EDISON

Oryzon Genomics

H122 update

Encouraging safety data in PORTICO

Pharma and biotech

Oryzon Genomics has announced promising preliminary blinded aggregate safety data from its ongoing Phase IIb PORTICO trial at the 10th European Conference on Mental Health. The study is investigating the use of vafidemstat, the company's lead asset in central nervous system (CNS) indications, for the treatment of borderline personality disorder (BPD). From the initial randomised 43 enrolled patients, no serious adverse events were reported, indicating that treatment was well tolerated. Additionally, following review by the independent data monitoring committee for PORTICO, the study received approval to continue. We see this as positive for the clinical development of vafidemstat, ensuring the trial remains on track to deliver interim readouts in Q123, representing the next major catalyst for the PORTICO trial. We continue to value Oryzon at €802m, or €15.1/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/20	9.5	(4.8)	(0.07)	0.0	N/A	N/A
12/21	10.6	(7.2)	(0.09)	0.0	N/A	N/A
12/22e	9.9	(7.0)	(0.10)	0.0	N/A	N/A
12/23e	10.0	(7.3)	(0.10)	0.0	N/A	N/A

Note: *Normalised, excluding amortisation of acquired intangibles and exceptional items.

It is estimated that c 1.6% of the US population suffers from BPD; however, with no drugs specifically approved for BPD, treatment for this indication remains an unmet need. As a reminder, the PORTICO study is a randomised, double-blind, placebo-controlled adaptive 14-week trial that aims to assess the efficacy of vafidemstat in the treatment of BPD. The trial's two primary endpoints aim to measure overall clinical BPD improvement and improvement in aggression symptoms. The latest safety data reported 41 adverse events (AEs) across 12 patients; however, the AEs were only mild with no patient discontinuation. In our view the recorded AEs do not represent a significant risk for the study. Moreover, the data aligns with aggregated safety data from seven previously completed Phase IIa studies, across which 300 patients have been treated with vafidemstat.

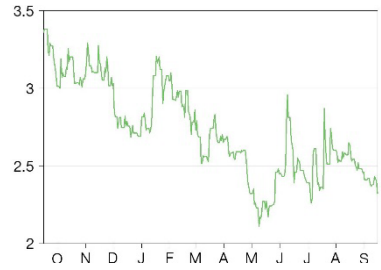
The PORTICO trial is currently active in four European countries (2020-003469-20) and the United States (NCT04932291) and aims to enrol up to 156 patients. Interim efficacy data (90 patients) is expected in Q123, with final readouts from the study anticipated in Q423.

Oryzon is also investigating vafidemstat in two further CNS indications, the ongoing Phase IIb EVOLUTION study in schizophrenia and the Phase Ib/II HOPE study in Kabuki syndrome, which is expected to begin recruiting patients in Q123.

16 September 2022

Price	**€2.32**
Market cap	**€125m**
	US$1.07/€
Net cash (€m) at 30 June 2022	5.37
Shares in issue	54.0m
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 company focused on epigenetics. Iadademstat is being explored for acute leukaemias and small-cell lung cancer. Vafidemstat, its central nervous system asset, has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder is now the lead study. Oryzon is rapidly expanding its central nervous system R&D pipeline.

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