EDISON

Oryzon Genomics

Company update

ALICE data published in *The Lancet Haematology*

Pharma and biotech

Oryzon Genomics has announced the publication of the final ALICE trial results in the recognised peer-reviewed journal *The Lancet Haematology*. The Phase IIa trial investigated iadademstat (Oryzon's lead oncology LSD1 inhibitor) in combination with azacitidine for the treatment of acute myeloid leukaemia (AML) in newly diagnosed elderly/unfit patients. The trial demonstrated strong efficacy signals, with an objective response rate (ORR) of 81.5%, with three patients still on treatment through compassionate use and in complete remission after four years from the start of treatment. A Phase Ib, investigator-sponsored, dose-finding study evaluating iadademstat (in combination with azacitidine and venetoclax) in the first-line setting is expected to start recruitment by mid-2024. We note that the company's near-term focus is the Phase Ib FRIDA study (in patients with advanced AML with an FLT3 mutation), from which interim data is expected imminently.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/22	15.7	(6.3)	(0.07)	0.0	N/A	N/A
12/23	14.2	(6.0)	(0.06)	0.0	N/A	N/A
12/24e	12.9	(4.1)	(0.03)	0.0	N/A	N/A
12/25e	33.7	15.4	0.29	0.0	6.9	N/A

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

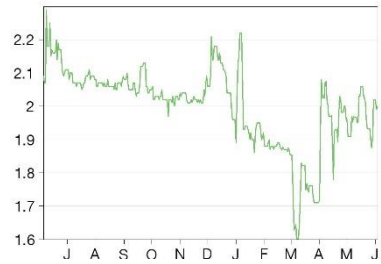
The Lancet Haematology is a recognised peer-reviewed medical journal and we see the publication of the final data from the ALICE trial as a reflection of Oryzon's efforts in the epigenetics space. The Phase IIa trial was an open-label study assessing the safety, tolerability, efficacy and optimal dosing of iadademstat in combination with standard-of-care (SoC) azacitidine as a first-line therapy in adult patients (n=27) with AML. Final results from the trial were presented in December 2022, demonstrating an ORR of 81.5% (22/27). Fourteen patients (52%) achieved complete remission (CR) or CR with incomplete haematological recovery (CRi), with 10 of the 11 evaluable CR/CRi patients testing negative for measurable residual disease. More importantly, the treatment showcased efficacy in patients with difficult to treat mutations, such as M5 AML (typically non-responsive to SoC, three patients with the mutation achieved CR/CRi in the trial) and TP53 (CR/CRi rate of 63%), indicative of the treatment's potential broad applicability. All three patients with the FLT3 mutation responded to the treatment.

Oryzon now plans to evaluate iadademstat in combination with azacitidine and venetoclax (in first-line AML patients under an investigator-sponsored Phase Ib trial, led by Oregon Health and Science University), recruitment for which is expected to commence by mid-2024. However, we expect that the emphasis will be on the in-house Phase Ib FRIDA study, due to present interim readouts imminently (at the European Hematology Association Congress to be held between 13 and 16 June 2024). The study, assessing iadademstat in combination with gilteritinib as second-line treatment (relapsed/refractory AML patients with FLT3 mutation), aims to recruit c 45 patients, with the first two cohorts (13 patients) completed and a third cohort currently being recruited. Another key near-term catalyst will be the initiation of the Phase I/II CRADA-MSKCC study (evaluating iadademstat in combination with checkpoint inhibitors for first-line, extensive-stage small cell lung cancer), expected to start by mid-2024.

4 June 2024

Price	**€2.00**
Market cap	**€124m**
Net debt (€m) at 31 March 2024	3.7
Shares in issue	62.0m
Free float	82%
Code	ORY
Primary exchange	Madrid Stock Exchange
Secondary exchange	N/A

Share price performance



Business description

Oryzon Genomics is a Spanish biotech focused on epigenetics. Iadademstat is being explored for acute leukaemia, small-cell lung cancer and neuroendocrine tumours. Vafidemstat, its central nervous system asset, has completed several Phase IIa trials and a Phase IIb trial for borderline personality disorder (now the lead programme), and is in a Phase IIb trial for schizophrenia.

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