EDISON

Oryzon Genomics

Clinical update

EHA data maintain first-line AML momentum

Healthcare

11 June 2026

Oryzon has presented updated positive data from two Phase Ib iadademstat acute myeloid leukaemia (AML) studies at the European Hematology Association (EHA) 2026 Annual Congress, with the key new information (vs the May update) coming from a larger and more mature ALICE-2 dataset. In ALICE-2 (iadademstat with venetoclax and azacitidine in newly diagnosed AML), 18 evaluable patients achieved a 100% overall response rate (ORR), with an 89% composite complete remission (CRc) rate and a 78% complete response (CR) rate (this builds on the May update, where there were 14 evaluable patients, a 100% ORR, 93% CRc rate and 79% CR rate). Importantly, the EHA data add detail in adverse-risk subgroups, with all patients with TP53 or RAS pathway mutations achieving CR. Median overall survival (OS) was not reached after a median follow-up of eight months, with estimated 12-month OS of 79%. Final ALICE-2 data are expected by year-end, ahead of a potential registrational first-line AML study in 2027. FRIDA data (FLT3-mutated relapsed/refractory (r/r) AML) remained consistent, with a 67% CRc rate, highlighting the promise of the candidate in difficult-to-treat disease settings.

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	16.8	(7.7)	(0.07)	0.00	N/A	N/A
12/27e	68.5	42.1	0.56	0.00	5.5	N/A

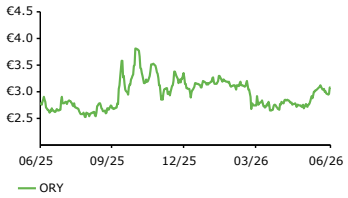
Note: PBT and EPS are normalised, excluding intangibles, exceptional items and share-based payments.

Key incremental details from the EHA update were the ALICE-2 outcomes in genomically defined adverse-risk patients. All patients with TP53-mutated disease (n=2) achieved CR, with TP53 variant allele frequency reduced from 14% to undetected in one patient and from 22% to 1% in the other. All patients with RAS pathway mutations (n=3) also achieved CR. While the populations remain small and require confirmation in larger studies, the data are relevant as Oryzon plans to focus the planned ALICE-3 trial on such adverse-risk populations, where current outcomes remain poor. The latest update also confirmed that responses remain early, with most CRs occurring in cycle 1, and that the triplet continues to show a favourable safety profile, laying a robust foundation for further development efforts. The survival and transplant data also add maturity to the May update. After the median follow-up of eight months, median OS and event-free survival (EFS) were not reached, with an estimated 12-month OS and EFS of 79% and 71%, respectively. Nine patients successfully transitioned to allogeneic haematopoietic cell transplantation, reflecting improvements in their health, with an estimated 12-month OS of 88% in this subgroup. This supports the rationale that deeper early responses may translate into more patients becoming eligible for potentially curative transplant.

The FRIDA data remain supportive. The study evaluates iadademstat with gilteritinib in FLT3-mutated r/r AML, with 23 patients enroled at the selected pharmacologically active dose and 18 evaluable for response. The CRc rate remained 67% in this heavily pre-treated population, and the combination was reported to have a manageable safety profile, without adding toxicity to standard-of-care gilteritinib. We continue to view FRIDA as supportive of iadademstat's broader AML activity, though we highlight that the current strategic priority remains first-line AML through ALICE-2 (now >80% enroled), and the planned ALICE-3 Phase II/III trial in 2027.

Price	**€3.11**
Market cap	**€248m**
Net cash/(debt) at 31 March 2026	€11.1m
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 (CNS) 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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