EDISON

Oryzon Genomics

Clinical study update

Continued positive responses in ALICE trial

Pharma and biotech

Oryzon presented a 42-month update of its ongoing Phase IIa ALICE trial for the treatment of acute myeloid leukaemia (AML) in newly diagnosed elderly/unfit patients. The latest positive efficacy and safety data in the single-arm, open-label study follows what has been a consistent trend of encouraging data readouts from this fully enrolled study. The study is currently evaluating the objective response (OR) in patients treated with LSD1 inhibitor iadademstat in combination with standard of care chemotherapy azacitidine in a front-line setting. Of the 27 evaluable patients, 22 (81%) achieved an OR significantly higher than that of azacitidine monotherapy, which achieves OR rates of c 30%. We will revisit our estimates and valuation based on the recent updates reported by Oryzon on iadademstat.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	DPS (€)	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

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

ALICE 42-month consistent efficacy

The latest data reported by Oryzon is yet another significant milestone in the fully enrolled ALICE study, which has displayed positive results throughout. While dose-finding data and safety/tolerability evaluation are the primary endpoints, efficacy was evaluated using the secondary endpoints: objective response rates (ORR), time to response and duration of response. Of the 27 evaluable patients, 22 (81%) achieved an OR, comprising 14 complete responses (CR) or complete responses with incomplete haematologic recovery (CRi), and eight partial responses (PR). The time to response was rapid: 20 of 22 patients (91%) responded after two 28-day cycles of treatment; and durable, as nine of the 14 CR/CRi patients (64%) responded for more than six months. Of further note, 12 CR/CRi patients (86%) achieved transfusion independence for red blood cells and platelets – a result that we believe should elicit a positive impact on overall patient compliance going forward.

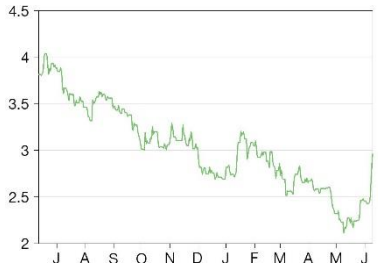
Comparable performance and promise for FRIDA

The OR rates observed from ALICE have remained consistently higher than historical response rates with classic chemotherapy (25–32%). The rates also align well with the combination chemotherapy developed by AbbVie/Genentech, which utilises the BCL2 inhibitor venetoclax in combination with azacitidine or decitabine for front-line AML treatment, which achieved an OR rate of 68%. The latest results from the ALICE study also provide encouraging signs for Oryzon's Phase Ib FRIDA trial investigating iadademstat in combination with gilteritinib for treating patients with FLT3-mutated AML in a second-line setting. The latest ALICE data reported that three out of three evaluable patients possessing the FLT3 mutation responded to treatment, thus providing promise for this further sub-population of AML patients.

10 June 2022

Price	**€2.96**
Market cap	**€156m**
	US$1.07/€
Net cash (€m) 31 December 2021	11.1
Shares in issue	52.8m
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 and SCLC. Vafidemstat, its 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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