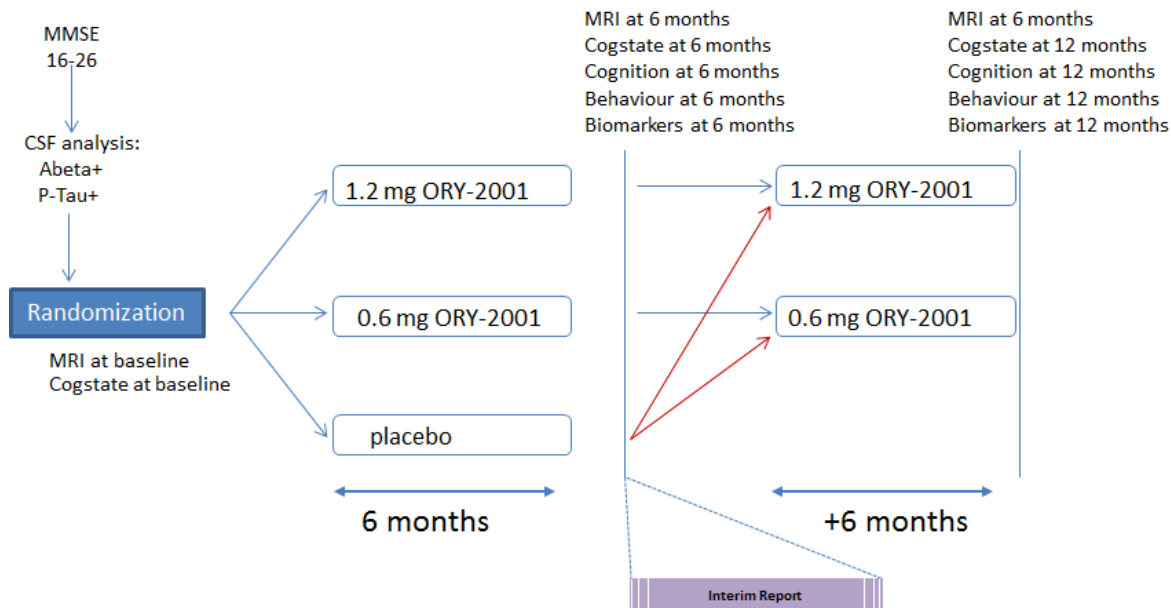
- ✓ **150 Mild to Moderate AD patients** (6+6 months)
- ✓ **Primary Objective:** Safety & Tolerability
- ✓ **Secondary Objectives :**
 - ✓ Cognition/Agitation/Apathy/Depression/QoL
 - ✓ Volumetric MRI
- ✓ **Biomarker guided study** (with 8 CSF Biomarkers)



- ✓ 125 patients in EU. 17 sites
- ✓ Spain, France & UK actively recruiting
- ✓ **+100 randomized** as per e.o. May



- ✓ A Twin study in US: around 25 patients
- ✓ IND approved mid March
- ✓ US Sites (3) opened
- ✓ FPI recruited in May



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IN EPIGENETICS

ladademstat

**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 positive *in vivo* results in different xenograft models. Best in Class. Full characterization published in top-rank journal.
- ✓ First LSD1i drug to enter into clinical trials. Encouraging results in a FiM Acute Leukemia Phase I/IIa trial

Cancer Cell
Article



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 Perdonés,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 Martinelli,¹ Nuria Valls,¹ Guido Kurz,¹ Matthew Fyfe,¹ Julio Cesar Castro-Palomino,¹ and Carlos Buesa¹

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

Phase I/IIa acute leukemia - 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

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POTENTIAL ONCOLOGICAL INDICATIONS:

Solid Tumors

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

HemONC

AML
MDS
Myelofibrosis
Non Hodgkin
Lymphoma

Brain/rare Tumors

Medulloblastoma
Glioblastoma

MoA well characterized in SCLC, AML and Medulloblastoma

ALICE: An **AML** trial with **LSD1i** in **Combination** with azacitidine in the **Elderly**

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 endpoint:** Safety and tolerability of the combo with hypomethylating agent Azacitidine
- ✓ **Secondary endpoints:** Responses; time to responses; duration of response; and overall survival

Preliminary Results

- ✓ Part 1 (Dose finding of the combo) Completed
- ✓ Preliminary Part 1 data with 6 patients reported at EHA-2019
- ✓ Extension Cohort with up to 18 more patients ongoing (next data set expected at ASH-2019)
- ✓ Additional reports to be presented in future Medical Conferences to be announced in 2020

