EDISON

Oryzon Genomics

Clinical data update

Strong iadademstat data supports development

Healthcare

13 May 2026

Oryzon Genomics has announced updated positive data from two iadademstat acute myeloid leukaemia (AML) studies to be presented at EHA 2026, further strengthening the clinical rationale for its LSD1 inhibitor franchise. In the Phase Ib ALICE-2 trial, evaluating iadademstat with venetoclax and azacitidine (VEN-AZA) in newly diagnosed AML, efficacy remains compelling, with 14 evaluable patients (75–80% of planned enrolment) achieving a 100% ORR, a 79% CR rate and a 93% composite complete remission (CRc) rate, improving from the 90% CRc previously reported in the first 10 patients. Separately, updated data from the FRIDA study (iadademstat plus gilteritinib in FLT3-mutated r/r AML) showed a 67% CRc rate across 18 evaluable patients at the selected expansion dose, reinforcing iadademstat's potential utility in both frontline and relapsed AML settings. Top-line ALICE-2 data are expected in Q426 and should support accelerated first-line AML development ahead of the planned ALICE-3 Phase II/III trial in 2027.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/24	7.4	(5.6)	(0.06)	0.00	N/A	N/A
12/25	10.9	(5.6)	(0.04)	0.00	N/A	N/A
12/26e	13.2	(6.6)	(0.05)	0.00	N/A	N/A
12/27e	71.5	44.0	0.58	0.00	4.7	N/A

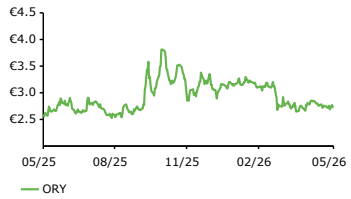
Note: PBT and EPS are normalised, excluding intangibles, exceptional items and share-based payments.

ALICE-2 is an investigator-sponsored Phase Ib trial evaluating iadademstat in combination with VEN-AZA in newly diagnosed AML. While the primary endpoint measure is dose-limiting toxicities, secondary efficacy endpoints include overall response rate (ORR), complete response (CR) rate and CRc, which includes CR, CR with partial haematologic recovery and CR with incomplete recovery (CRi). Positive initial data were presented at ASH 2025 from the first 10 evaluable patients and these efficacy trends have been maintained with the latest update (February 2026 cutoff) showing a CRc rate of 93% across 14 evaluable patients, including a 79% CR rate. At a median follow-up of six months, estimated 12-month overall survival (OS) was 74%. The data compare favourably with the Phase III VIALE-A study (n=431) testing VEN-AZA in previously untreated AML patients, which reported a CR+CRi rate of 66.4% and a CR of 36.7%. While cross-trial comparisons should be interpreted cautiously, we believe this early efficacy, if sustained in larger randomised studies, could position iadademstat as a potentially meaningful addition to frontline AML treatment. Management plans to present data for additional patients at the EHA, followed by topline results (n=20) expected in Q426.

FRIDA is Oryzon's self-sponsored Phase Ib study evaluating iadademstat and gilteritinib in relapsed/refractory (r/r) FLT3-mutated AML. Primary endpoints are safety and recommended Phase II dose, while secondary endpoints include response rates and OS. The study is currently in dose expansion at the selected active dose, with the latest update showing a CRc rate of 67% across 18 evaluable patients, consistent with previously reported ASH 2025 data. We believe the encouraging ALICE-2 data and the evolving frontline AML treatment landscape, where VEN-AZA is increasingly becoming standard-of-care across both chemo-unfit and chemo-fit patients, support the rationale for developing iadademstat in first-line AML. We expect management to pursue the narrower r/r settings as a label expansion opportunity, should the planned ALICE-3 study prove successful.

Price	**€2.76**
Market cap	**€220m**
Net cash/(debt) at 31 December 2025	€16.5m
Shares in issue	79.9m
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 haematological diseases, including acute myeloid leukaemia and sickle cell disease, alongside other indications. 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, and management is preparing for an additional Phase II trial in autism spectrum disorder.

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