Pioneering personalized medicine in epigenetics

ORYZON

CORPORATE PRESENTATION

March 2022

ORY:SM / ORY.MC

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Epigenetic Champion Developing New Therapies in CNS and Oncology

Growing epigenetic platform with an expanding pipeline to bring treatments to **High Unmet Medical needs in CNS and Oncology**

Focus on developing highly potent and selective **LSD1 inhibitors with best-in-class characteristics**

2 Programs with potential accelerated approval pathways defined: **Iadademstat in Oncology and Vafidemstat in CNS**

Listed in Europe (Madrid)
MK Cap ~$200M
Cash & Cash equivalents of $32.5M as per Dec 31st 2021
Runway expected till 1Q2023

Deep pipeline with multiple shots on goal

CNS: vafidemstat (ORY-2001) - CNS optimized LSD1 inhibitor

Indication	Borderline Personality Disorder	Schizophrenia Negative Symptoms & Cognition	Kabuki Syndrome	SetD1A Compass related SCZ	Aggression in AD
Study	PORTICO	EVOLUTION	HOPE	New Study	New Study *Continuation of REIMAGINE-AD*
Phase	**Phase IIb**	**Phase IIb**	**Phase Ib/II**	**Phase Ib/II**	
Status	Recruiting	Recruiting	In preparation	Under study	Under study
Anticipated Milestones	Interim analysis 4Q22	Study updates 2022	IND 1H22/FPI 1H22		

Oncology: iadademstat (ORY-1001) - Selective LSD1 inhibitor

Indication	AML 1L Elderly/Unfit	AML R/R-Flt3mut+	ED-SCLC 1L	NETs R/R
Study	ALICE *(Combo w azacitidine)*	FRIDA *(Combo w gilteritinib)*	STELLAR *(Combo w ICI)*	NET Basket *(Combo w other agents)*
Phase	**Phase IIa**	**Phase Ib**	**Phase Ib/II**	**Phase Ib/II**
Status	Ongoing – fully enrolled	IND approved	In preparation	In preparation
Anticipated Milestones	2H22 EHA/ASH Final Data	FPI 1H22	IND 1H22/FPI 2H22	IND 1H22/FPI 2H22

Note: Finalized clinical trials for iadademstat and vafidemstat are not shown. See www.oryzon.com for more details

Deep pipeline… With 3 significant investment propositions till end of 2023

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ORYZON, the only company developing epigenetic drugs in CNS

VAFIDEMSTAT
A Phase II LSD1 inhibitor for CNS diseases

CNS disorders: a field evolving towards Precision Medicine

LSD1 is key for the function of the CNS and is involved in multifactorial CNS disorders and monogenic syndromes

Large multifactorial indications

- Unknown origins
- Still diagnosed by predominant symptoms
- Confounding comorbidities
- May include genetically better defined subpopulations
- Large market opportunities

Small/rare monogenic indications

- Molecular diagnosis
- Allows smart drug design based on MoA
- Fast Market Approval conceivable
- Small markets but premium price
- May expand label to similar indications

Vafidemstat may be developed in both indications based on different formulations and commercial channels

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Vafidemstat: an LSD1 inhibitor to treat large multifactorial CNS indications including borderline personality disorder (BPD) and schizophrenia (SCZ)

Mechanism of Action

- A potent (nM) oral inhibitor of the lysine histone demethylase LSD1 with **high BBB penetration**, optimized for CNS disorders
- **LSD1i induces** the expression of genes involved in **neuronal plasticity**
- LSD1i **downregulates** the expression of genes involved in **neuroinflammation**
- LSD1i also **modulates** the response of immediate early genes in response to environmental stress and improves **aggressivity and sociability**

Key Clinical Data

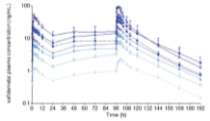
- **+300 subjects treated** with vafidemstat
- **Safety and effectiveness demonstrated as a single agent**
- No Hem or other organ toxicity. Vafidemstat has not been associated with sedation, weight gain or extrapyramidal side effects. % SAE similar to placebo
- REIMAGINE trial (basket trial in BPD, ASD and ADHD). Preliminary data presented at EPA-2020 conference showed:
  - **Statistically significant improvements in aggression** in each of the three disease groups, as well as in aggregate
  - **Improvements** also observed in **overall patient functioning**, particularly in BPD patients

