

Oryzon Genomics

First look at ORY-1001 Phase I/IIa data

Oryzon's share price soared more than 30% this morning after the abstracts were made available online ahead of the American Society of Hematology (ASH) meeting on 3-6 December. During the poster session at ASH, Oryzon will be presenting the preliminary data from the Phase I/IIa trial with its lead product ORY-1001. In our view, the combination of no negative surprises in the safety profile and the first ever clinical data indicating potential efficacy in a subgroup acute leukemia patients is behind the share price rally today. We expect management to provide comprehensive data at the upcoming ASH meeting on 5 December, when Oryzon will also host an investor meeting. The company has also revealed that multiple sclerosis is now officially included in the development plan of its second product ORY-2001. Our valuation is under review.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	15.5	11.3	0.48	0.0	N/A	N/A
12/15	7.2	(0.1)	(0.01)	0.0	N/A	N/A
12/16e	4.8	(4.9)	(0.16)	0.0	N/A	N/A
12/17e	2.8	(6.2)	(0.22)	0.0	N/A	N/A

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

The study included different subsets of relapsed or refractory (RR) acute leukaemia patients treated with ORY-1001, lysine specific demethylase 1 (LSD1) inhibitor. Our initial assessment is that the safety data did not deliver any negative surprises (interim safety and tolerability results have already been announced). Our main focus was on initial efficacy signs. These were measured in a subset of 14 patients with mixed-lineage leukemia (n=10) and acute erythroleukaemia (n=4). Objective responses were seen in five of 14 patients (36%). There was evidence of morphologic blast differentiation in blood and/or bone marrow in 9/14 patients (64%). Undifferentiated ("young") blood cells are characteristic of these cancers.

The next step is for comprehensive data to be provided at ASH. According to the licensing deal with Roche, after the completion of the Phase I/IIa trial, Roche could be solely responsible for further clinical development and commercialisation of ORY-1001. Our focus now is on obtaining clarification about this process.

Preliminary clinical data

Pharma & biotech

16 November 2016

Price **€2.92**

Market cap **€83m**

Net cash (€m) at end Q316 3.6

Shares in issue 28.5m

Free float 30%

Code ORY

Primary exchange Madrid Stock Exchange

Secondary exchange N/A

Share price performance



Business description

Oryzon Genomics is a Spanish biotechnology company focused on developing novel epigenetic compounds. Lead compound ORY-1001 is partnered with Roche and is undergoing a Phase I/IIa study for acute leukaemia. ORY-2001 has potential for Alzheimer's disease and has entered Phase I. ORY-3001 is a new preclinical asset.

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