EDISON

Oryzon Genomics

KOL event

KOL event highlights vafidemstat potential in BPD

Healthcare

11 July 2025

At Oryzon Genomics' key opinion leader (KOL) event, vafidemstat's path through Phase III in borderline personality disorder (BPD) was laid out. The significant unmet need was highlighted, as there are currently no FDA-approved drugs specifically indicated for BPD, despite a global prevalence of 1–2%, and clinicians are limited to prescribing medications (such as antipsychotics and/or mood stabilisers) off-label, often with limited durable effectiveness. Given vafidemstat's encouraging track record in the clinic targeting agitation and aggression (A/A) in BPD, alongside its novel epigenetic mechanism of action, the KOLs spoke about their willingness to use vafidemstat with their patients, especially since this symptom domain is one of the most common (70% of patients) and debilitating components of the condition, both for the patients and people around them. Oryzon submitted the protocol for the Phase III PORTICO-2 programme to the FDA in June 2025 and management anticipates receiving regulatory feedback within Q425, potentially representing an important upcoming catalyst.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/23	14.2	(6.1)	(0.06)	0.00	N/A	N/A
12/24	7.4	(5.6)	(0.06)	0.00	N/A	N/A
12/25e	38.9	39.3	0.55	0.00	5.3	N/A
12/26e	43.3	32.0	0.43	0.00	6.8	N/A

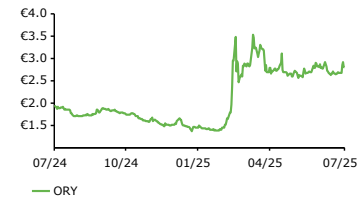
Note: PBT and EPS are normalised, excluding intangibles, exceptional items and share-based payments.

The KOL event effectively outlined vafidemstat's path through Phase III and beyond, with the KOLs communicating that vafidemstat could be an effective new drug to complement current psychotherapy regimes. Oryzon's planned PORTICO-2 programme was also discussed in detail. This is intended to be a randomised, double-blinded, placebo-controlled Phase III trial, aiming to enrol c 350 BPD patients, evaluating vafidemstat treatment over an 18-week period. The STAXI-2 Trait Anger scale (a clinician-rated scale that was used in the prior Phase IIb PORTICO trial) will be employed as the primary patient-reported efficacy measure. This will be used alongside the Overt Aggression Scale-Modified (OAS-M), a clinician-rated scale, as a key secondary endpoint measure. The KOLs agreed that these two endpoints used in parallel should effectively capture both how the patients feel at any given time and how their A/A changes over time. While these primary and secondary endpoints are focused on measuring outcomes based on changes in aggression, additional secondary outcome measures will also be used to assess more general improvements in BPD symptoms and quality of life.

Beyond BPD, the KOL event touched on the potential of vafidemstat to address other neurological conditions in which aggression can be a significant symptom. These include schizophrenia, autism spectrum disorder (ASD) and attention deficit hyperactivity disorder (ADHD). The Phase IIb EVOLUTION trial in schizophrenia is currently ongoing and Oryzon also plans to explore ASD utilising its Med4Cure IPCEI-EU grant. These efforts will aim to build on prior positive data obtained for vafidemstat from the REIMAGINE trial, which demonstrated preliminary efficacy in BPD, ASD and ADHD. These additional programmes have the potential to bolster the value proposition for vafidemstat, in our view, though we acknowledge that they are earlier-stage programmes.

Price	**€2.94**
Market cap	**€231m**
Pro forma net cash at 31 March 2025 (including proceeds from the April 2025 equity raise and grant income)	€31.2m
Shares in issue	78.5m
Free float	82.0%
Code	ORY
Primary exchange	MADRID
Secondary exchange	N/A

Share price performance



Business description

Spanish biotech Oryzon Genomics is focused on epigenetics. Iadademstat is being explored for acute leukaemias, small-cell lung cancer and neuroendocrine tumours. Central nervous system asset vafidemstat has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder (Phase III clinical trial protocol submitted to the FDA). It is also currently involved in a Phase IIb trial for schizophrenia.

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