EDISON

Oryzon Genomics

First patient dosed in iadademstat + ICI SCLC trial

Healthcare

15 April 2025

Oryzon Genomics has announced that the first patient has been dosed in iadademstat's Phase I/II trial, sponsored by the National Cancer Institute, (NCI) in extensive-stage small cell lung cancer (SCLC). The trial is evaluating lead oncology candidate iadademstat in combination with an immune checkpoint inhibitor (ICI), either atezolizumab or durvalumab, with primary objectives focussed on safety, tolerability, dose-finding and efficacy. Should the results of this trial be positive, they may support Oryzon's plans for its STELLAR programme, a randomised, multi-centre Phase II study of iadademstat in combination with a checkpoint inhibitor for first-line extensive-stage SCLC. Management has indicated that additional data from STELLAR could aid an accelerated approval pathway.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/23	14.2	(6.1)	(0.06)	0.00	N/A	N/A
12/24	7.4	(5.6)	(0.06)	0.00	N/A	N/A
12/25e	38.9	25.7	0.43	0.00	6.5	N/A
12/26e	43.3	30.8	0.50	0.00	5.5	N/A

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

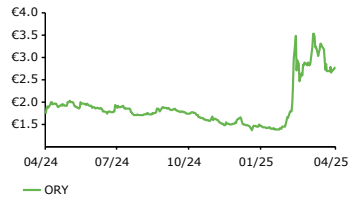
As per the announcement, patient dosing has commenced for the NCI-sponsored Phase I/II trial (NCT06287775) assessing iadademstat plus an ICI in SCLC. The study is being conducted under a Cooperative Research and Development Agreement (CRADA) that Oryzon has in place with the NCI. Management noted that this is the first clinical trial investigating the company's lead oncology candidate in combination with ICIs, which could maximise its potential. This study aims to enrol 45–50 patients with extensive-stage disease who have initially received standard-of-care chemotherapy and immunotherapy, and is targeting the first-line setting. Multiple leading US-based cancer centres are involved in this trial, including the Memorial Sloan Kettering Cancer Center (MSKCC) as one of the main sites, as well as JHU Sidney Kimmel Comprehensive Cancer Center.

For now, we keep our long-term estimates unchanged, but we will revisit our assumptions as the programme progresses. For a more detailed overview of Oryzon's ongoing clinical activities, please refer to our previous update note.

Iadademstat is a potent and selective inhibitor of LSD1 (also known as KDM1A), a histone-modifying enzyme that forms parts of complexes associated with the regulation of genes implicated in various cancers and conditions of the central nervous system. Oryzon is, therefore, focused on the clinical development of iadademstat in indications where LSD1 expression is upregulated, including acute myeloid leukaemia, SCLC and neuroendocrine tumours.

Price	**€2.78**
Market cap	**€183m**
Net cash/(debt) at 31 December 2024	€(10.5)m
Shares in issue	65.8m
Free float	82.0%
Code	ORY
Primary exchange	MADRID
Secondary exchange	N/A

Share price performance



Business description

Spanish biotech Oryzon Genomics is focused on epigenetics. Iadademstat is being explored for acute leukaemias, small-cell lung cancer (SCLC) and neuroendocrine tumours. Central nervous system (CNS) asset vafidemstat has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder (preparations for Phase III are underway). It is also currently involved in a Phase IIb trial for schizophrenia.

Analysts

Jyoti Prakash, CFA +44 (0)20 3077 5700
Arron Aatkar, PhD +44 (0)20 3077 5700

healthcare@edisongroup.com
Edison profile page

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London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom