EDISON

Oryzon Genomics

Clinical data update

Encouraging interim update on FRIDA

Pharma and biotech

Oryzon Genomics has reported positive interim data from the Phase Ib FRIDA study, evaluating iadademstat in combination with gilteritinib in advanced acute myeloid leukaemia (AML) patients. Results from the first two cohorts (13 patients) showed a favourable safety profile and efficacy signals, with 69% of patients reporting bone marrow (BM) blast cell clearance in the first cycle. Moreover, 38% of patients achieved complete remission with full or partial hematologic or blood count recovery. While we caution against direct read-across between clinical trials, this compares favourably to the 26.3% rate (excluding remissions after bone marrow transplantation during the trial) delivered by gilteritinib in the Phase III ADMIRAL study, potentially supporting the synergy of the combination. Oryzon noted that the first two cohorts achieved full target engagement and indicated the scope for dose reduction (to aid faster platelet recovery) under the FDA's OPTIMUS guidance. A third cohort is being recruited following this guidance.

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	6.6	N/A

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

The Phase Ib FRIDA study (n=45) is an open-label, single-arm trial assessing iadademstat in combination with gilteritinib as a second-line treatment for relapsed/refractory AML patients harbouring an FMS-like tyrosine kinase 3 mutation. The first part of the study aims to identify the minimum safe and biologically active dose. This will be followed by an expansion stage at the selected dose to assess the efficacy of the combination.

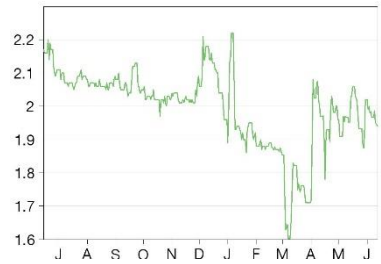
Interim data from the first two cohorts treated over a four-week period (cohort one: n=6, 100µg iadademstat; cohort two: n=7, 75µg iadademstat) was presented at the European Hematology Association Congress. Of the 13 patients treated, 11 were refractory to standard treatments, such as induction chemotherapy, venetoclax and the targeted therapy midostaurin, and two had prior bone marrow transplants. The results demonstrated a favourable safety profile for the combination with no drug-drug interaction, or dose limiting toxicities. Encouraging efficacy signals were observed with 69% of the patients (nine of 13) achieving BM blast leukaemia cell clearance in the first cycle. Roughly 38% of the patients (five of 13) achieved either complete remission (CR), complete remission with partial haematological recovery (CRh) or complete remission with incomplete blood count recovery. This compares favourably to the Phase III results (ADMIRAL study) from the FLT3 inhibitor, gilteritinib, which reported a CR/CRh of 26.3% in the comparable treatment cohort, though we caveat that the results from the FRIDA study will need to be reproduced in randomised studies to confirm superior efficacy.

Management noted that the first two cohorts achieved full LSD1 target engagement (c 90%) supporting the case for dose reduction. This should also aid faster platelet count recovery in the BM, which may result in improved response rates. Cohort three, which has already recruited two participants, will assess the 75µg dose but for a three-week period. We expect rolling updates in H224.

14 June 2024

Price	**€1.90**
Market cap	**€118m**
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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