Route to Market

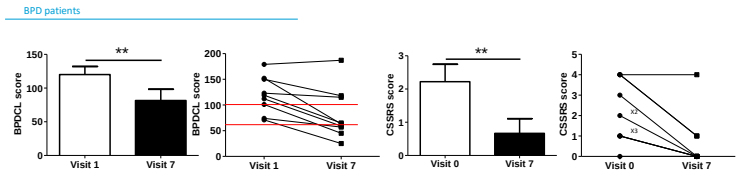
- Clinical development program is focused on two CNS indications: **BPD** (PORTICO Phase IIb study) and **SCZ** (EVOLUTION Phase IIb study) both actively recruiting
- BPD alone has a global market potential of **~$3Billion by 2027**

FiM: 110 volunteers:

87 treated with vafidemstat and 23 with placebo

Safe	Brain Penetrant	Oral, once a day
		
No differences between placebo and vafidemstat-treated patients	An optimal CSF : plasma ratio of 0.9	PK data supports once daily dosing in both adult and elder subjects

A Proof of Concept (REIMAGINE)



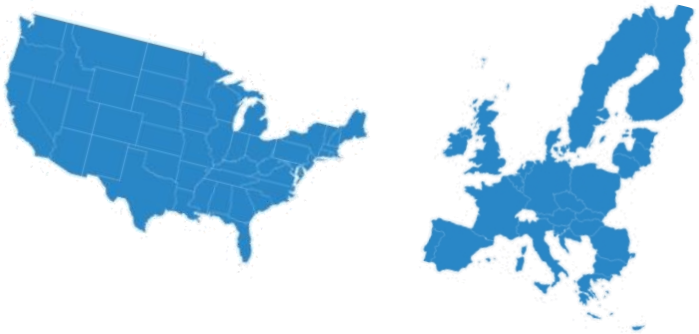
Overall improvement in BPDCL scale to diagnosis threshold level Supporting general treatment of the disease

28th European Congress of Psychiatry, EPA 2020

Borderline personality disorder: a snapshot

A Prevalent & impairing disease

9 million in US & EU



Two main types of symptoms

Unstable-extreme interpersonal relationships

+

Aggression & self-aggression

No approved drugs yet

Patients in off-label antypsychotics

Vafi improves these symptoms in PC models

Expected Market Value in 2027

US$ ~3 billion

Highest Revenue Drug Category: Anti-psychotics followed by anti-depressants

Aggregated sells: ~ 1 Billion

Very low competition

0 Phase III trials

2 Phase II trials

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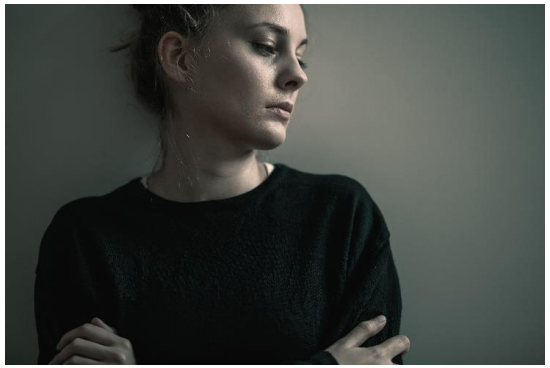
Ongoing Study: a Phase IIb in Borderline Personality Disorder

PORTICO:

An adaptative randomized double blind Phase IIb trial with vafidemstat in Borderline Personality Disorder patients



- BPD is a **serious psychiatric condition** affecting 1.6% in the general population. Prevalence is 9 million people in US and EU
- BPD patients often experience emotional instability, impulsivity, irrational beliefs and distorted perception, and intense but unstable relationships with others
- **High unmet need**: no drugs specifically approved for BPD. 1.4 million patients in US are being treated with off-label anti-psychotics
- **PORTICO** will enroll approximately 156 patients
- Two primary independent endpoints:
  - Overall clinical BPD improvement, and
  - Improvement in aggression
- Actively enrolling in EU and US

An interim analysis (90 patients) is anticipated by the end of 2022. Assuming current accrual expects:

