EDISON

Oryzon Genomics

Clinical update

Clinical milestone reached with FRIDA initiation

Pharma and biotech

Oryzon Genomics has announced it has enrolled the first patient in its Phase Ib FRIDA study investigating iadademstat in combination with Astellas' FDA-approved FLT3 inhibitor gilteritinib to treat FLT3+ relapsed/refractory (r/r) acute myeloid leukaemia (AML) patients. The FRIDA study is central to Oryzon's overall strategy as management believes the second-line AML setting may represent a potentially quicker route to market for iadademstat, targeting an AML patient population with limited and sub-optimal treatment options. FRIDA will recruit up to 45 patients across 10–15 trial sites in the United States and, in our view, its initiation marks a significant clinical milestone for the company.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/21	10.6	(7.2)	(0.09)	0.0	N/A	N/A
12/22	15.7	(6.6)	(0.07)	0.0	N/A	N/A
12/23e	17.3	(4.2)	(0.03)	0.0	N/A	N/A
12/24e	19.0	(10.0)	(0.14)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, other income and exceptional items.

The FRIDA trial is an open-label, multi-centre study with the primary objective of assessing the safety and tolerability of the iadademstat and gilteritinib combination in r/r FLT3+ patients, and to determine the Recommended Phase 2 Dose (RP2D) for the drug combination. Key secondary outcomes from the study include early efficacy assessments to measure rates of complete remission and complete remission with partial haematological recovery (CR/CRh), duration of treatment response and levels of measurable residual disease (MRD). Approximately 50% of patients relapse after first-line AML treatment and 30% possess an FLT3 mutation, with gilteritinib monotherapy currently the standard of care. The median overall survival for gilteritinib treatment is 9.3 months in r/r FLT3+ patients and, in our view, combinational treatments such as iadademstat may provide scope for synergistic efficacy enhancements.

Iadademstat has already demonstrated an encouraging safety and efficacy profile in first-line AML patients, with positive data reported from the recently completed Phase II ALICE study. In our view, a potentially promising result from this trial was the observation that those evaluable AML patients (n = 3) possessing an FLT3 mutation (FLT3+) all responded to iadademstat treatment. However, we acknowledge that the current data only represent a small number of patients so there may be limitations in extrapolating from this finding.

While FRIDA represents one of Oryzon's key strategic priorities, iadademstat is also being investigated in a Phase II study in collaboration with the Fox Chase Cancer Center for the treatment of high-grade neuroendocrine carcinomas and planning for a Phase Ib/II trial (STELLAR) in metastatic small-cell lung cancer is underway.

16 March 2023

Price	**€2.11**
Market cap	**€119m**
Net cash (€m) at end-December 2022	4.0
Shares in issue	56.3m
Free float	80%
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 leukaemias, small-cell lung cancer and neuroendocrine tumours. Vafidemstat, its central nervous system (CNS) asset, has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder is now the lead study, but Oryzon is rapidly expanding its CNS R&D pipeline.

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