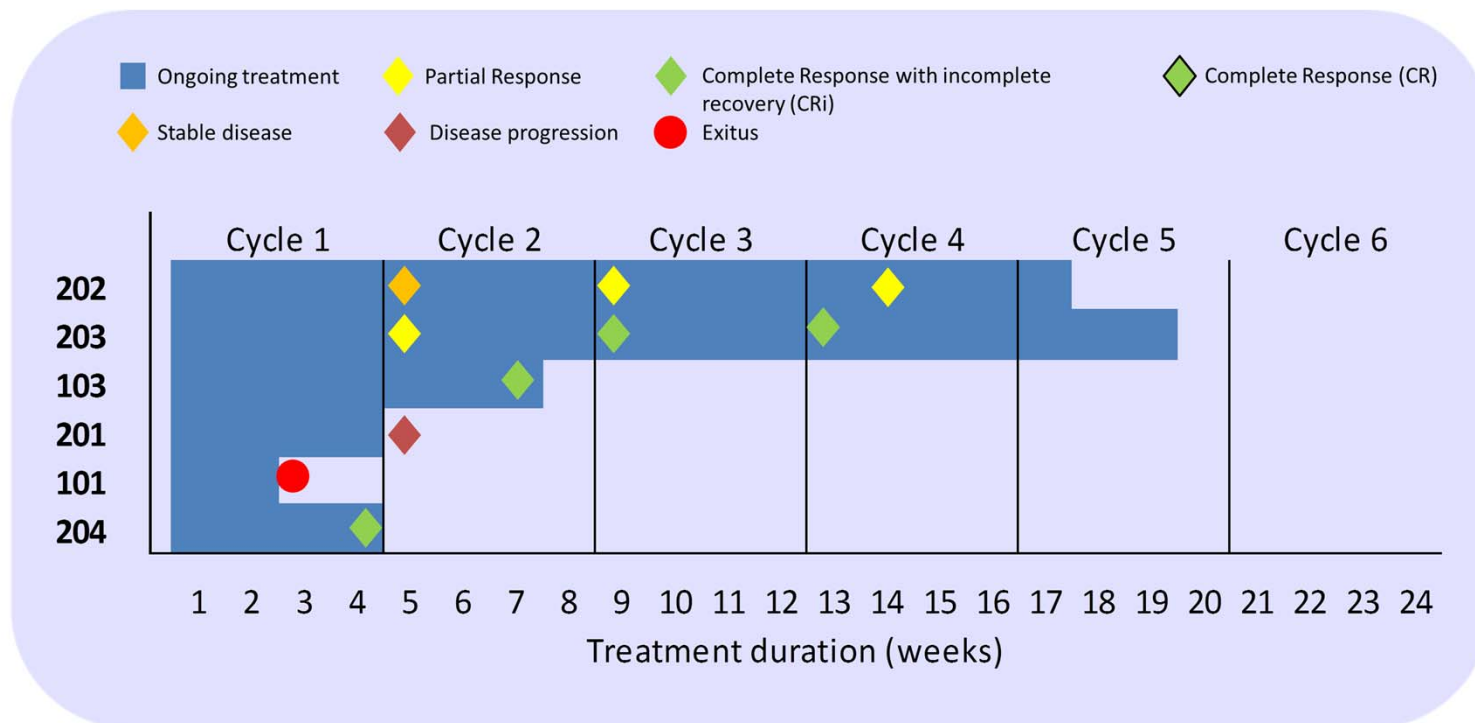


Amsterdam 13-16 June 2019

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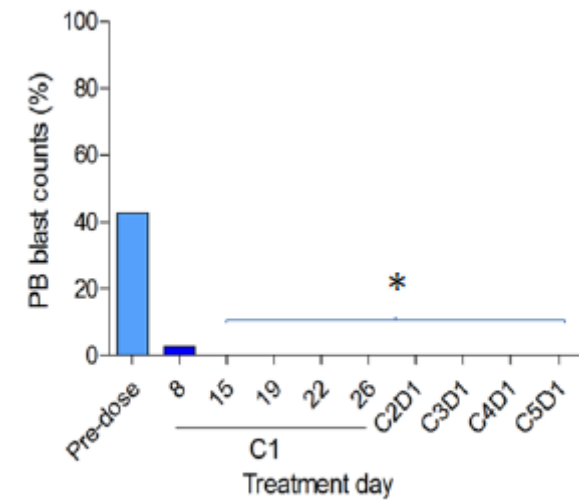
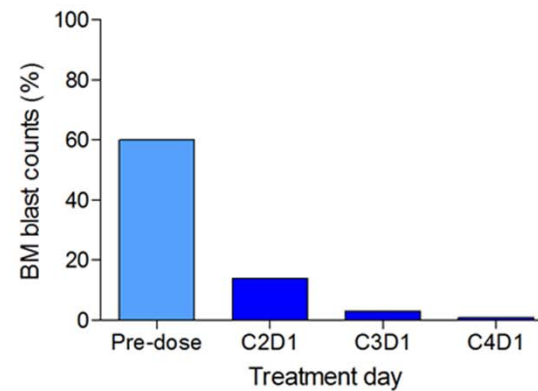
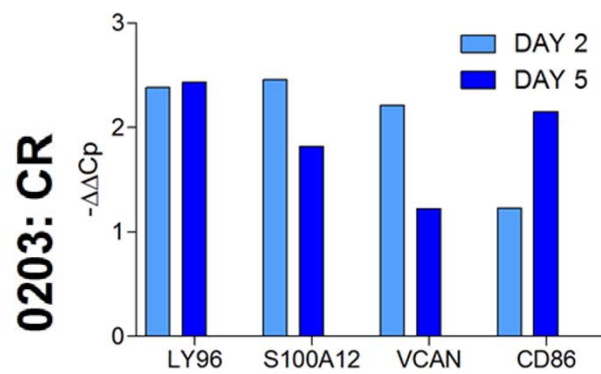
Preliminary Results (5 evaluable patients out of 6)

- ✓ Combo **well tolerated**
- ✓ Fast responses (median time to response 1.5 months)
