EDISON

# Oryzon Genomics

Clinical update

## Progress for iadademstat across the board

Healthcare

4 November 2025

**Oryzon has announced encouraging updates for iadademstat. In acute myeloid leukaemia (AML), positive data was reported for two programmes, including the lead oncology programme, FRIDA. Updated interim data from FRIDA (iadademstat in combination with gilteritinib in relapsed/refractory AML) showed an overall response rate (ORR) of 67%, suggesting improved outcomes compared to gilteritinib alone. In a separate Phase I study exploring the synergy between iadademstat, venetoclax and azacitidine, in newly diagnosed AML, the preliminary interim data (n=8) showed a 100% ORR. We view this as a positive indicator of the novel combination, but we acknowledge that it is from a relatively small population. Beyond malignant haematological indications, Oryzon has also enrolled the first patient in its sickle cell disease (SCD) trial. If successful, we believe this could bolster the value proposition for iadademstat, with applications beyond oncology.**

| 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 | 8.9 | (3.9) | (0.01) | 0.00 | N/A | N/A |
| 12/26e | 48.3 | 35.9 | 0.48 | 0.00 | 7.3 | N/A |

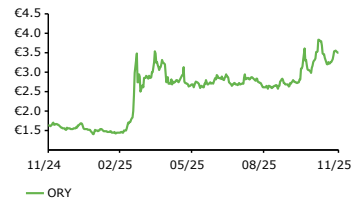
Note: PBT and EPS are normalised, excluding intangibles, exceptional items and share-based payments.

Three abstracts relating to iadademstat were accepted for the American Society of Hematology (ASH) Annual Meeting (December 2025), including positive clinical updates in AML. The Phase Ib FRIDA trial explores the recommended Phase II dose (RP2D), safety and tolerability of iadademstat plus gilteritinib in second-line AML. According to the latest update, 34 patients were enrolled, with four dose-level cohorts evaluated in the escalation stage. With the combination considered tolerable at the tested doses, FRIDA is in the expansion stage at one of these doses. Of the 12 evaluable patients at this dose, a 67% ORR, and a 58% complete response (CR) rate were reported, comparing favourably to monotherapy data for gilteritinib (CR rate <50%). The second AML update corresponds to the Oregon Health & Science University-sponsored study in first-line AML, in combination with venetoclax and azacitidine. Preliminary data from the first eight patients show the combination is safe, and led to an ORR of 100%, with 88% achieving complete remission. Encouragingly, after a median follow-up of nine months, the estimated six-month overall survival was 88%, without any dose-limiting toxicities. Updated data will be presented at ASH 2025, which we expect will highlight the potential of iadademstat as an effective new treatment option in this difficult-to-treat indication. The third abstract will present a new trial in myeloproliferative neoplasms, testing iadademstat plus ASTX727 (oral decitabine and cedazuridine). This is sponsored by the National Cancer Institute and represents an expandable opportunity.

Separately, Oryzon announced the first patient has been enrolled in the RESTORE trial, swiftly following regulatory clearance from the EMA. This is a Phase Ib, multi-centre, open-label study assessing iadademstat in adults with SCD. It will recruit c 40 patients and assess safety and tolerability in this population. It will also determine the RP2D, and measure effects in inducing foetal haemoglobin (HbF) expression (increases in HbF is an FDA-recognised outcome considered clinically meaningful for treating SCD). Since iadademstat has demonstrated safety in c 200 participants in prior clinical trials, the RESTORE study represents a potentially expandable opportunity for Oryzon, exploring iadademstat beyond oncology indications.

| | |
|---|---|
| **Price** | **€3.56** |
| **Market cap** | **€284m** |
| Pro forma net cash/(debt) at 30 June 2025 (including the €13.3m grant income received in July 2025) | €26.3m |
| 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.

### Analysts

Jyoti Prakash, CFA +44 (0)20 3077 5700
Arron Aatkar, PhD +44 (0)20 3077 5700

healthcare@edisongroup.com
Edison profile page

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London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom