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Oncosil Medical (OSL) | BUY: Positive early OncoPac-1 data presented at EANM 2017

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Shane Storey +61 7 3212 1351

Alert

Announcement highlights

Oncosil Medical has reported first data from its OncoPac-1 clinical trial, in a presentation delivered at the European Association of Nuclear Medicine (EANM) Congress in Vienna. As a reminder, OncoPac-1 is a global clinical trial testing the safety and efficacy of the OncoSil™ medical device as a treatment for unresectable, locally advanced pancreatic cancer (LAPC). The first phase of the trial is a 'run-in' component, which is providing regulators with an assessment of both device and procedural safety in the first 20 patients. Twenty-eight patients have been recruited thus far, and 14 have been implanted with the device. Oncosil's EANM presentation featured safety and local tumour response data from the first 12 patients. The data was cut at the point where 12 patients had had radiological evaluations at week 8 (8w), 4 patients at 16w and one patient at 24w.

Key results:

- Procedural safety looks straightforward. OncoSil™ delivery via endoscopic ultrasound (EUS) was described as "easy and uncomplicated" across several clinical sites and EUS practitioners.

- Device-related safety OK. There have been no serious adverse events attributed to the OncoSil™ device or the implantation procedure. There was no evidence of radiation-related toxicity (OncoSil™ microparticles contain the radionuclide ^{32}P).

- Encouraging tumour responses. Oncosil has reported 100% Disease Control Rate (DCR) at 8w. Substantial tumour volume reductions were also described – up to 73% volumetric reduction observed 4 weeks post implant, with a median volumetric reduction of 34.5% at 4 weeks post implantation.

Wilsons' view

Initial analysis

Procedural simplicity and safety the #1 take-away. Positive anecdotal feedback about the device is very encouraging. Oncosil has done a lot of work understanding dosimetry and ensuring that the ~100 Gray radiation dose is delivered uniformly and with good coverage of the tumour volume. As with all EUS

procedures, the skill of the operator can be a factor in clinical outcomes. The interaction with FDA in the design of OncoPac-1 added much to the clinical protocol and ensuring that the device can be deployed in a safe, consistent and reproducible manner.

Safety data potentially unlocks two developments for Oncosil: a) CE Mark in Europe in 2018, enabling first commercial sales; and b) the expansion of OncoPac-1 clinical trial into a larger, randomised, controlled stage in ~300 patients. As a reminder, OncoPac-1 is a registration directed, pivotal trial which ultimately could form the basis of an FDA approval for OncoSil™.

Efficacy data positive but uncontrolled in this study phase. The efficacy data presented at EANM does not comment on OncoSil™'s efficacy specifically, because all patients in this part of the trial received chemotherapy before and after being implanted (gemcitabine combined with nab-paclitaxel or GNP). Treatment with GNP is associated with linear reductions in primary pancreatic tumour burden over the first 24w of therapy. OncoSil's early data does compare well against previous Phase III studies with GNP alone, but it is generally not valid to compare different clinical trials in that way. The EANM data is consistent with the first OncoSil™ trials published in 2008/9 (17 patients), which achieved median target tumour response of 23.5% and a DCR of 82.4%.

We will not know OncoSil™'s intrinsic, incremental efficacy until the randomised component of the OncoPac-1 trial is completed, comparing the two trial arms: tumour responses in patients treated with chemotherapy + OncoSil™ compared to responses using chemotherapy alone.

Earnings implications

None.

Investment view

We maintain a BUY rating noting that our last published price target was $0.38 per share. Our valuation for Oncosil is based on a discounted cash flow (DCF) which is heavily discounted for clinical development and commercialisation risks. We are enthusiastic about the OncoSil™ device and its ability to deliver a decisive dose of radiation therapy to primary tumours with good safety. Primary tumours account for 35% of deaths from pancreatic cancer and remain the principal target in early LAPC treatment. Our market analysis points to potential peak sales in the order of US$300m per annum in this indication. We will review our valuation in a formal way following consultations with the company and other clinical contacts.

Note that if we completely "de-risked" our OncoSil™ model (setting all success probabilities to 100%) and priced future cash flows using a WACC of 8.5% (more in line with established medical device companies) – our valuation could push as high as $2.20 per share on a fully diluted basis.

Such projections are subject to market influences and contingent upon matters outside the control of Wilsons and therefore may not be realised in the future. Past performance is not an indication of future performance.

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