- ✓ **80% OR** (4/5 evaluable patients) : **75% CRi** and 25% PR
- ✓ 1 patient in CRi with decreasing need of transfusions



Peripheral differentiation

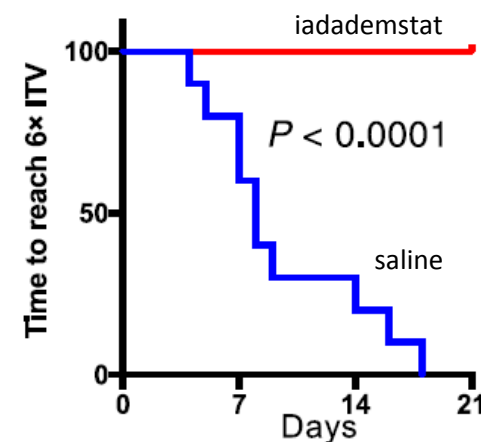
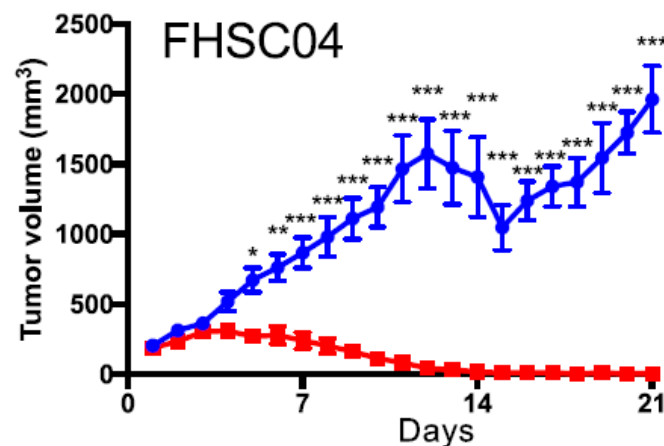
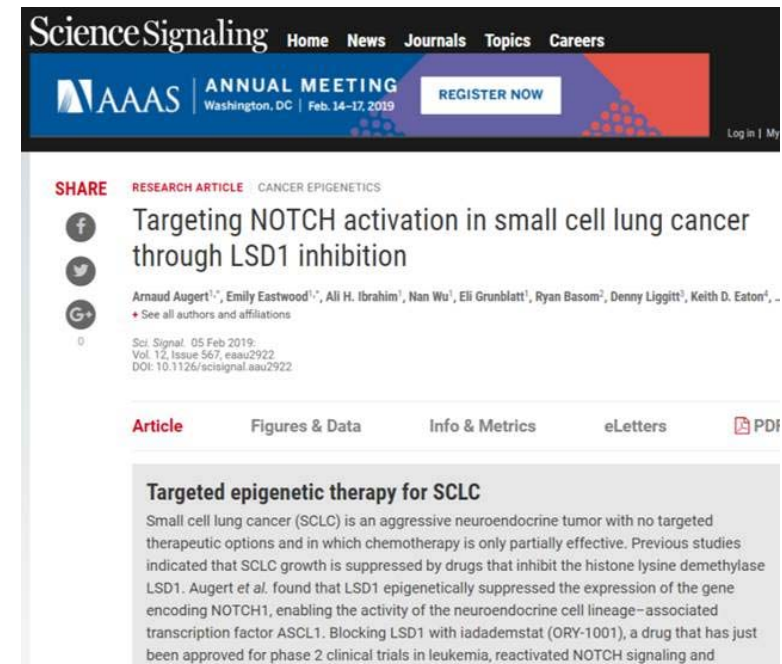
Potent early differentiation in responding patients



