

Onxeo Clinical trial news

First Phase Ib DRIIV results released

On 18 September 2019, Onxeo released initial results from the first cohort of patients (n=3) in its ongoing Phase Ib DRIIV study with AsiDNA. The three patients had a progressive metastatic cancer (non-small cell lung cancer, triple negative breast cancer, gastric cancer) and were treated with AsiDNA plus carboplatin. No dose-limiting toxicity was observed. Two of the three patients have shown stable disease (RECIST) since the start of the treatment (more than four and five months). While it is too early to draw any conclusions on efficacy, stable disease status in 2/3 patients and a good safety profile appear encouraging. In the second part of the study, patients with various solid tumours will receive a combination of AsiDNA plus carboplatin and paclitaxel (standard of care in many solid tumours). Preliminary results are expected by end 2019.

	Revenue	PBT*	EPS*	DPS	P/E	Yield
Year end	(€m)	(€m)	(€)	(€)	(x)	(%)
12/17	9.5	(19.7)	(0.24)	0.0	N/A	N/A
12/18	6.1	(4.2)	0.05	0.0	N/A	N/A
12/19e	3.3	(11.9)	(0.22)	0.0	N/A	N/A
12/20e	3.3	(12.2)	(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.

AsiDNA belongs to the DNA damage repair inhibitor class, like PARP inhibitors, but has a unique mechanism of action. It is the only oligonucleotide decoy agonist in development that disrupts and exhausts the tumour DNA damage response mechanism. The combination of AsiDNA with DNA-damaging chemotherapies, such as platinum-based anticancer drugs, is expected to produce synergies.

The ongoing Phase Ib DRIIV study is an extension of the Phase I dose escalation trial (n=22), which showed that intravenous administration of AsiDNA had no serious drug-related side effects and had a positive effect on activity biomarkers. This study was then extended (currently ongoing Phase Ib) and started enrolling patients in May 2019. This is the first study testing AsiDNA in combination with carboplatin plus paclitaxel, in up to 18 patients (nine + nine if dose-limiting toxicity is reached) with solid tumours eligible for such treatments (eg lung, breast, ovarian or head and neck cancers).

Our last published valuation of Onxeo is €129m or €2.3/share, which we will revise depending on Phase Ib results. Please see our recent <u>outlook report</u> for a detailed description of the investment case

Pharma & biotech

19 September 2019

Price	€0.62
Market cap	€35m

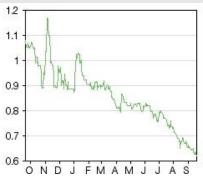
Net cash (€m) at end of Q219 6.3

Shares in issue 55.9m
Free float 80%

Code ONXEO

Primary exchange Euronext Paris
Secondary exchange OMX Copenhagen

Share price performance



Business description

Onxeo is focused on cancer indications, specialising in novel DNA damage response inhibitors. AsiDNA, a novel DNA break repair inhibitor from Onxeo's platON platform, is in a Phase lb trial with preliminary results expected in Q419. AsiDNA has a broad potential and can be combined with various anticancer treatments.

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