EDISON

Targovax

R&D results

Positive signals from Phase I/II mesothelioma trial

Pharma & biotech

Today, Targovax reported randomised data from the Phase I/II study (n=31) in unresectable malignant pleural mesothelioma. The results confirmed a good ONCOS-102 safety profile. The key clinical response endpoint mPFS was 8.4 months (active arm) vs 6.8 months (control) and above the historical control of 5.7–7.3 months. mPFS results are still early, with many patients not included in the analysis (additional data will serve as a potential catalyst later in 2020). Overall, as we described in our last note, mesothelioma is one of the most difficult cancers to treat, with classic chemotherapy still being the standard of care. While the size of the study limited the analysis for statistical significance (the trial was not designed to check for a statistically significant clinical effect), the mPFS results and the fact that clinical outcomes correlate with a cancer-specific immune response are clearly positive signals. Targovax has presented preliminary plans for the next trial. Our valuation is under review, while we analyse the details of the trial results.

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/17	0.0	(122.3)	(2.6)	0.0	N/A	N/A
12/18	0.0	(147.3)	(2.8)	0.0	N/A	N/A
12/19e	0.0	(136.2)	(2.4)	0.0	N/A	N/A
12/20e	0.0	(120.7)	(1.9)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding exceptional items.

The exploratory, randomised, open-label trial (n=31) compared oncolytic virus ONCOS-102 plus standard of care (pemetrexed/cisplatin; n=20) versus standard of care treatment (n=11) in first- and second-line settings. The primary goal of the study was to evaluate the **safety and tolerability** of ONCOS-102, which is typical for this stage. Key secondary endpoints evaluated **tumour-specific immunological activation** and correlation with a clinical response, **overall response rate** (ORR), **median progression-free survival** (mPFS) and **overall survival** (OS, data not mature). In addition to the overall results, first-line and second-line (or later) patient subpopulations were also evaluated. Descriptive patient data showed that the experimental arm had generally more advanced patients, implying a higher hurdle for ONCOS-102.

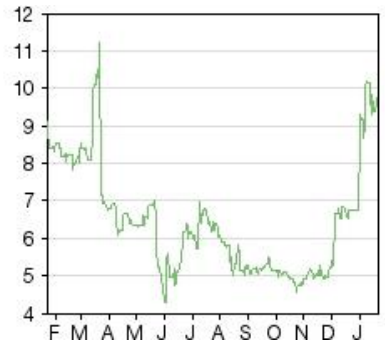
Overall mPFS in the experimental arm was 8.4 months vs 6.8 months in the control group. In first-line patients, the mPFS was 8.9 months vs 6.8 months (second-line group data not mature enough for analysis). mPFS was the clearest efficacy signal, which compares well with historical controls (5.7–7.3 months). The ORRs in first-line patients were 30% in the experimental arm vs 33% in the control arm (the experimental arm had more advanced patients). The ORRs in second-line patients were 11% in the experimental arm (n=9) vs 60% (n=5). The response in the control arm is clearly unusually high and likely the result of a small sample. This skewed analysis of the ORRs in the overall population. Still, such ORR data compare well to historical controls of c 20% (one trial reported an ORR of 41%, but the FDA disputed that). Targovax has introduced the potential design for the next trial (which could become a pivotal programme).

22 January 2020

Price	**NOK9.74**
Market cap	**NOK617m**

Net cash (NOKm) at end Q319 (excludes government loans)	104.0
Shares in issue	63.4m
Free float	90%
Code	TRVX
Primary exchange	Oslo Stock Exchange
Secondary exchange	N/A

Share price performance



Business description

Targovax is an immunoncology company headquartered in Oslo, Norway, with an oncolytic virus platform, ONCOS. ONCOS-102 is prioritised in several indications including mesothelioma and melanoma. Targovax is also working on next-generation oncolytic viruses in its preclinical R&D pipeline.

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