EDISON

Oryzon Genomics

Clinical update

Promising PORTICO interim results

Pharma and biotech

Oryzon has announced promising results from an interim analysis of the Phase IIb PORTICO study, a trial evaluating vafidemstat as a treatment for borderline personality disorder (BPD). An independent data monitoring committee (IDMC) conducted an analysis of the first 90 patients who completed the treatment and recommended that the trial continue without any modifications to the design. These interim results, along with positive safety data reported in September 2022, are encouraging for the clinical development of vafidemstat in this indication, in our view. Management anticipates that top-line data will be shared in early 2024 and we believe this represents the next most significant catalyst for the PORTICO trial.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/21	10.6	(7.2)	(0.09)	0.0	N/A	N/A
12/22	15.7	(6.6)	(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, other income and exceptional items.

Oryzon specialises in treatments for central nervous system (CNS) and oncology indications. The company's lead CNS asset, vafidemstat, is a novel drug targeting the epigenetic modulator lysine-specific demethylase 1 (LSD1). The PORTICO study is a Phase IIb multicentre, double-blind, randomised, placebo-controlled trial investigating the use of vafidemstat for the treatment of BPD. In September 2022, Oryzon reported no serious adverse events from the first 43 patients enrolled in the trial and that approval for the study to continue was granted by an IDMC. The two independent primary objectives for the trial are improvements in agitation and aggression, as well as overall improvement of BPD.

This month, Oryzon announced the results from an interim analysis of the first 90 patients completing the treatment. This analysis, again conducted by an IDMC, has determined the trial to be non-futile and recommended that it should continue without any modifications. The results of this analysis provide further support that vafidemstat is a safe and well-tolerated drug and has the potential to be an effective treatment for BPD. The trial is actively recruiting patients in Europe and the United States, with the aim to enrol around 188 patients in total.

Management has said that top-line data will be available in early 2024, at which point Oryzon will carefully assess the primary, secondary and exploratory endpoints. A decision will then be made on next steps for the clinical development of vafidemstat in CNS indications and this may involve a follow-on Phase III clinical trial in BPD. We believe that the announcement of top-line data in early 2024 represents the next most significant catalyst for the PORTICO trial and Oryzon's CNS portfolio.

Vafidemstat is also under development in the CNS space for the treatment of schizophrenia in the EVOLUTION study and updates are expected in 2023. Oryzon is also expecting to launch this year a personalised medicine programme for Kabuki syndrome (a rare CNS indication) as the therapeutic mechanism of LSD1 inhibition has been validated in pre-clinical studies.

4 April 2023

Price	**€2.40**
Market cap	**€135m**
Net cash (€m) at end-December 2022	4.0
Shares in issue	56.3m
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. Iadademstat 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.

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