EDISON

Oryzon Genomics

Clinical update

First Phase II patient enrolled is clinical milestone

Pharma and biotech

Oryzon Genomics has announced that it has enrolled the first patient into its collaborative Phase II trial investigating the use of its lead LSD1 inhibitor, iadademstat, in the treatment of relapsed and refractory (r/r) high-grade neuroendocrine carcinomas (NECs). The trial will be conducted in collaboration with the Fox Chase Cancer Center, a leading investigational cancer institute in the US, with Oryzon providing funding, iadademstat and technical advice. In our view, the first patient enrolment marks a significant clinical milestone for the study and begins iadademstat's potential expansion into additional indications. We maintain our valuation of Oryzon at €847m or €15.5 per share. However, we will provide a further update in line with Oryzon's full year results, which are expected in February 2023.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/20	9.5	(4.8)	(0.07)	0.0	N/A	N/A
12/21	10.6	(7.2)	(0.09)	0.0	N/A	N/A
12/22e	14.4	(5.0)	(0.05)	0.0	N/A	N/A
12/23e	15.9	(5.8)	(0.06)	0.0	N/A	N/A

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

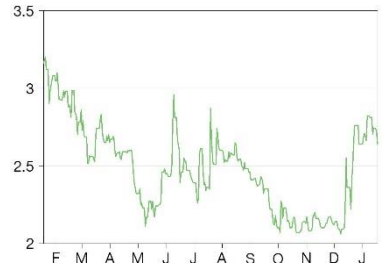
NECs are a rare form of cancer (US incidence is estimated at 12,000 new cases every year), which can form in various areas of the body, including the gastrointestinal tract (c 43% of cases), the lungs (c 30% of cases) and pancreas (c 7% of cases), meaning that symptoms can be varied, often leading to late diagnosis. While rare (c 5% of gastrointestinal NECs are high grade), high-grade (G3) NECs are extremely aggressive cancers with poor overall survival. Platinum-based chemotherapy is the established standard of care for advanced NECs; however, patients commonly relapse and there is currently no standard second-line treatment. Those who receive second-line treatment often exhibit extremely poor response rates, typically c 5–15%. We therefore believe the r/r setting represents a distinct opportunity for Oryzon and iadademstat in this indication.

As a reminder, Oryzon is investigating iadademstat in multiple oncology programmes, including the Phase I (FRIDA) study in r/r FLT3+ acute myeloid leukaemia and is preparing a Phase Ib/II (STELLAR) trial in metastatic small-cell lung cancer in combination with immune checkpoint inhibitors. Additionally, Oryzon recently reported encouraging results from its completed Phase IIa ALICE study in Acute Myeloid Leukaemia, in which iadademstat displayed an encouraging efficacy profile, achieving an objective response rate of 81% and median overall survival of 11.1 months.

18 January 2023

Price	**€2.35**
Market cap	**€129m**
	US$1.08/€
Estimated net cash (€m) at end-September 2022	9.7
Shares in issue	54.7m
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, SCLC and NECs. 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.

Analysts

Soo Romanoff +44 (0)20 3077 5700

Dr Adam McCarter +44 (0)20 3077 5700

healthcare@edisongroup.com

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia