EDISON

Oryzon Genomics

Clinical update

ASH 2025: Promising iadademstat updates

Healthcare

9 December 2025

Oryzon Genomics announced the presentation of promising updates for two clinical studies involving iadademstat at the American Society of Hematology (ASH) 67th Annual Meeting. Notably, a Phase Ib trial (ALICE-2) testing the candidate in combination with azacitidine and venetoclax showed a 100% overall response rate (ORR) across 10 newly diagnosed acute myeloid leukaemia (AML) patients, and a composite complete remission (CCR) rate of 90%. The second update corresponds to the lead FRIDA programme (iadademstat plus gilteritinib in FLT3-mutant relapsed/ refractory (r/r) AML), showing a CCR rate of 67% across 15 evaluable patients at the selected dose level. Importantly, across both studies, iadademstat was safe and well tolerated, which, alongside the encouraging efficacy data, positions it favourably for further development efforts, in our view. Oryzon is exploring partnership opportunities for iadademstat to unlock its full value.

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	9.5	(4.7)	(0.02)	0.00	N/A	N/A
12/26e	48.3	35.9	0.48	0.00	6.8	N/A

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

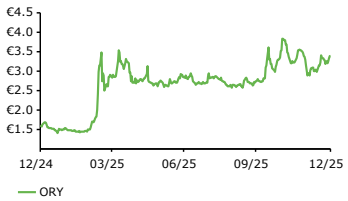
ALICE-2, sponsored by Oregon Health & Science University, is a Phase Ib trial investigating the synergy between iadademstat, azacitidine and venetoclax, in AML. While the primary endpoint measure is dose-limiting toxicities, secondary endpoints focus on efficacy, including ORR and CCR, where CCR includes: complete remission (CR); CR with partial haematologic recovery (CRh); and CR with incomplete recovery (CRi). Data from the first 10 patients showed an encouraging ORR of 100% and a CCR rate of 90% (including a CR rate of 80%). Median overall survival (OS) was not reached, and the six-month OS rate was 66%. Dose-finding for maximum tolerated dose (MTD) determination is ongoing, and the trial continues to enrol patients, planning to reach 21 MTD-evaluable patients. Importantly, the triple combination was found to be safe and well tolerated.

FRIDA is a self-sponsored Phase Ib programme, testing iadademstat plus gilteritinib in r/r AML patients harbouring the FLT3 mutation. Primary outcome measures focus on treatment-emergent adverse events and determination of the recommended Phase II dose, while secondary endpoints include response rates, including CR, CCR and OS. According to the latest update, 37 patients were enrolled, with four dose-level cohorts evaluated in the escalation stage. The study is now in the expansion stage at one selected active dose, where there are 17 patients enrolled at this level; the combination has been well tolerated thus far. Preliminary efficacy data show a CCR rate of 67%, and a CR+CRh rate of 47%, in the 15 evaluable patients at this dose. We believe this compares favourably to the monotherapy data for gilteritinib (CR+CRh rate of 34%). We also highlight that approximately half of the patients included in this trial had previously failed on venetoclax treatment, meaning it includes a population known to exhibit poor responses to gilteritinib monotherapy, who are in urgent need of more effective treatment options.

We believe the updates exemplify the potential of iadademstat in these difficult-to-treat indications, adding to the promising data package for the candidate, as management seeks partnership opportunities.

Price	**€3.22**
Market cap	**€257m**
	US$1.17/€
Net cash at 30 September 2025	€20.7m
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 malignancies, small-cell lung cancer and additional 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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