EDISON

Oryzon Genomics

KOL event

KOL event: Offering a real-world solution in BPD

Pharma and biotech

Oryzon hosted a key opinion leader (KOL) event highlighting the potential of vafidemstat in borderline personality disorder (BPD). The KOLs discussed the limited options for treating BPD, as there are no approved drugs, and the current therapies are often ineffective. While the PORTICO trial did not reach statistical significance on its primary endpoints, vafidemstat was favoured over placebo in all efficacy measures, with statistical significance in two key secondary endpoints. During the event, the KOLs shared their perspectives from working with BPD patients, and claimed that improvements of 25% or over, across any measure of overall severity and agitation/aggression, would mark a clinically meaningful outcome. As this was achieved in PORTICO, we believe that vafidemstat has the potential to be an effective treatment option for this underserved patient population. Oryzon is conducting a detailed analysis of the trial results and plans to request an end-of-Phase II (EoP2) meeting with the FDA in Q224 to discuss a registrational Phase III programme.

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	15.9	(6.6)	(0.07)	0.0	N/A	N/A
12/24e	19.0	(10.0)	(0.13)	0.0	N/A	N/A

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

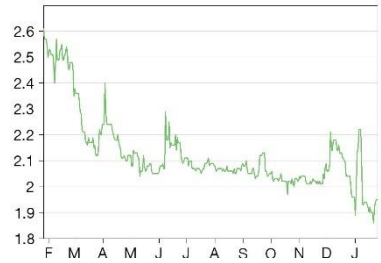
While the top-line PORTICO results did not meet the primary endpoint, we continue to see a sizable opportunity for Oryzon in BPD. We are encouraged that the trial favoured vafidemstat across all primary and secondary efficacy measures, highlighting the broad potential of the drug, in our view. During the KOL event, the KOLs added that as BPD patients can be particularly sensitive to side-effects, the favourable safety and tolerability profile of vafidemstat to date supports further clinical development. The sentiment throughout the event was that BPD is a neglected condition, despite it having a prevalence of 1.6% in the general population, and c 20% in the inpatient psychiatric population. It was also noted that many psychiatric patients with BPD may receive inaccurate diagnoses. Many of these patients take multiple drugs (such as antipsychotics) as there are no approved alternatives, but these are often not effective in managing the condition. However, with the PORTICO results showing that BPD patients saw global improvements, we believe this may offer a glimmer of hope to this underserved population, although we recognize the lack of statistical significance in the PORTICO primary endpoint provides regulatory uncertainty.

Management has re-affirmed its plans to conduct a detailed analysis of the data in Q124. An update from the initial results was the announcement that a statistically significant improvement was observed in an exploratory endpoint measuring cognition, and while we caution against direct read across, this may be a positive sign for Oryzon's ongoing EVOLUTION trial, assessing vafidemstat in schizophrenia. We expect an update on the PORTICO analysis in May (scientific conference) and note that Oryzon plans to request an EoP2 meeting with the FDA in early-Q224. Provided these guided timelines are met, we expect an outcome potentially as early as Q324, which could represent a significant inflection point for the company.

29 January 2024

Price	**€1.95**
Market cap	**€116m**
Gross cash (€m) at end-September 2023 (excluding drawdowns/conversions from the €45m debt facility announced in Q423)	8.4
Shares in issue	59.7m
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 (now the lead programme), and is in a Phase IIb trial in schizophrenia.

Analysts

Soo Romanoff +44 (0)20 3077 5700

Dr Arron Aatkar +44 (0)20 3077 5700

healthcare@edisongroup.com

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London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom