

A GLOBAL LEADER IN EPIGENETICS

INVESTOR PRESENTATION MADX: ORY OCTOBER 2019

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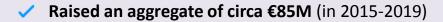
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Company Highlights

- A **clinical stage** biopharmaceutical company developing innovative therapies in the field of **Epigenetics**
- Two molecules already with positive data in humans
- 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



- Cash runway expected till 2H2021*
- One of the most LIQUID companies in the MicroCap group in the Spanish Stock Market
 - 45.7 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

* On July 26th, the company completed a Private Placement with International Investors raising gross proceeds of €20M (circa \$22.2M at the exchange rate on that day)



BOLSA DE MADRID



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

	June 30th, 2019	June 30th, 2018
Cash and cash equivalents Marketable securities	27,868 669	30,986 165
Total Assets	73,125	68,352
Deferred revenue	0	0
Total Stockholders' equity	50,888	40,697

¹ Spanish GAAPs



- Epigenetic dysfunctions are associated with aberrant gene expression and disease
- Epigenetic drugs can restore these transcriptional imbalances
- 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 the most abundant histone demethylase in the prefrontal cortex

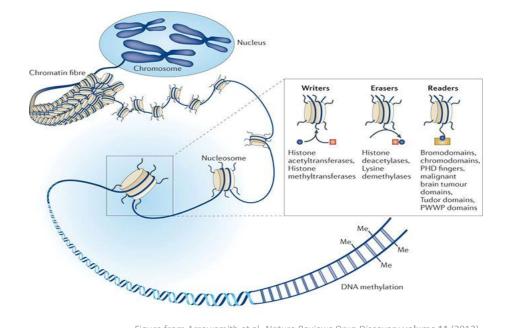


Figure from Arrowsmith et al. Nature Reviews Drug Discovery volume 11 (2012)



Lysine specific histone demethylase 1 (LSD1): an epigenetic "eraser" that removes methyl groups from histones Image: Colspan="2">Image: Colspan="2" Image: Colspan="



A broad pipeline to address unmeet medical needs with an attractive market opportunity

INDICATION	STUDY*	RESEARCH PRECLINICAL	PHASE I	PHASE IIA	PHASE IIB	PHASE III	CNS Market Need
VAFIDEMSTAT (ORY-200	01) - CNS optimized LSD1 inhibitor						
Aggression in BPD	REIMAGINE / PORTICO (*)]		Aggression is a common feature in many psychiatric diseases. +50% in ADHD(***)
Aggression in ADHD	REIMAGINE / ENTRANCE (*)						Global BPD market expected to grow to \$2.6B in 2027
Aggression in ASD	REIMAGINE / COLONNADE (*)						
Aggression in AD	REIMAGINE-AD / GATEWAY (**)						45 million people with AD worldwide; 20% shows aggresiveness
Alzheimer's disease (Mild Moderate)	ETHERAL monotherapy						AD main disruptions: memory loss, aggression and apathy. AD global costs per annum of \$605B
Multiple Sclerosis (RR & SP)	SATEEN monotherapy						
IADADEMSTAT (ORY-10)	01) - selective LSD1 inhibitor		, i i i i i i i i i i i i i i i i i i i	· · · · · · · · · · · · · · · · · · ·			Oncology Market Need
AML (Elderly Unfit)	ALICE Combo w Aza						Global AML market of \$990m in 2019. Room for new Combos according to KoLs
SCLC (First Line Relapsed)	CLEPSIDRA Combo w Platinum/Etoposide						SCLC is a serious unmet medical need, with a MOS
ORY-3001 - selective LSI	D1 inhibitor						of 8–12 months and 5% 2-year OSR
Non Oncological	Preclinical finished						Global SCLC market +300,000 patients/y. FDA approved label extension of Pembro but only 19%
OTHER PROGRAMS							of ORR (****)
Undisclosed							Projections of Rova-T when in Phase III were +5B peak sales/y

* IN BLUE, NEW PHASE IIB STUDIES UNDER PREPARATION OR EVALUATION

** Contingent to + results in REIMAGINE-AD

(***) J Child Adolesc Psychopharmacol. 2016 Feb 1; 26(1): 19–25. (****) Keynote study in 83 patients





A GLOBAL LEADER IN CNS EPIGENETICS

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



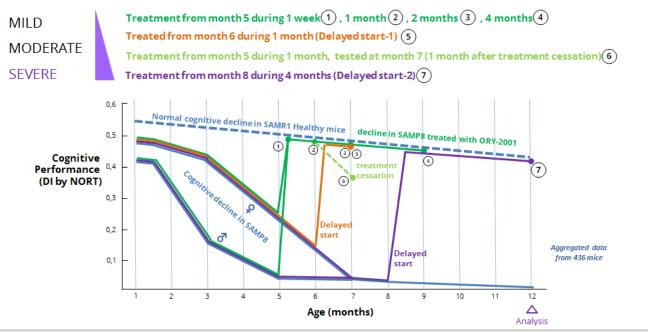
- ✓ Vafidemstat is a **small molecule** LSD1 inhibitor optimized for CNS
- Excellent Pharmacology. High oral bioavailability
- Positive results in 7 different animal models and in in-vitro models
 - Cognition
 - Neuroprotection
 - Neuroinflammation
 - Social Withdrawal / Apathy
 - Aggression / Agitation
 - 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 multiple clinical studies

Phase IIb studies under preparation



In Psychosis & In Alzheimer's SAMP8 In Schizophrenia SETD1a Schizophrenia NMDA In Huntington disease model vafidemstat R6/1 model vafidemstat +/- model receptor-hypofunction mice model T-448 restores memory by the improves memory by the iadademstat (ORY-1001) NORT model NORT model improves working memory (TAKEDA) LSD1 inhibitor improves memory Vafidemstat Fully Restores Memory Measured by NORT in SAMP8 AD Model

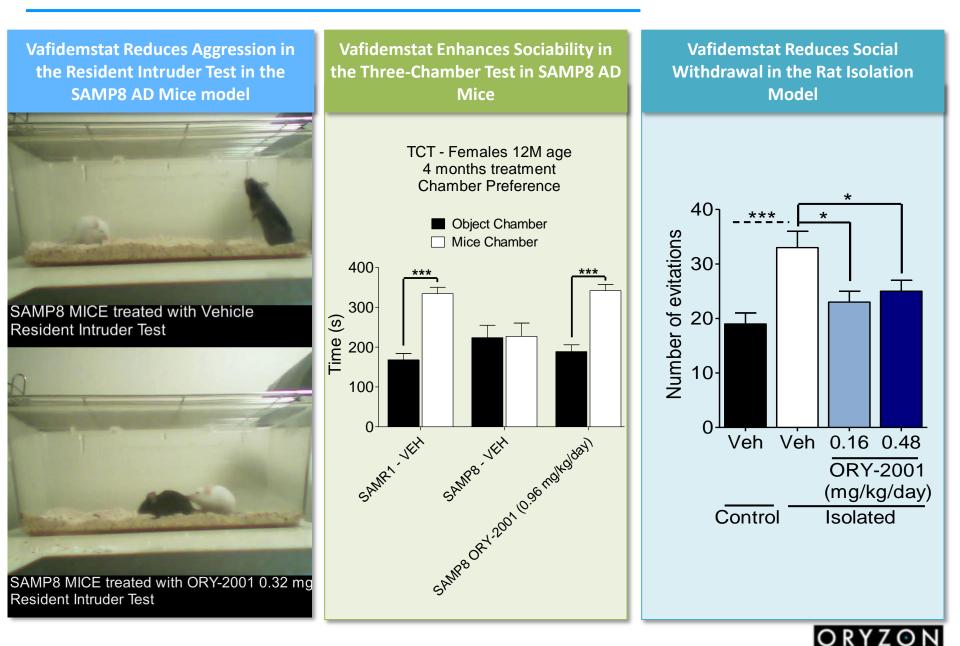


Cognition and memory impairments are found in AD and dementias but also in Autism, Schizophrenia, Depression, Bipolar disorder and other psychiatric conditions



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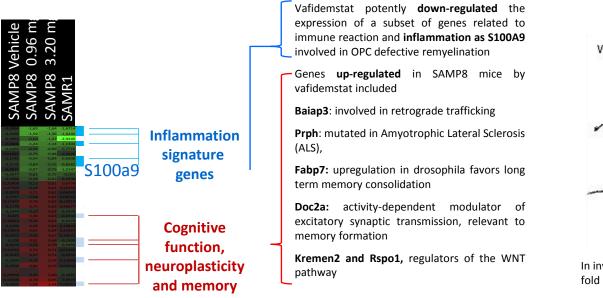
Vafidemstat Produces Significant Behavioural Changes