Final read out 4Q 2023

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EVOLUTION an ongoing PoC Schizophrenia study with vafidemstat

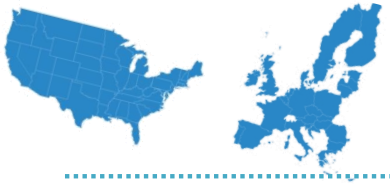
EVOLUTION:
An adaptative randomized double blind Phase IIb trial with vafidemstat in schizophrenia patients

- Double blind, placebo controlled adaptive trial design (n=100)
- Vafidemstat as add-on to SoC. 6 months of treatment
- Primary endpoints: efficacy to address SCZ Negative and cognitive symptoms
- Actively recruiting patients in EU

- Prevalence SCZ and related psychotic disorders in the US range between 0.25% and 0.64%. Prevalence is around 5 million people in US and EU
- SCZ patients experience: ***Psychotic symptoms*** including hallucinations, delusions, abnormal thinking and disorganized speech; ***Negative symptoms*** include loss of motivation, disinterest or lack of enjoyment in daily activities, social withdrawal and difficulty showing emotions. ***Cognitive symptoms*** include problems in attention, concentration, and memory
- **No current approved treatments for the cognitive impairment or the negative symptoms of SCZ**
- LSD1i restores phenotypes in various SCZ mice models

A Prevalent & impairing disease
20 millio ww.

~5 million in US & EU



Market Value in 2021

US$ ~8 billion

Three main types of symptoms

Positive or Negative
+
Cognitive Impairment

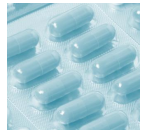
100% **60%** **70%**

Highest Revenue Drug Category: long-acting injectable (LAI) antipsychotics

Single Best seller:
+ $ 3 Billion

No approved drugs yet for

Negative symptoms (60%)
Cognitive Impairment (70%)



Vafi improves these symptoms in PC models

Moderate competition

14 Phase III trials
12 Phase II trials

ORYZON is pioneering personalized medicine in CNS

VAFIDEMSTAT
A Phase II LSD1 inhibitor for CNS diseases

Vafidemstat: an LSD1 inhibitor targeting genetically defined neurodevelopmental syndromes, e.g. Kabuki

Mechanism of Action

- A potent (nM) oral inhibitor of the lysine histone demethylase LSD1 with **high BBB penetration**, optimized for CNS disorders
- **LSD1i can compensate complex phenotypes caused by single gene deficiencies that are the cause of some rare neurodevelopmental syndromes**
- Specifically, in Histone Methyltransferase deficiencies, LSD1i restores brain chromatin methylation balance and rescues multi-systemic deficits

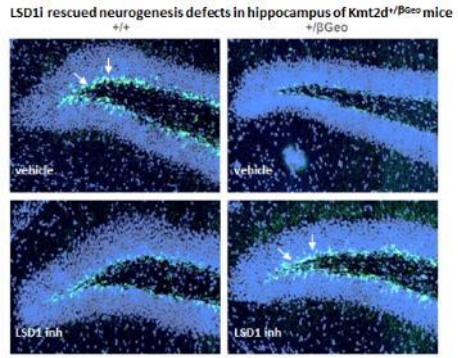
Key Clinical Data

- **+300 subjects treated** with vafidemstat
- **Safety and effectiveness demonstrated as a single agent**
- No Hem or other organ toxicity. Vafidemstat has not been associated with sedation, weight gain or extrapyramidal side effects. % SAE similar to placebo
- REIMAGINE trial (basket trial in BPD, ASD and ADHD) preliminary data presented at EPA-2020 conference showed:
  - **Statistically significant improvements in aggression in all cohorts** and in **overall patient functioning**, particularly in BPD patients
- Kabuki patients have cognitive, memory, anxiety and immune issues. Most of them have been mitigated by vafidemstat in preclinical or clinical studies

Route to Market

- Initial clinical development program focused on new registration enabling study **HOPE** for patients with Kabuki syndrome (KS) type1
- **Approx. 6,000+ pts with KS type 1 will be eligible for HOPE, with a significant market potential.** Application to larger pediatric population to follow rapidly as safety and efficacy are demonstrated.
- Additional well-established genetically-defined diseases emerging **as possible label extensions**