* Values correspond to 0% Blasts

Iadademstat opportunity in SCLC

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

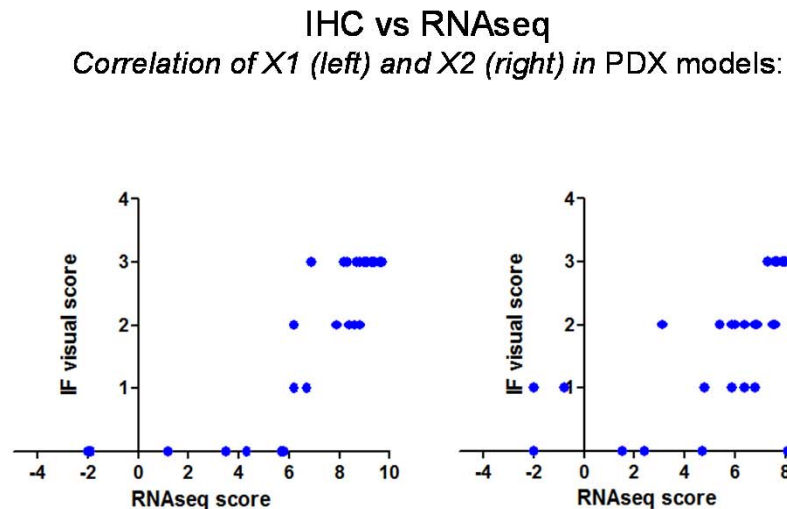
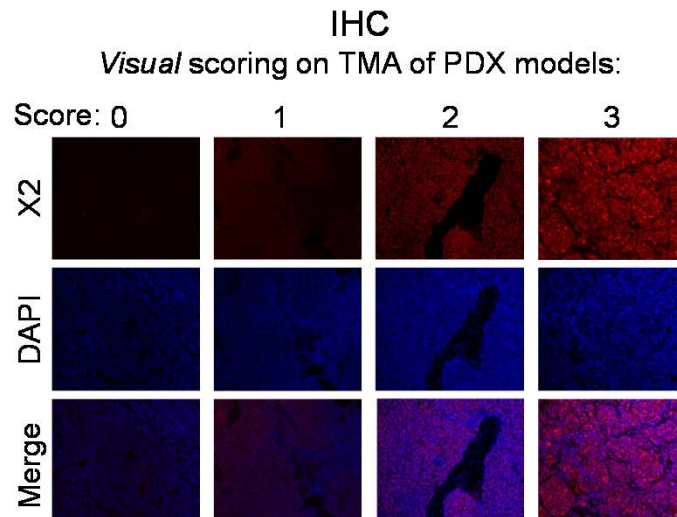
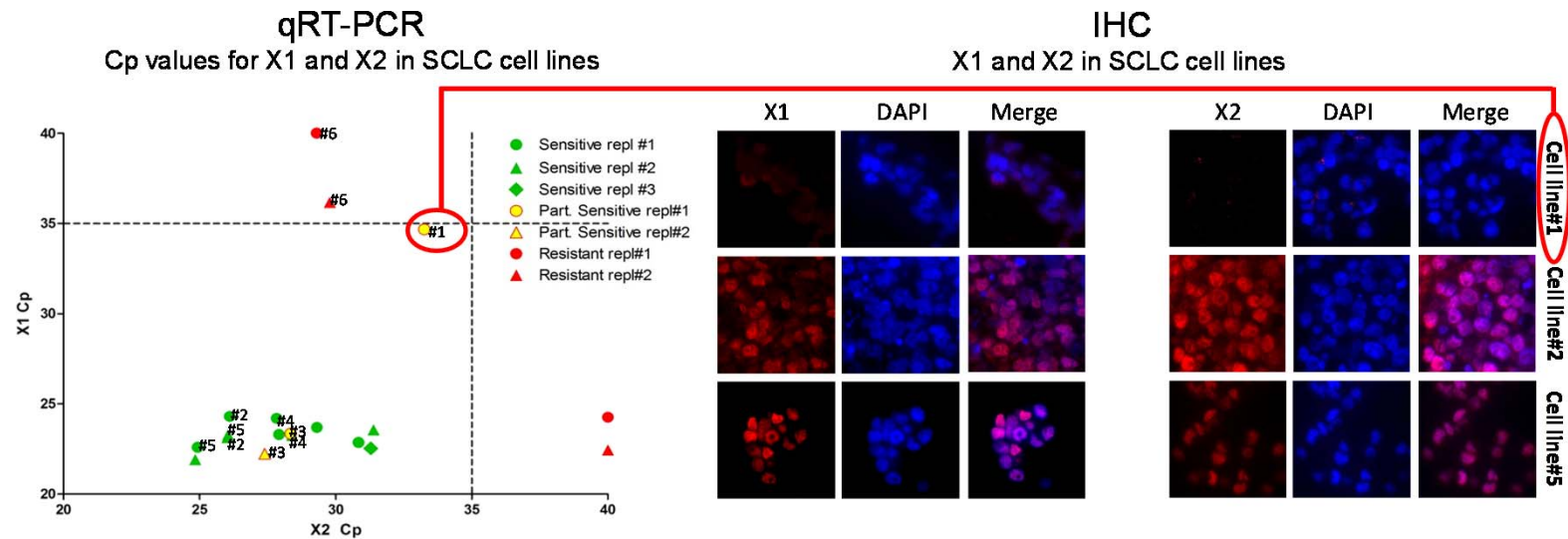


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ladademstat in SCLC: Increasing our chances by biomarker-based patient stratification

✓ Analysis of sensitive versus resistant cell lines

- ✓ GE candidates were confirmed by qRT-PCR and IHC



CLEPSIDRA: A Combination trial of LSD1 and Etop-Platinum in Small Cell Lung Cancer in **biomarker-ID** Relapsed pAtients

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

- ✓ 6 Patients enrolled. One patient at cycle 7.
- ✓ Satisfactory and dynamic recruitment pace



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

Anticipating a rich flow of catalysts / clinical data

Iadademstat Phase IIs in oncology

CLEPSIDRA

ALICE

2019

Vafidemstat Phase IIs in CNS

REIMAGINE

ETHERAL

SATEEN



Amsterdam; June
AML data



Barcelona; Sept
SCLC data



Orlando; Dec.
AML data



Sept. Copenhag.
Psychiatry Aggression



Oct. Athens
Psychiatry Aggression



Dec. San Diego
AD aggression



2020

April Vienna
AD Global EU 6m data



July Amsterdam
AD Global US 6m data



Potential Conferences where data may be presented.

ORYZON – a unique investment opportunity in an epigenetic platform



- ✓ A differential proposition in **EPIGENETICS** drugs in **CNS and ONCOLOGY** around one of the most interesting targets in the field: **LSD1**
- ✓ **2 molecules** already in **Phase II** with promising clinical signals in human patients
- ✓ **Pioneers in CNS epigenetics**
 - ✓ Vafidemstat is efficacious in Psychiatric disorders (BPD and ADHD)
 - ✓ **Phase II/III in Borderline personality disorder under preparation.** Additional options in ASD or ADHD
 - ✓ Vafidemstat may be also clinically relevant in neurodegenerative disorders (Phase IIs in MS and AD ongoing)
- ✓ **Most advanced LSD1i (iadademstat) in Oncology**
 - ✓ 2 Phase II trials ongoing in combo with respective SoC in AML and SCLC
 - ✓ **Positive preliminary efficacy results** reported in dose finding part of AML trial
 - ✓ **SCLC trial is a biomarker-guided** study to stratify responsive patients
- ✓ **Rich pipeline** of clinical **news** expected in the next 2-4 Qs
- ✓ Clinical Operations in US started and under expansion
- ✓ A **cash efficient** company with a seasoned international management team
- ✓ **160m Euros market cap.** Highest liquid stock in the microcap group in MadridSEXC
- ✓ Perseverant **presence in the US market in the last 4 years.** Two successful PIPEs executed in 2017-18 led by US Investment Banks and with participation of US investors
- ✓ A public company in Europe with **plans to** get dual listed in **NASDAQ**

ORYZON
A GLOBAL LEADER
IN EPIGENETICS



CARLOS BUESA

CEO & President
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TAMARA MAES

Chief Scientific Officer
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ROGER BULLOCK

Chief Medical Officer
rbullock@oryzon.com

MICHAEL ROPACKI

VP Clinical Development
mropacki@oryzon.com



EXPERIENCED MANAGEMENT TEAM

▪ CEO



CARLOS BUESA: CEO & President. Spain/US

PhD in Biochemistry and Molecular Biology. Founder and CEO since inception. Advanced programs on finance, business development, negotiation skills and human resources. He is also PADE at the IESE Business School. He is Board Member of the VC Fund Invaready and Deputy President of the Spanish BioIndustry Association.

▪ CSO



TAMARA MAES: CSO & VicePresident. / Spain

PhD in Biotechnology. Founder and Chief Scientific Officer since inception. Responsible of the creation of the whole pipeline of the company and the biological target validation programs. She is SAB member on several public institutions as CSIC and private companies. Since 2016 Scientific Advisor of the ADDF

▪ VP Clinical Development



MICHAEL T. ROPACKI: US

Vice President of Clinical Development

PhD in Clinical Neuropsychology. Dr. Ropacki has held roles of increasing responsibility for + 10y at Johnson & Johnson, his last as Director of Clinical Development, Neuroscience, Research and Development, for Janssen R&D serving as the Clinical Lead responsible for developing and leading the Cognitive Health in Aging Registry. Prior to that role he served as Global Medical Affairs Leader, Head of Late-Stage Development at Janssen AD Immunotherapy, LLC.

▪ Medical Director



ROGER BULLOCK: UK /PT/ Spain

Chief Medical Officer

Graduated in Physiological Sciences at Keble College in Oxford University and got his MB.BS at London University

Extensive experience as clinical researcher, having participated in more than 70 clinical trials in Alzheimer's disease and other CNS conditions

30-year research career, +than 100 peer-reviewed publications and book chap

He has worked as a consultant for companies active in the CNS space, including Lilly and Merck

▪ Clin Ops Director



SONIA GUTIERREZ: /Spain

Chief of Clinical Operations

BSc. Pharm. & MSc. & PDD in IESE Business School. More than 20 years of experience in the clinical research and operations area at different Intnal. Pharma & Biotech companies. CNS: +13y in Lundbeck involved in + 40 Clinical Trials in CNS. Experience in oncology and other indications in Regeneron and other companies.

▪ IP Director



NEUS VIRGILI : /Spain

Chief IP Officer

B.Sc. in Organic Chemistry from the University of Barcelona

Qualified European Patent Attorney

She has over 20 years experience in pharmaceutical IP

Since 2011 IP Officer at Oryzon

▪ CFO



ENRIC RELLO: / Spain

Chief Financial Officer

J.D.; PhD in Economics & Business Administration.

PLD - Program for Leadership Development, Harvard Business School.

BSc & MSc in Business Administrations & Laws, HBS Finance Excell. Prog. Harvard Business School.

From 1997 till 2007 CFO of SANDOZ (NOVARTIS), Spanish Arm.

CFO at Oryzon since 2011

▪ BDO



EMILI TORRELL: /Spain

Chief BD Officer

B.Sc. in Sciences, Autonomous University of Barcelona

MBA at ESADE and PDG at IESE Business School

In the business development area from 1990 in the most relevant Spanish companies Prodesfarma, Almirall and Laboratorios Esteve

From 2007 BD Director at Oryzon

- An experienced and respected managerial teams in the Biopharmaceutical industry
- Team members have a track record in product discovery & in advancing successfully through product development phases
- Demonstrated ability to close world class deals and to lead, and participate in international consortia

ORYZON