EDISON

Oryzon Genomics

Clinical updates

ASH data to reinforce 1L AML opportunity

Healthcare

4 November 2026

Oryzon has announced updated positive clinical data for iadademstat in first-line (1L) acute myeloid leukaemia (AML), with three abstracts accepted for presentation at the American Society of Hematology (ASH) 2026 annual meeting in December. The key findings come from ALICE-2, evaluating iadademstat with venetoclax and azacitidine in newly diagnosed AML patients, unfit for chemotherapy treatment. Among 19 evaluable patients, the overall response rate was 95%, with an 84% composite complete remission (CRc) rate and 74% complete response rate, consistent with the previously reported rates of 100%, 89% and 78%, respectively, across 18 patients. After median follow-up of 8 months, 12-month overall survival (OS) was 76%, with median OS not yet reached. We believe these findings strengthen the rationale for the planned registrational ALICE-3 study.

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)	(0.03)	0.00	N/A	N/A
12/26e	20.0	(7.5)	(0.05)	0.00	N/A	N/A
12/27e	73.8	42.4	0.54	0.00	4.4	N/A

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

The latest ALICE-2 dataset, based on a July 2026 cut-off, continues to show encouraging efficacy and manageable safety for the iadademstat triplet combination treatment. Looking beyond the top-line OS figures, patients with ELN2022 intermediate- or adverse-risk disease had estimated 12-month OS of 100% and 74%, respectively. Importantly, the high proportion of adverse-risk patients (82% of enroled patients) adds further encouragement to the findings, in our view, suggesting that the clinical activity extends to populations where existing treatment outcomes remain particularly challenging. While we highlight that the small dataset warrants caution, we view the sustained remission rates and early survival findings as supportive of advancing iadademstat in 1L AML.

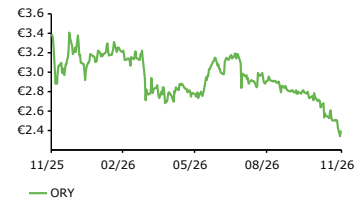
The FRIDA Phase Ib study, evaluating iadademstat with gilteritinib in heavily pre-treated FLT3-mutated relapsed/refractory AML, also had an update, reporting a 67% CRc rate and 31% estimated 12-month OS at the recommended Phase II dose, with manageable safety. Separately, interim findings from an ongoing Phase II myeloproliferative syndromes study showed a 50% acute leukaemia partial response rate with iadademstat plus ASTX727, without dose-limiting toxicities. Although preliminary, these results provide additional evidence of iadademstat's activity across haematological malignancies.

Oryzon also recently announced Spanish regulatory authorisation for VIVALDI, a CETLAM-sponsored Phase Ib study evaluating iadademstat in combination with venetoclax and azacitidine in newly diagnosed AML patients with poor prognostic features, including TP53 and RAS pathway mutations. The study will involve 13 Spanish hospitals and should provide complementary clinical evidence and operational experience to support the European arm of ALICE-3.

ALICE-3 is being planned as a potentially registrational Phase III study in 1L AML, targeting initiation in 2027, subject to regulatory agreement and financing. The programme is expected to prioritise high- (TP53 mutations) and intermediate-risk (RAS mutations) patients. The reported tolerability, acceptable haematological recovery and emerging dose-selection evidence should help inform the trial design.

Price	**€2.39**
Market cap	**€202m**
	$1.12/€
Pro forma net cash at 30 June 2026 (including €12m raise in July 2026)	€17.0m
Shares in issue	84.3m
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 AML and sickle cell disease, alongside other indications. CNS asset vafidemstat has completed several Phase IIa trials and a Phase IIb trial in BPD (Phase III in preparation). It is also involved in a Phase IIb trial for schizophrenia, and management has regulatory clearance for an additional Phase II trial in Phelan-McDermid Syndrome.

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