A Proof of Concept



*Modified from Zhang et al, Molecular Therapy: Methods & Clinical Development, Vol. 20, 779-791 (March 2021)

A Market opportunity

COMPASS-related Pathologies

SET1 (COMPASS)-like complex methylates histone H3 lysine 4 to activate promoters & define the boundaries of enhancers and superenhancers. LoF produces a variety of syndromes:

- **KMT2D (MLL2) – Kabuki Syndrome**
- **KMT2F (SetD1a) - Schizophrenia susceptibility**
- KMT2A (MLL1) - Wiedemann–Steiner syndrome
- KMT2B - Dystonia 28, Childhood-Onset
- KMT1D - Kleefstra syndrome –ASD
- KMT2C- KMT2C Syndrome -ASD
- KMT2G (SetD1b) - Syndromic intellectual disability

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Corporate Strategy: a Phase Ib/II trial in Kabuki syndrome patients with registrational potential

HOPE:
An adaptative randomized double blind Phase I/II trial with vafidemstat in KS Type 1 patients

- Kabuki syndrome (KS) is caused by **mutations in the KMT2D/MLL2 gene (KS Type I, about 70% of cases) or the KDM6A gene (KS Type II)**
- KS is a **congenital, rare, multisystem disorder** characterized by multiple multiorganic abnormalities including intellectual disability
- **Strong preclinical rationale exist for inhibiting LSD1 in KS**
- Phase Ib objectives: evaluate safety/tolerability, and determine the RP2D
- Phase II objective: evaluate efficacy of vafidemstat at the RP2D in KS Type1 patients
- ~50 patients
- IND 1H2022 /FPI 1H2022
- Recruitment expected in 12-15 months

HOPE can potentially support an application for an accelerated approval if a significant clinical benefit in the population is demonstrated over placebo

Vafidemstat has a growing avenue for personalized therapy in CNS

COMPASS-related Pathologies

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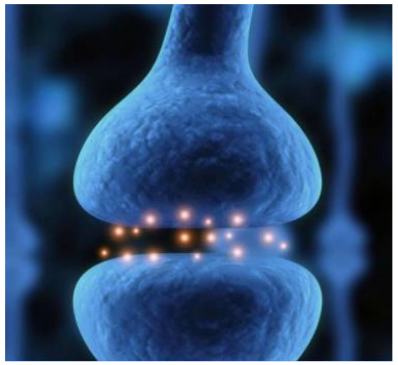


Glutamatergic pathway-related Pathologies

- **Shank3 : Shankopaties – PMS / ASD**
- NMDA-R hypofunction SCZ

Other yet unknown genetic relationships

- Rett Syndrome
- ASD syndromes
- Other schizophrenia subpopulations

Beyond monogenic syndromes, LSD1 is also involved in the direct or indirect regulation of genes or regulators of specific pathways involved in CNS diseases, e.g. miR137, whose targets are genes involved in schizophrenia and Huntington's disease, opening the door for targeting subpopulations of large CNS indications

ORYZON has an ambitious epigenetic program in Oncology

IADADEMSTAT
A Phase II LSD1 inhibitor in Oncology

Iadademstat: first and potentially best-in-class LSD1 inhibitor in AML

Mechanism of Action

- Most potent (nM) oral inhibitor of the lysine histone demethylase LSD1
- High LSD1 expression is common in AML & correlates with poor prognosis
- LSD1 is required for leukemic stem cell survival and blocking leukemic cell differentiation
- Iadademstat **prevents leukemic stem cell survival and promotes rapid differentiation/death of leukemia cells**

