

# **Oryzon Genomics**

Clinical milestone reached with FRIDA initiation

Oryzon Genomics has <u>announced</u> it has enrolled the first patient in its <u>Phase Ib</u> 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.

ladademstat has already demonstrated an encouraging safety and efficacy profile in first-line AML patients, with positive data reported from the recently completed <a href="Phase II ALICE study">Phase II ALICE study</a>. 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 <a href="Phase II">Phase II</a> 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.

Clinical update

Pharma and biotech

16 March 2023

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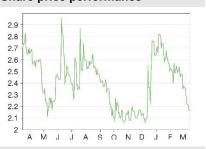
Price €2.11 Market cap €119m

Net cash (€m) at end-December 2022 4.0

Shares in issue 56.3m
Free float 80%

Primary exchange Madrid Stock Exchange Secondary exchange N/A

Share price performance



## **Business description**

Oryzon Genomics is a Spanish biotech focused on epigenetics. ladademstat is being explored for acute leukaemias, small-cell lung cancer and neuroendocrine tumours. Vafidemstat, its central nervous system (CNS) asset, has completed several Phase Ila trials and a Phase Ilb trial in borderline personality disorder is now the lead study, but Oryzon is rapidly expanding its CNS R&D pipeline.

### Analysts

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