EDISON

Oryzon Genomics

Clinical update

Positive safety data for vafidemstat in PORTICO

Pharma and biotech

Oryzon has announced positive aggregate safety data for vafidemstat, which is being evaluated in the ongoing PORTICO trial as a potential treatment for borderline personality disorder (BPD). The independent data monitoring committee (DMC) has reviewed the safety data from the first 167 patients treated in the trial and reported no cases of treatment-related serious adverse events (AEs) or deaths. The DMC has therefore recommended that PORTCIO proceeds without modification until patient enrolment is completed (expected n=188), which is anticipated to be in Q323. We view this as an encouraging update for the clinical development of vafidemstat and believe that the announcement of top-line data, expected in Q124, may represent the next most significant catalyst for the PORTICO trial and for Oryzon's central nervous system (CNS) portfolio.

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	(6.4)	(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, other income and exceptional items.

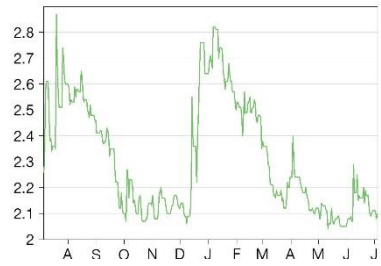
Oryzon has shared positive aggregate safety data from the ongoing PORTICO trial. The safety review was conducted by the independent DMC and was based on the initial 167 randomised participants in the trial as of the 23 May 2023 data cut-off. From the blinded data, there were no reports of treatment-related serious AEs or deaths. An aggregated number of 306 AEs have been reported, affecting a total of 98 patients treated with either vafidemstat or a placebo. It was noted that most of these AEs were considered mild (216) or moderate (78). Only a small number of AEs reported to date have been considered severe (12), affecting nine patients, six of which have discontinued treatment or withdrawn from the trial. We note that this blinded PORTICO safety review is aligned with aggregate safety data from seven completed trials involving vafidemstat, across which around 400 patients have been treated with the drug. Independent DMC members also reviewed the unblinded data and recommended that PORTICO continue without modification. The results of this review provide further support that vafidemstat is a safe and well-tolerated drug and has the potential to be an effective treatment for BPD, in our view.

As a reminder, vafidemstat is a novel drug targeting epigenetic modulator lysine-specific demethylase 1 and is Oryzon's lead CNS asset. The PORTICO trial is a multicentre, double-blind, randomised, placebo-controlled, Phase IIb clinical trial assessing vafidemstat for the treatment of BPD. The two independent primary objectives for the trial are improvements in agitation and aggression, as well as overall improvement of BPD severity. An independent interim analysis was conducted in March 2023, based on the first 90 patients who completed at least two thirds of the trial, and it was determined that PORTICO was not futile and should continue without modification or increasing the number of patients to be recruited. The trial plans to recruit 188 patients in total, which is expected to be complete in Q323. We view the top-line data (anticipated in Q124) as a key driving factor in shaping the future development strategy for vafidemstat.

5 July 2023

Price	**€2.10**
Market cap	**€118m**
Estimated net cash (€m) at end-March 2023	0.9
Shares in issue	56.2m
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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