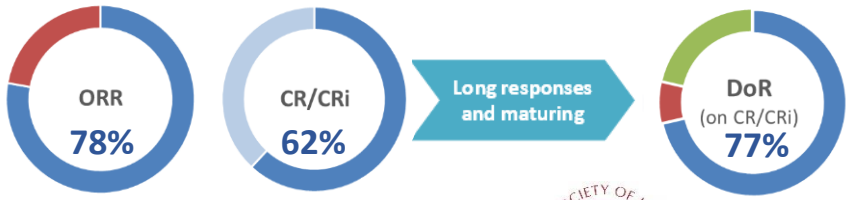
Key Clinical Data

- +100 pts treated with iadademstat in 4 Phase I/II oncological trials
- **Safety and effectiveness demonstrated as a single agent and in combination**
- **ALICE trial (1L unfit in combo with azacitidine).** Fully accrued, 36 pts. ASH-2021 preliminary reported data showed:
  - **ORR 78%** (21/27 evaluable patients); 62% CR/CRi; 5 MRD(-)
  - **Fast & Lasting responses**: mTTR 55d and 77% CR/CRi for ≥ 6 months
  - 67% transfusion independence in CR/CRi pts
- No lung, hepatic, renal, or cardiac toxicity. Major on target Hem toxicity of the combo was **thrombocytopenia (~40% G3)** but transient and manageable

Route to Market

- Initial clinical development program focused on **Flt3mut R/R AML in combination with gilteritinib** (Xospata®): **FRIDA study.** Additional label extension opportunities
- Flt3mut is approx. 30-40% AML (**~ 6,000 pts annual incidence in the US**) Flt3mut R/R AML has a market potential of +**$600M by 2027** based on Analyst's market projections for Xospata®

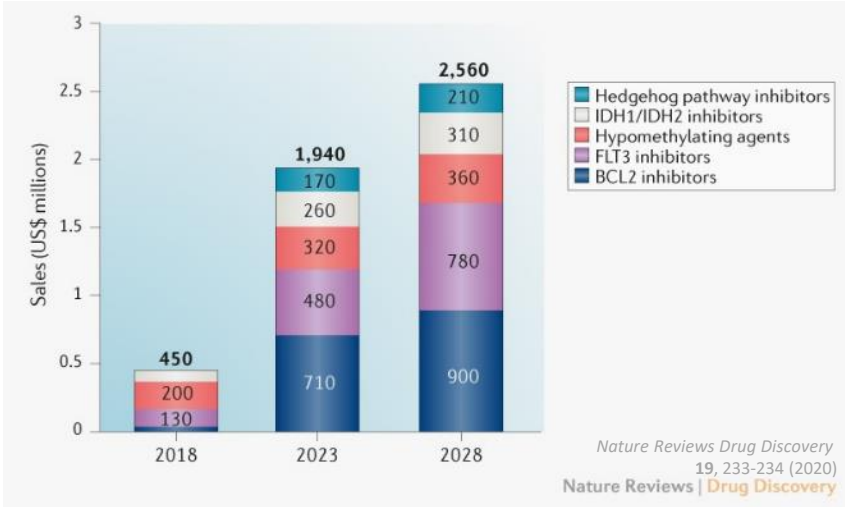
A Proof of Concept (ALICE)



Last public report presented at ASH2021

https://www.oryzon.com/sites/default/files/events/20211213_ASH2021_poster.pdf

A Market opportunity



Nature Reviews Drug Discovery
19, 233-234 (2020)
Nature Reviews | Drug Discovery

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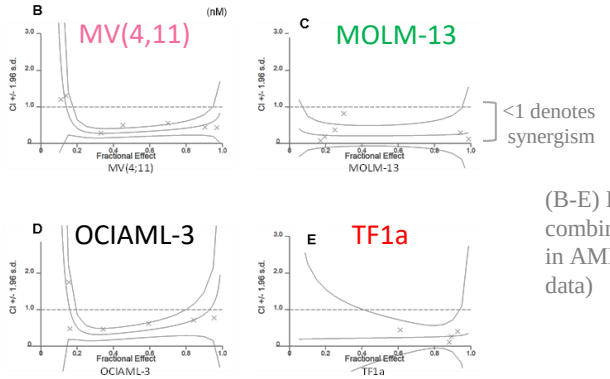
Corporate Strategy: a Phase Ib trial in R/R AML as a foundation stone for an accelerated development

FRIDA:
A Phase Ib in FLT3 mut+ R/R AML patients combining iadademstat and gilteritinib (Xospata®)



(B-E) In vitro synergistic effects combining iadademstat with gilteritinib in AML cell lines (Company internal data)

