EDISON

# Onxeo

R&D news

## First significant milestone with AsiDNA achieved

Pharma & biotech

**Yesterday Onxeo announced its first preclinical proof-of-concept data with AsiDNA demonstrating the potential to be administrated intravenously. AsiDNA, a first-in-class DNA repair inhibitor, has already been tested in a Phase I trial with melanoma patients and showed promising results in terms of safety and initial signs of efficacy administered via local injection. After Onxeo acquired the drug in February 2016, the company repositioned the development and now seeking to establish a pre-clinical dossier to start human trials with intravenous injection, which would vastly increase the addressable indications. Yesterday's announcement was the first substantial step in this direction, as Onxeo showed that AsiDNA was effective alone or in combination with carboplatin in murine models of triple negative breast cancer (TNBC).**

| Year end | Revenue (€m) | PBT* (€m) | EPS* (€) | DPS (€) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/14 | 22.1 | 0.2 | (0.05) | 0.0 | N/A | N/A |
| 12/15 | 3.5 | (20.0) | (0.44) | 0.0 | N/A | N/A |
| 12/16 | 4.4 | (20.4) | (0.48) | 0.0 | N/A | N/A |
| 12/17e | 7.8 | (21.7) | (0.46) | 0.0 | N/A | N/A |

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

AsiDNA acts as a decoy that attracts DNA repair enzymes, leaving actual damaged DNA in cancerous cells (eg spontaneous or after treatment with chemotherapy) unrepaired, leading to cell death. Onxeo confirmed that this is achieved by hyper-activating two key DNA repair proteins, DNA-PK and PARP, which are then 'distracted' from repairing the actual DNA damage. From the data released so far, AsiDNA standalone significantly decreased tumour growth in the TNBC model and improved survival. Onxeo also tested the drug in combination with the classic neoadjuvant (ie given before surgery) chemotherapy, carboplatin. Despite AsiDNA being administered in lower doses than in the standalone trial, the combination with carboplatin outperformed other arms (untreated, low dose AsiDNA alone or carboplatin alone).

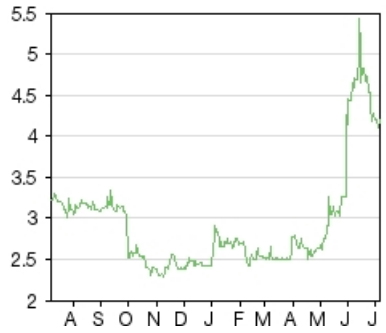
Next, Onxeo will also study AsiDNA administered together with PARP inhibitors, which target more downstream single-strand break repair pathways, and therefore the combination with AsiDNA could have interesting synergies. PARP inhibitors piqued the market's interest after the first drug Lynparza (olaparib, AstraZeneca) was launched in late 2014 and brought $218m in sales in 2016. EvaluatePharma estimates sales of all PARP inhibitors will total to $4.6bn by 2022.

Onxeo indicated that it aims to file the investigational new drug application by end-2017, which will likely allow initiation of Phase I in H118, in our view. The Phase I trial will be in a variety of tumours, which will allow selecting the best indication to progress forward. Onxeo is also working on a potential biomarker, so called micronuclei, to stratify the patient population according to the likelihood of response to treatment. If successful, this would be a particularly attractive pathway for standalone treatment with AsiDNA.

**6 July 2017**

| | |
|---|---|
| **Price** | **€4.14** |
| **Market cap** | **€209m** |
| Net cash (€m) at end-Q117 | 22 |
| Shares in issue | 50.6m |
| Free float | 85% |
| Code | ONXEO |
| Primary exchange | Euronext Paris |
| Secondary exchange | OMX Copenhagen |

### Share price performance




### Business description

Onxeo is focused on orphan cancer and has three orphan oncology assets in various stages of development (Livatag, belinostat and AsiDNA). Royalty-earning Beleodaq (belinostat) is launched in the US, along with two non-core, partnered, specialty products.

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