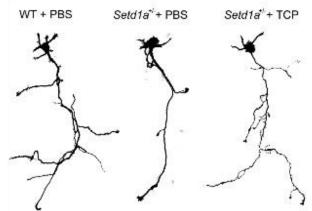
MoA: an upstream epigenetic mechanism producing a dual activity, antinflammatory and prosynaptic

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 up-regulates genes associated with:
 - Cognition, notably memory and executive functioning
 - Neuroplasticity
- vafidemstat potentiates the response capacity of IEGs to stress
- vafidemstat reduces the expression of inflammatory genes including S100A9 and others



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



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

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



Safe and well tolerated in a +100 healthy volunteers (young and elderly) Phase I (MAD+SAD) study

- No hematological impact at planned doses
- Efficiently crossed the BBB (70-90%)
- Oral PK Half Life of 22h allowing once daily oral
- PK/PD data allowed definition of recommended Phase II doses

Safe and well tolerated so far in diverse Phase II studies

- Vafidemstat has been already administered to +220 volunteers and patients
- Phase IIs (MS, AD, ADHD, BPD and ASD patients) with no safety signals to date
- Longest exposure to date: 15 months





Duration	8 Weeks treatment + 4 weeks of follow up				
Cohorts to be recruited					
Borderline Personality Disorder	6 patients	Done – Data reported in April 2019]	upscaled later to an	
Attention Deficit and Hyperactivity Disorder	6 patients	Done – Data reported in April 2019	-	aggregated of 30 patients. Recruitment	
Autism Spectrum Disorder	6 patients	Done – Data reported in Sept 2019		completed	

Endpoints

Safety

Efficacy:

Aggression / Agitation measured by CGI-S

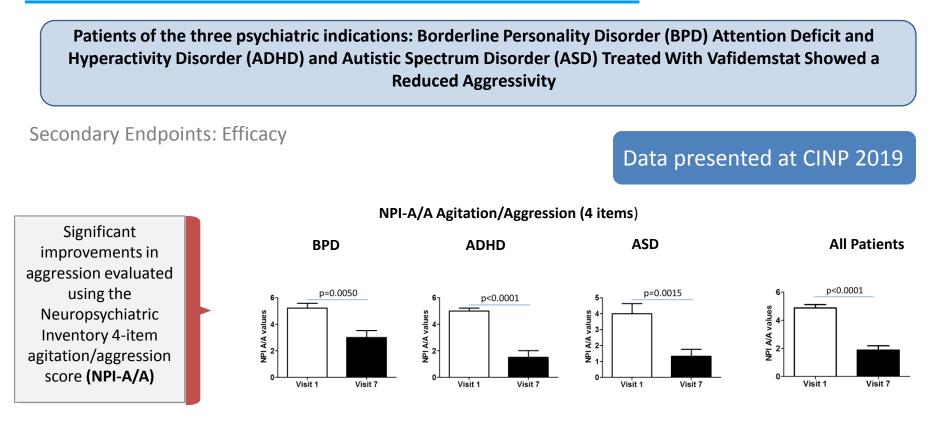
Aggression / Agitation measured by CGI-I

Aggression / Agitation measured by NPI A/A 4 items

Psychiatric status measured by NPI Global assessment (12 items)

Change in specific disease scales





Also significant improvements in aggression evaluated using the Clinical Global Impression of Severity (CGI-S) and Improvement (CGI-I) scales

REIMAGINE data presented at



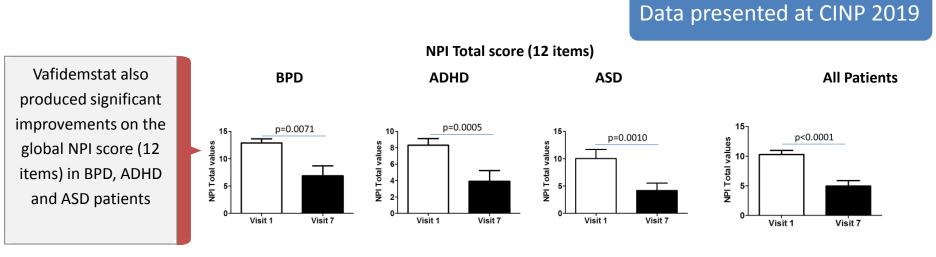




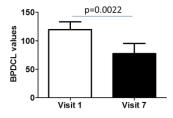




The significant improvements in the NPI global score and overall specific scales for BPD and ADHD suggest that vafidemstat has a **broader psychiatric effect beyond aggression**



Remarkably, vafidemstat not only improved aggression but also produced significant improvement on the GLOBAL Borderline Personality Disease Checklist (BPDCL) scale **BPDCL Total score**





Next steps: Vafidemstat, a meaningful therapeutic option for BPD

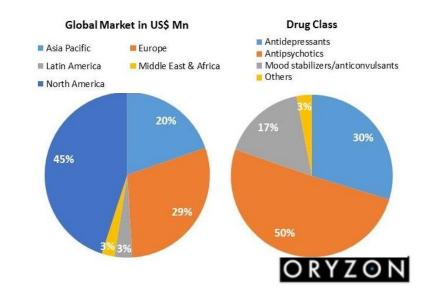
"I find myself able now to control my negative emotions and my frustration"

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 (≤ 9.1M 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
- ✤ A new Phase IIb in BPD (*Portico*) under preparation
- Additional Phase IIb in adult aggressive ADHD (*Entrance*) and ASD (*Colonnade*) under evaluation
- And if +data in Reimagine-AD, a Phase IIb in AD aggressive patients (*Gateway*) will be performed



Duration	24 Weeks treatment + 4 weeks of follow up			
Open Label / Single arm (1.2mg/d)	12 patients	Recruitment Finished (Data report expected in April 2020)		

- Safety
- Efficacy: Aggression / Agitation measured by NPI A/A 4 items, CMAI and CGI-A/A
- Memory status measured by MMSE
- Caregiver burden measured by changes in the Zarit Burden Interview (ZBI)

First proposition in AD: Vafidemstat as a symptomatic drug

- 45 million people affected worldwide
- 20% of the outpatients and 40% of the inmate patients display aggresiveness
- Vafidemstat is safe and highly brain-penetrant in humans
- Positive effects in different preclinical models on memory, aggression, sociability and apathy, all core features in AD patients
- Vafidemstat reduces aggression in BPD, ADHD and ASD patients

Vafidemstat may also provide clinical benefit in AD either as a single or multi-symptomatic drug or as a disease modifier





An ambitious Phase II trial, ETHERAL: Epigenetic THERapy in ALzheimer's Disease

Besides aggression, vafidemstat may provide also further benefits to AD patients

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

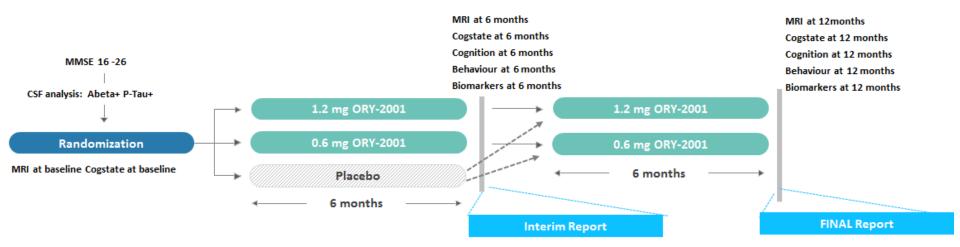
- 150 Mild to Moderate AD patients (6+6 months)
- Primary Objective: Safety & Tolerability
- Secondary Objectives:
 - Cognition/Agitation/Apathy/Depression/QoL
 - Volumetric MRI
- Biomarker guided study (with 8 CSF Biomarkers)



117 patients in EU. 17 sites Spain, France & UK



A Twin study in US: around 25-28 patients IND approved mid March US Sites (3) opened FPI recruited in May





Vafidemstat appears to be safe in AD patients: ETHERAL first data report

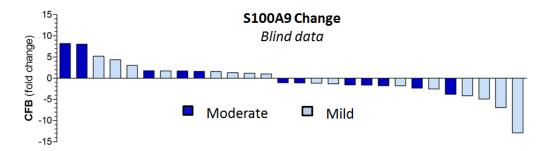
One of the main goals in ETHERAL is to establish safety of vafidemstat in long-term administration, at therapeutically relevant doses in a frail and elder AD population

Vafidemstat treatment appears so far to be safe and well tolerated:

- Four SAEs were reported in three subjects, all suspected to be unlikely related to the treatment
- Platelet, neutrophils and other hematological parameters do not show clinically relevant variations due to vafidemstat treatment
- No abnormal and clinically significant liver enzymes levels or other laboratory findings have been reported to-date

Biomarker and other functional evolution in ETHERAL (blind analysis) is compatible with an informative study

Variations on the S100A9 CSF levels observed in the first 33 patients completing the first 24 weeks of therapy (blind analysis) might be compatible with the preclinical data that shows that vafidemstat decreases S100A9 levels in the CNS. S100A9 is a proinflammatory protein reported to be highly overexpressed in PFC in AD patients



individual patient CSF S100A9 Change from Baseline (CFB) is shown as fold induction after 24 weeks treatment







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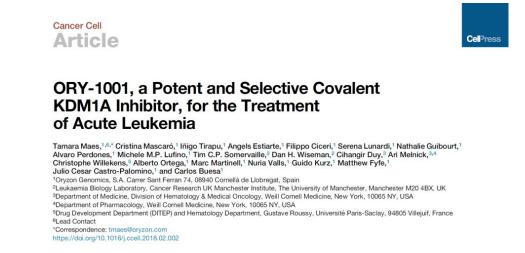
ladademstat

A Phase II stage clinical compound in Oncology



ladademstat (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



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



POTENTIAL ONCOLOGICAL INDICATIONS:



MoA well characterized in SCLC, AML and Medulloblastoma



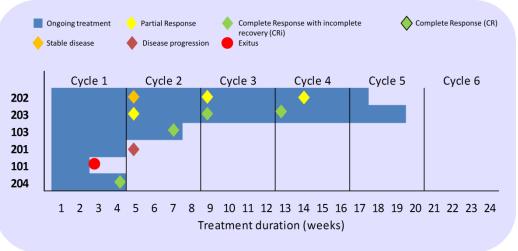
ALICE: An AML trial with LSD1i in Combination with azacitidine in the Elderly

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



- 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
- Additional reports to be presented in future Medical Conferences



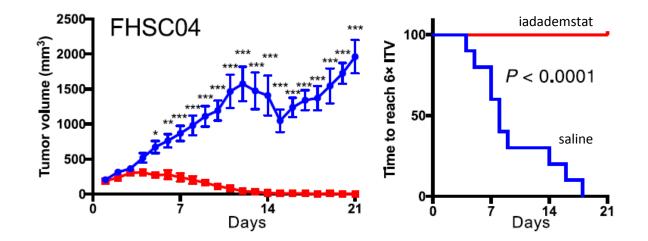


ladademstat opportunity in Small Cell Lung Cancer (SCLC)

- LSD1 is a target well characterized in SCLC and validated in preclinical models. LSD1 inhibitors are effective in several invitro 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 SCLC cell lines, tumors and plasma from patients
- Phase II trial ongoing in second line SCLC patients using these biomarkers to stratify patients and identify superresponders



Small cell utilg cancer (SCCC) is an aggressive includendocrine utilion with the 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

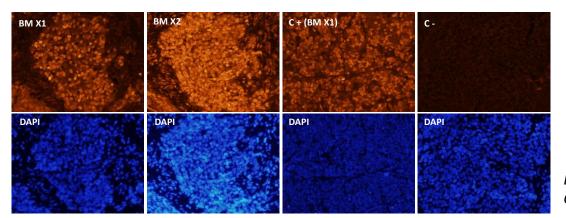




CLEPSIDRA: A **C**ombination trial of LSD1 and Etop-Platinum in Small Cell Lung Cancer in **biomarker-ID** Relapsed pAtients

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
- 4-6 cycles iadademstat+platinum/etoposide, thereafter iadademstat monotherapy (at investigators' criteria)
- 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



Biomarker analysis from a CLEPSIDRA patient

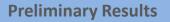
Current status:

10 Patients enrolled. One patient at cycle 13

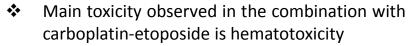


ladademstat: SCLC - Phase II CLEPSIDRA - preliminary efficacy signals

ESM

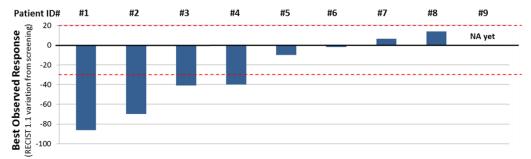


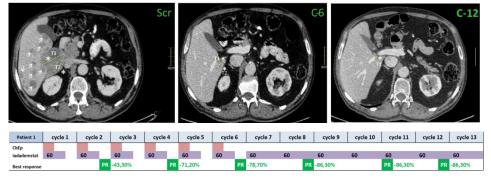




- 75% response rate (6/8 evaluable patients):
 4PRs and 2 long-term SD
- Current level of observed responses suggests that patient selection by Biomarkers may be effective to increase ratio of ORs
- Iadademstat alone is safe and shows no hematological, general or neuronal toxicity in ED-SCLC patients, suggesting potential for monotherapy and other combos
- Patient #1 showed initially 78.7% of tumor reduction after 6 cycles of triplet. Since then, and on iadademstat alone, patient is still in remission after 9 months (cycle 12) with 86.3% of tumor reduction by RECIST values and with all minor lesions still progressively being reduced or disappearing according to the 3 CT-Scans done since C6





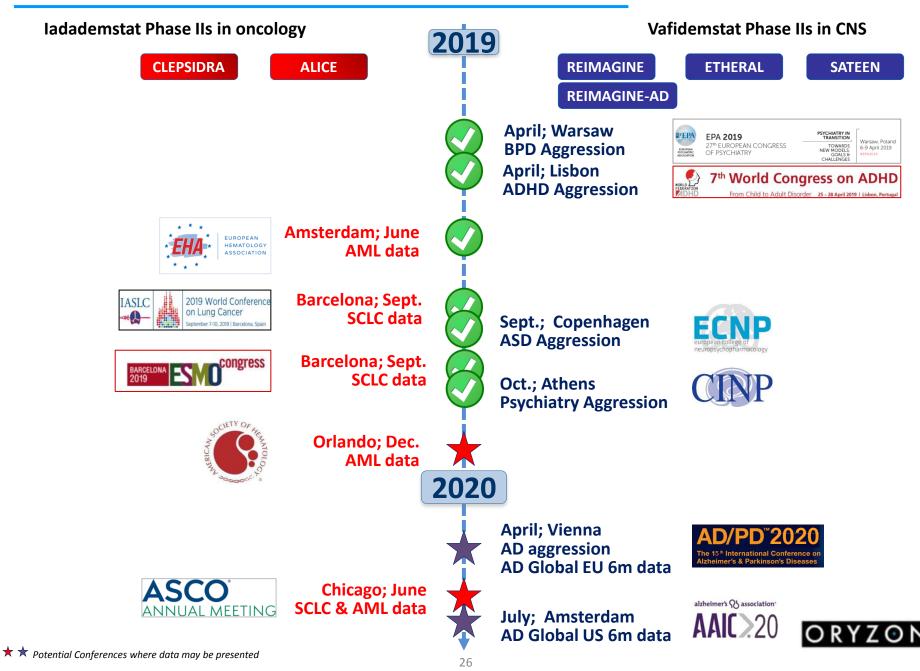


CT-Scans for Patient #1 at screening, Cy6 and Cy12

More Results in future Medical Conferences



Anticipating a rich flow of catalysts / clinical data







- A differential proposition in EPIGENETICS drugs in CNS and ONCOLOGY around one of the most interesting targets in the field: LSD1
- **2 molecules** in **Phase II** with promising clinical signals in human patients
- Pioneers in CNS epigenetics
 - ✓ Vafidemstat shows efficacy in psychiatric disorders (BPD, ADHD, ASD)
 - Phase IIb in Borderline personality disorder under preparation. Additional options in ADHD or ASD under evaluation
 - 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 from Phase II AML and SCLC trials
 - SCLC trial is a biomarker-guided study to stratify responsive patients
 - Options to get accelerated approval
- 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
- ✓ €135M market cap. One of the most liquid stocks in the microcap group in MadridSEXC
- Perseverant presence in the US market in the last 4 years. Two successful PIPEs executed in 2018-19 led by US Investment Banks and with participation of US investors
- A public company in Europe with plans to get dual listed in NASDAQ





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.

Board Member of the VC Fund Inveready and



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.

SAB member on several public institutions as CSIC (2009-2013) and private companies. Since 2016 Scientific Advisor of the ADDF.







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 chapters.

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

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.

S	ON	IIA	Gl	JTI	IER	REZ:	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 International Pharma & Biotech companies. CNS: +13v in Lundbeck involved in + 40 Clinical Trials in CNS.

Experience in oncology and other indications in Regeneron and other companies.

NEUS VIRGILI : Spain

Chief IP Officer

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

Qualified European Patent Attorney.

Over 20 years experience in pharmaceutical IP.

Since 2011 IP Officer at Oryzon.

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 Administration & Law.

HBS Finance Excell. Prog. Harvard Business School.

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

CFO at Oryzon since 2011.

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 team 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 A GLOBAL LEADER IN EPIGENETICS



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MICHAEL ROPACKI VP Clinical Development mropacki@oryzon.com