- R/R AML is an underserved population: **Majority of AML patients relapse after 1L treatment and require further treatment**
- FLT3 is the most common mutation in AML (**30-40%**) and patients have adverse prognosis. 2L R/R FLT3 mutated patients are now treated with **gilteritinib,** yet it remains a subpopulation with **high medical need (mEFS 2.8 months & CR+CRi 34%)**
- **Strong rationale**: High preclinical synergy observed in vitro between iadademstat and gilteritinib
- Primary objectives: evaluate safety/tolerability, and determine the RP2D of the combination
- Secondary objectives: evaluate efficacy of the combination (CR rate, DoR, MRD)
- Up to 45 patients
- IND approved March 2022 / FPI 1H2022
- Agreement with FDA to discuss next steps for pivotal trial development after this Phase Ib

Iadademstat: potentially first and best-in-class LSD1 inhibitor in SCLC and Neuroendocrine tumors

Mechanism of Action

- Most potent (nM) oral inhibitor of the lysine histone demethylase LSD1
- High expression of LSD1 is common in SCLC, correlates with poor prognosis
- LSD1 is required for survival & proliferation of **neuroendocrine/SCLC tumor cells**
- **Iadademstat blocks LSD1's actions and promotes neuroendocrine/SCLC tumor differentiation and death**
- **Iadademstat synergizes with ICIs and boosts the host immune system by increasing T cell infiltration and preventing T-cell exhaustion**

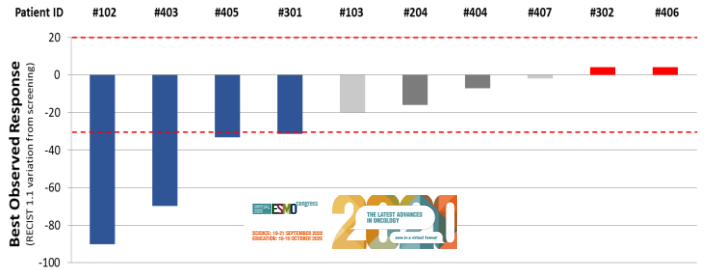
Key Clinical Data

- +100 pts treated with iadademstat in 4 Phase I/II oncological trials
- **Safety demonstrated as a single agent** (R/R ED-SCLC)
- **CLEPSIDRA trial**: iadademstat in combination with SoC chemotherapy in R/R Pt-sensitive ED-SCLC showed preliminary efficacy but challenging to manage overlapping thrombocytopenia, however as monotherapy was well tolerated
  - **ORR 40%:** (4 PR/10 evaluable patients); 2 additional long-term SD (CBR 60%)
  - DoR 4.5 months
  - 1 patient received **15 cycles iadademstat monotherapy** after conclusion of 6 cycles chemo+iadademstat combo and tumor response continued to improve (up to 90% tumor reduction)
  - No lung, hepatic, renal, or cardiac toxicity. **No hematotoxicity as a single agent (0 out 6 patients)**

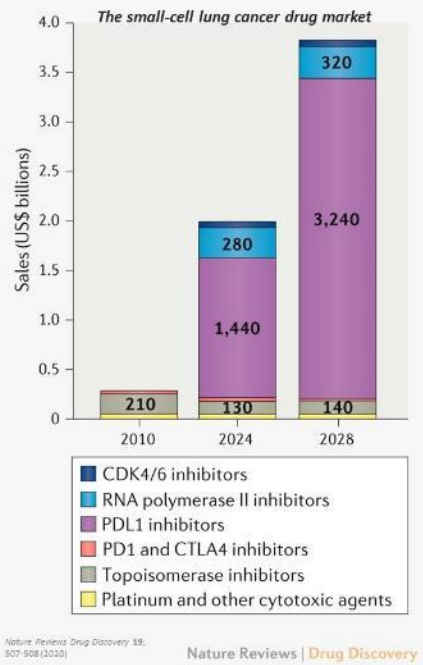
Route to Market

- Clinical development program focused on new **1L SCLC study in combo with ICI**: **STELLAR study**
- SCLC is approx. 15% of lung cancer (around 28,000 pts in the US in 2021, similar in EU5 and close to 100,000 in China). 1L SCLC has a global market potential of **~$3.5Billion by 2027 expanding at a CAGR of 19.4% over the forecast period**

A Proof of Concept (CLEPSIDRA)



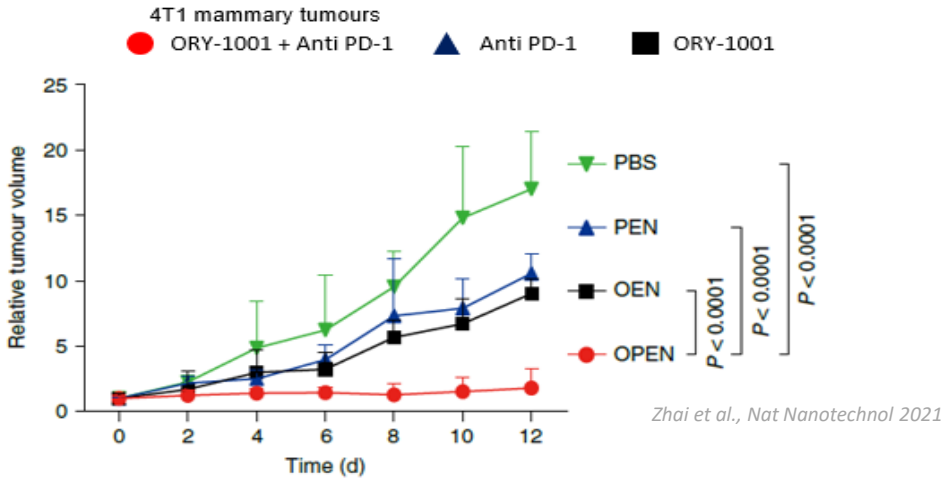
A Market opportunity



Corporate Strategy: a Phase Ib/II trial in 1L ED-SCLC with potential for accelerated development

STELLAR:

A randomized controlled Phase Ib/II study of iadademstat plus a checkpoint inhibitor in 1L patients with metastatic SCLC



Zhai et al., Nat Nanotechnol 2021

- **High unmet medical need** and a relative low bar for improving efficacy due to the modest efficacy improvements (**2 months OS increment with recent approval of ICI in combo with chemotherapy**) shown in the IMPower-133, CASPIAN and Keynote-604 trials in 1L SCLC
- **Strong rationale** for combination: preclinical proof of strong synergy between iadademstat and ICI
- Phase Ib objectives: evaluate safety/tolerability, and determine the RP2D and MTD of iadademstat in combination with ICI
- Phase II objective: evaluate efficacy of the combination of iadademstat and ICI vs ICI alone in maintenance after SoC chemotherapy measured as PFS
- IND 1H2022 / FPI 2H2022

STELLAR can potentially support an accelerated approval if a significant clinical benefit in the population is demonstrated over the efficacy of SoC treatment

