WILSONS

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Theme Alert

Sector Healthcare

Company

Immutep Limited (IMM)

NSCLC benefit stuns in PD-L1 ≥50%

Recommendation OVERWEIGHT

12-mth target price (AUD) $0.9

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Announcement Highlights

Immutep have released their European Society for Medical Oncology (ESMO) 2023 congress abstracts, including an updated data readout from their TACTI-002 program from the 1L NSCLC cohort (Part A). Importantly, key endpoints (ORR, OS) continued to demonstrate increases with the combination of Efti + pembrolizumab, when comparing to pembrolizumab/ SOC only historical trials. Overall survival (OS), the primary endpoint for the upcoming Phase III trial, remained at 25.0 months in the focus cohort, being PD-L1 ≥1%. This compares to ~16.7 months with pembrolizumab alone in a comparative patient population. Response rates (ORR) also have lifted across PD-L1 subtypes (~2-3% per group) remaining at 48% for the PD-L1 ≥1% focus cohort, with median PFS also lifting by an incremental 2.2 months to 11.2 months since last data readout. The high PD-L1 expressers (TPS ≥ 50%) were the standout with median OS of 38.8 months, almost doubling current options (~20 months for SOC including chemotherapy combos; highlighted in blue below). These data, when compared to their chosen SOC comparator regimen for TACTI-004 (nivolumab + ipilimumab + 2 cycle chemo), show marked survival superiority (mPFS, mOS) (**Figure 1** below), which if replicated in the upcoming Phase III program (TACTI-004) should support the emergence of Efti as a revolutionary new IO combination therapy option for current anti-PD-1 blockbusters. We look forward to incremental data and detail to come following the ESMO presentation on Oct 21st.

Wilsons' View

Figure 1: Cross-trial comparison in 1L NSCLC of current SOC and TACTI-004 comparator

		TACTI-004 SOC comparator	Standard of Care (SOC)			
	Efti + pembrolizumab	**Nivolumab + ipilimumab + 2-cycle chemo**	**Pembrolizumab**	**Atezolizumab**	**Pembrolizumab + chemo**	**Nivolumab + ipilimumab**
	EXPERIMENTAL	SOC (PD-L1 ≥1%)	SOC (PD-L1 ≥50%)	SOC (PD-L1 ≥50%)	SOC (PD-L1 ≥1%)	SOC (PD-L1 ≥1%)
Targets	APC activator + Anti-PD-1	Anti-PD-1 + Anti-CTLA-4 + chemo	Anti-PD-1	Anti-PD-L1	Anti-PD-1 + chemo	Anti-PD-1 + Anti-CTLA-4
Study	TACTI-002	Checkmate-9LA	Keynote-042	IMpower110	Keynote-407	Checkmate-227
Phase	II	III	III	III	III	III
Therapy Line	1L	1L	1L	1L	1L	1L
n	90 (of 114)	361	637	277	278	583
PD-L1 TPS <1%	36%	37%	nil	nil	34%	32%
TPS 1-49%	42%	35%	53%	61%	37%	33%
TPS ≥ 50%	22%	21%	47%	39%	26%	35%
Median PFS (all PD-L1)	6.6 m	6.7 m	-	-	8.0 m	5.1 m
mPFS PD-L1 <1%	4.2 m	5.8 m	-	-	6.3 m	5.1 m
mPFS PD-L1 ≥ 1%	**11.2 m**	**7.1 m**	**5.4 m**	**5.7m**	**8.2 m**	**5.1 m**
mPFS PD-L1 ≥ 50%	16.3 m	7.5 m	7.1 m	8.1 m	NR	NR
Median OS (all PD-L1)	**22.6 m**	**15.6 m**	-	-	**17.1 m**	**17.1 m**
mOS PD-L1 <1%	15.5 m	16.8 m	-	-	15.0 m	17.2 m
mOS PD-L1 ≥ 1%	**25.0 m**	**15.8 m**	**16.7m**	**17.5 m**	**18.9 m**	**17.1 m**
mOS PD-L1 ≥ 50%	**38.8 m**	**18.0 m**	**20.0 m**	**20.2 m**	NR	NR
DoR median	21.6 m	11.3 m	20.2 m	not estimatable	8.8 m	19.6 m
ORR (all PD-L1)	**40%**	**38%**	-	-	**63%**	**33%**
ORR PD-L1 <1%	31%	31%	-	-	67%	27%
ORR PD-L1 ≥ 1%	**48%**	**43%**	**27%**	**29%**	**59%**	**36%**
ORR PD-L1 ≥ 50%	55%	50%	39%	38%	NR	44%

Black boxes highlight the relevant comparator treatment groups and PD-L1 cohort (TPS ≥1%) that is relevant for the Phase III TACTI-004 program.
Source: Company data, IMM, published trials as noted.

Earnings implications. No changes.

Investment view. We maintain our OVERWEIGHT rating and $0.90/sh risked PT on Immutep.

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