

# **Oryzon Genomics**

# Favourable safety reported in PORTICO Phase II

Oryzon presented a positive update on vafidemstat's ongoing Phase IIb PORTICO trial in borderline personality disorder (BPD) at the ECNP Congress. The aggregated blinded safety data, as of 23 August, demonstrated a well-tolerated safety profile for a cohort with baseline characteristics reflecting real-world demographics of a typical BPD population. This is a critical consideration for therapies to progress and be successful once commercialised. We also note a low rate of discontinuations (2%) due to treatment-emergent adverse events (TEAEs) and zero discontinuations attributed to serious TEAEs. Screen failure and dropout rates, at 37% and 21%, respectively, were also favourable compared to other agents in development for BPD, such as brexpiprazole, which had higher rates (62% and 27%). As a reminder, the primary objective of the PORTICO trial is efficacy of vafidemstat, and we anticipate top-line data in Q124. Although the shared data was blinded, the overall results suggest a favourable safety profile for vafidemstat and we await next year's efficacy readout as (if positive) it will be a key catalyst and potentially increase the probability of success for vafidemstat in BPD.

	Revenue	PBT*	EPS*	DPS	P/E	Yield
Year end	(€m)	(€m)	(€)	(€)	(x)	(%)
12/21	10.6	(7.2)	(0.09)	0.0	N/A	N/A
12/22	15.7	(6.4)	(0.07)	0.0	N/A	N/A
12/23e	17.3	(4.2)	(0.03)	0.0	N/A	N/A
12/24e	19.0	(10.0)	(0.14)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

At the ECNP Congress, Oryzon presented aggregated baseline characteristics, demographics and safety data from the ongoing <a href="Phase IIb PORTICO trial">Phase IIb PORTICO trial</a> in BPD. Analyses of aggregated blinded data, as of 23 August 2023, indicate a 2% discontinuation rate due to TEAEs and no discontinuations due to serious TEAEs. Additionally, screen failure (37%) and dropout rates (21%) appear favourable when compared to other agents in development for BPD, such as brexpiprazole, which reported screen failure and dropout rates of 62% and 27%, respectively.

The baseline data demonstrated that the trial enrolled a representative real-world BPD population as it allowed patients with common comorbidities and concomitant medications typically excluded in other BPD trials. This is a critical consideration as the therapy progresses through the clinical and regulatory phases and potential launch, as it seeks to address the needs of a broader patient population. Currently there are no drugs specifically approved for BPD patients and there is a significant unmet need.

As a reminder, PORTICO is a global, double-blind, randomised, placebo-controlled, adaptive 14-week Phase IIb trial evaluating the efficacy and safety of vafidemstat. The primary objectives are to investigate vafidemstat's efficacy in treating agitation and aggression, as well as overall disease severity. The trial is fully recruited and top-line results are anticipated in Q124.

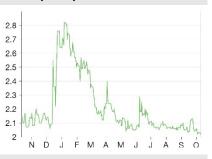
## Operational update

## Pharma and biotech

#### 11 October 2023

Price	€2.03
Market cap	€118m
Net debt at 30 June 2023	€1.56m
Shares in issue	57.9m
Free float	80%
Code	ORY
Primary exchange	Madrid Stock Exchange
Secondary exchange	N/A

### Share price performance



## **Business description**

Oryzon Genomics is a Spanish biotech focused on epigenetics. ladademstat is being explored for acute leukaemias, small-cell lung cancer and neuroendocrine tumours. Vafidemstat, its central nervous system (CNS) asset, has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder is now the lead study, but Oryzon is rapidly expanding its CNS R&D pipeline.

## **Analysts**

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