Planned PoC basket trial in neuroendocrine tumors (NETs) with iadademstat

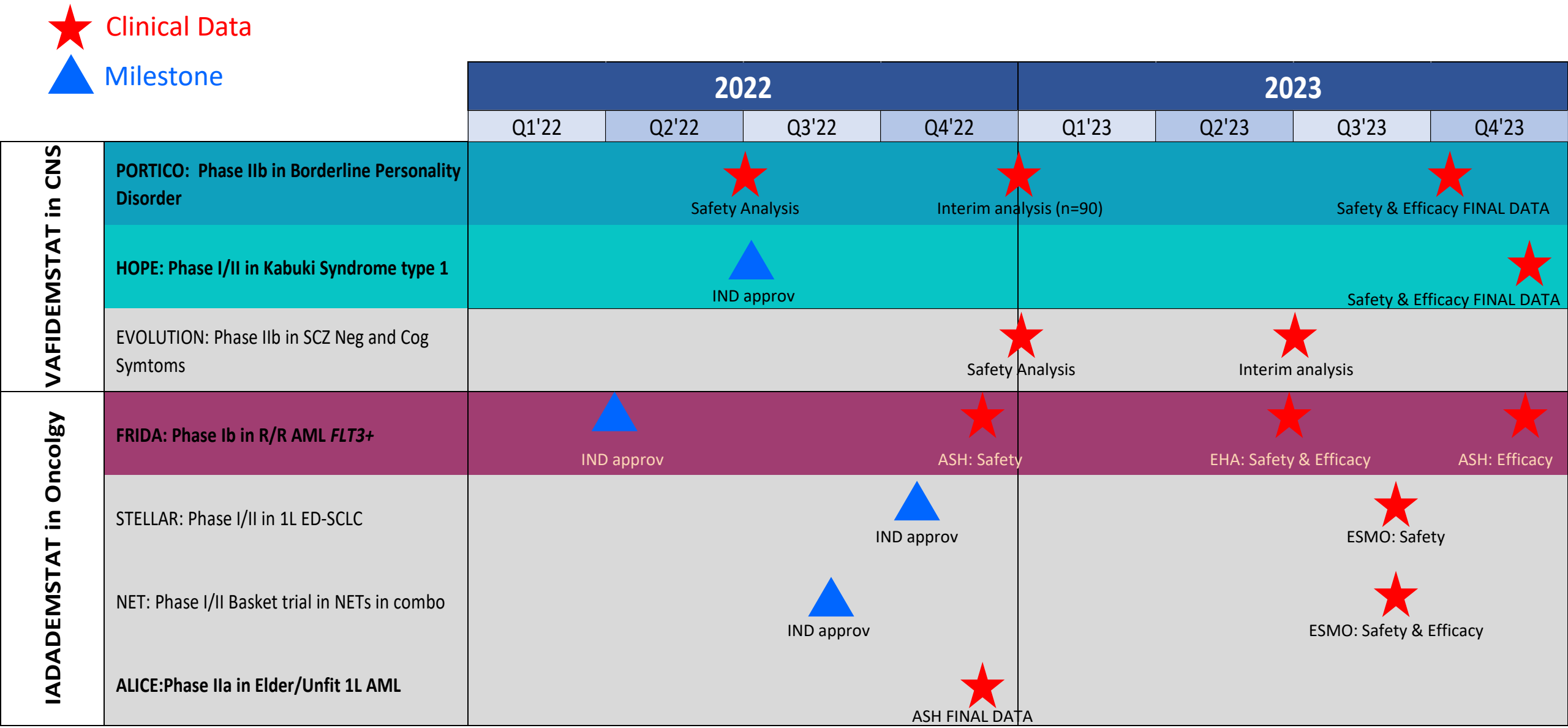
A Phase Ib/II study of iadademstat in combination with synergistic agents in platinum R/R SCLC and extrapulmonary high grade neuroendocrine carcinomas

- **Label expansion opportunity**
- **High unmet medical need: Treatment of platinum relapsed (<6 mos)**
- **Low hanging fruit: NETs has dismal outcomes** ranging from ORR 5% (extrapulmonary) to ~20-30% in SCLC; and PFS 3 to 4 months respectively
- **Strong rationale** for combination of iadademstat with nonTCP-inducing synergistic agents in several tumors
- 2 cohorts (SCLC and extrapulmonary NETs)
- Phase Ib objectives: evaluate safety/tolerability, and determine the RP2D and MTD of the combinations
- Phase II objective: evaluate efficacy of the combination measured as ORR
- IND submission 1H2022 / FPI 2H2022

- SEER database estimated that the incidence of NETs in the US was 6.98 cases per 100,000 people in 2012. This analysis suggested that the incidence of NETs is increasing and that the prevalence of individuals with NETs in the US may exceed 170,000*. Approximately 40% of the SCLC pts wit ED receive second line systemic therapy.
- There is no SoC for these patients. Currently patients are treated with salvage chemotherapy (topotecan, temozolomide, irinotecan, taxanes or lurbinectedin for platinum resistant patients)

* NCCN Neuroendocrine and adrenal tumors v. 4.2021 Dec 2021

2022-23 Company Milestones & Principal investment thesis



ORYZON

A unique dual EPIGENETIC proposition in CNS and ONCOLOGY

- A validated approach with multiple shots on goal
- One and only epigenetic company in CNS
- 2 Phase II programs
- Differentiated pipeline of first- and potentially best-in-class LSD1 therapies
- Derisked: Safety proven in 400+ subjects dosed

Value Creation in 2022-23

Multiple inflection points

- Final data for 1L AML PoC ALICE
- Read-out Phase IIb in BPD
- Kabuki Syndrome Phase I/II trial start in 2022 with potential to support registration. Read-out end 2023
- 1L ED-SCLC and 2L AML trials start in 2022 with potential to support accelerated development
- Additional trial initiations in Oncology & CNS

Pioneering personalized medicine in epigenetics