EDISON

Oryzon Genomics

Clinical update

First patient dosed in new AML combination study

Pharma and biotech

Oryzon Genomics has announced the commencement of patient dosing in the investigator-initiated Phase Ib trial evaluating iadademstat as a combination treatment in first-line acute myeloid leukemia (AML). The study, which aims to recruit c 24 patients, is sponsored by Oregon Health & Science University (OHSU). It is designed to evaluate the safety, tolerability and optimal dose of iadademstat when administered alongside standard-of-care treatments venetoclax and azacitidine. It will also test for preliminary efficacy. Oryzon has previously generated encouraging results when investigating iadademstat in combination with azacitidine for newly diagnosed AML patients (ALICE trial) and this new study will explore potential further synergies of the broader combination.

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	(6.1)	(0.06)	0.0	N/A	N/A
12/24e	8.6	(4.9)	(0.05)	0.0	N/A	N/A
12/25e	31.6	15.5	0.28	0.0	6.5	N/A

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

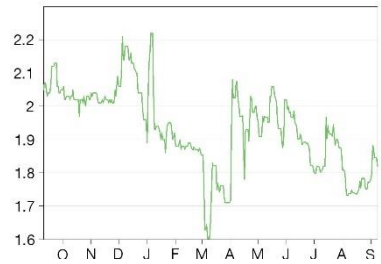
As per the announcement, the first AML patient has been treated in the Phase Ib trial of iadademstat, in combination with venetoclax and azacitidine. As this is an investigator-initiated study, we understand that Oryzon will have limited control over the trial but we view the latest update as a sign that the study is progressing as planned, maintaining the prior guided timeline of Q324 for commencement of patient dosing. We believe that a key objective of this study will be to build on the positive results from the Phase IIa ALICE trial (n=27), which assessed iadademstat in combination with azacitidine in newly diagnosed AML patients. The ALICE trial showed an overall response rate of 81.5%, with 52% of patients achieving complete remission (CR) or CR with incomplete haematological recovery (CRi), and 10 of the 11 evaluable CR/CRi patients testing negative for measurable residual disease (a key relapse risk factor in AML). Venetoclax plus azacitidine is the gold standard treatment for AML patients intolerant to intensive induction therapy (advanced age or comorbidities), and we believe Oryzon's strategy of assessing the triplet combination warrants merit, given the potential of combination approaches to enhance the durability of responses for cancer patients.

Iadademstat is a potent and selective inhibitor of LSD1 (also known as KDM1A), a histone-modifying enzyme that forms part of complexes responsible for the regulation of genes implicated in various cancers. As such, Oryzon is developing iadademstat as a potential treatment in indications where LSD1 expression has been found to be upregulated, such as AML, small cell lung cancer and neuroendocrine tumours. In our view, the most significant upcoming catalyst for the company's oncology pipeline will be the next FRIDA trial update, which is expected in December 2024 (previous update in June 2024). FRIDA is a Phase Ib trial investigating iadademstat in combination with the tyrosine kinase inhibitor gilteritinib for relapsed or refractory AML patients harbouring the FLT3 mutation. For a more detailed discussion of Oryzon's ongoing activities following its Q224 results, please see our prior update note.

9 September 2024

Price	**€1.82**
Market cap	**€116m**
Net debt (€m) at 30 June 2024	3.2
Shares in issue	64.0m
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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