WILSONS

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Theme Alert

Sector Healthcare

Company

Immutep Limited (IMM)

No longer a need to weigh up chemo

Recommendation OVERWEIGHT

12-mth target price (AUD) $0.91

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Announcement Highlights

Immutep have released Overall Survival (OS) data from their Phase II TACTI-002 trial in 1L non-small-cell lung cancer (NSCLC). Initial median OS of 25 months with a combination of Efti + pembrolizumab in those with PD-L1 positive tumours (TPS ≥1%) compares very favourably with other 1L options, be it anti-PD-1 monotherapy (Keytruda: 16.7 months; Opdivo: 13.4 months) or anti-PD-1 combinations with chemotherapy (Keytruda: >15.9 months) or other checkpoint inhibitors (anti-CTLA-4: 17.1 months) – from registrational trials in comparable TPS populations (**Figure 1**). The confirmed OS benefit compared to existing IO agent(s) (± chemotherapy), should distinguish the Efti + Keytruda combo as the initial go-to in clinician's minds (subject to confirmation by randomised clinical trials). This OS data suggests clinicians many no longer need to weigh up incremental survival benefit with add-on chemo, and associated side effect burden, with the Efti combination able to deliver on OS (matching/bettering chemo) with a superior tolerability profile. This is compelling and we expect IMM to be a hot topic of discussion at ASCO in a few weeks' time (June 2-6th), having demonstrated such impressive OS data in the absence of chemotherapy.

Wilsons' View

Initial analysis

Figure 1: Comparison of TACTI-002 response in 1L NSCLC vs other IO/chemo 1L trials

	Efti + pembrolizumab	Pembrolizumab	Atezolizumab + tiragolumab	Pembro+ chemo	Nivolumab + ipilimumab	Nivolumab
Targets	APC activator + Anti-PD-1	Anti-PD-1	Anti-PD-L1+ Anti-TIGIT	Anti-PD-1+ chemo	Anti-PD-1+ Anti-CTLA-4	Anti-PD-1
FDA approval	-	April 2019	-	Oct 2018	May 2020	2L: 2015
Study	TACTI-002	Keynote-042	CITYSCAPE	Keynote-407	Checkmate-227	Checkmate-017/057 pooled analysis
Phase	II	III	II	III	III	III
Therapy Line	1st	1st	1st	1st	1st	1st
n	114	637	67	278	396	427
PD-L1 TPS <1%	28%	nil	57%	34%	32%	38%
TPS 1-49%	33%	53%		37%	33%	43%
TPS ≥50%	18%	47%	43%	26%	35%	19%
Median PFS (all PD-L1)	6.9 m	5.4 m	5.6 m	6.4 m	7.2 m	2.3-3.5m
Median OS (months) for TPS ≥ 1%	**25.0m**	16.7m	23.2m	15.9 m	17.1m	13.4m
DoR median	21.6 m	20.2 m	17.6m	7.7 m	19.6 m	17.2-25.2 m
ORR (all PD-L1)	**40%**	27%	39%	58%	33%	19-20%
Response criteria	iRECIST	RECIST v1.1	RECIST v1.1	RECIST v1.1	RECIST v1.1	RECIST v1.1
Adverse Events (AEs)						
Discontinuation AEs	10%	8%	15%	23%	18%	6%

Source: per footnotes overleaf, IMM.

Roche TIGIT overhang could impact excitement. We remember back to the readout from Roche's Phase II CITYSCAPE trial combining anti-PD-1 (atezolizumab) with their anti-TIGIT asset (tiragolumab) where they previewed data that was similar/as compelling as Immutep's (median OS: 23.2 months; ORR 39%; DoR 17.6 months). This created excitement in the IO market, heralding this new anti-TIGIT as the next IO revolution. Since, with the advent of several failed Phase III trials with the tiragolumab combo (noting that Roche continue to progress the asset), the markets positivity toward new IO-IO combos may have dampened. Of course, the readthrough between Roche's experience and Immutep's are not at all related (different target). We simply assess the market has had recent expectations for a new IO combo dulled, and hence IMM is not experiencing the full extent of investor excitement this new OS data should warrant, in our view.

Earnings implications

Incremental de-risking of the NSCLC program as it heads into a registrational trial later this year. No changes to our forecasts/model assumptions.

Investment view

Maintain our OVERWEIGHT recommendation and $0.91/sh risked PT on Immutep.

Footnote references:

Brahmer et al. 2015. Nivolumab versus Docetaxel in Advanced Squamous-Cell Non-Small-Cell Lung Cancer. NEJM. 373: 123-135.

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Horn L et al. 2017. Nivolumab Versus docetaxel in previously treated patients with advanced non-small-cell lung cancer: Two year outcomes from two randomised, open-label, Phase III trials (CheckMate 017 and CheckMate 057). J Clin Oncol. 35(35): 3924-3933.

Mok T et al. 2019. Pembrolizumab versus chemotherapy for previously untreated, PD-L1-expressing, locally-advanced or metastatic non-small-cell lung cancer (KEYNOTE-042): a randomised, open-label, controlled, phase 3 trial. Lancet. 10183: 1819-1830.

Paz-Ares L et al. 2018. Pembrolizumab plus chemotherapy for squamous non-small-cell lung cancer. NEJM. 379: 2040-2051.

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