WILSONS ADVISORY

Date 28 June 2024

Theme Company Update

Sector Healthcare

Company

Immutep Limited (IMM)

TACTI-003 download: take a pause

We maintain our OVERWEIGHT recommendation and risked PT of $1.13/sh on Immutep. Release of topline data from the Phase IIb TACTI-003 trial in 1L metastatic head and neck cancer (HNSCC) overall was solid – with the combination of Efti and Keytruda demonstrating superior objective response rates (ORR) to Keytruda alone (monotherapy), across all PD-L1 expression levels. We reiterate that this trial was not powered to show significance. The ORR in the CPS 1-19 cohort of course, did not dazzle; particularly when compared to a Keytruda monotherapy ORR that delivered >2x its historical reference points. We have maintained that accelerated approval (AA) remained an option, but not a given for Immutep, and have valued the HNSCC opportunity for Immutep, accordingly. This *should* be a key question for investors. Unfortunately, the important datapoint that seems to be missed in yesterday's readout, was the materially improved ORR in the Part B cohort (those with CPS <1, or 'cold' tumours). Management's guide to ~34% ORR across all expression levels, would suggest that the 26.9% ORR released in April, now sits at >35%, potentially offering >6-fold increase in response rate for these patients, vs Keytruda monotherapy and, a chemo-free 1L SOC. Despite some recent competitive updates, which we include in the note, Efti remains solo in the CPS <1 group. We preface all of this with the fact that we still await progression-free survival (PFS) and overall survival (OS) data in 2025. Let's not forget that Immutep will soon commence a Phase III trial in NSCLC, with strong Phase II OS data at hand, as well as free optionality with IMP-761, Immutep's autoimmune asset finally moving into a Phase I trial.

Key Points

TACTI-003 summary. Part A. Randomised, controlled cohort enrolled all patients with CPS ≥1. ORR in all patients CPS ≥1 (n=118) was 32.8% for Efti + Keytruda vs 26.7% for Keytruda mono. No p-values were provided but data was not significant (n.s.). Disaggregated to CPS 1-19 (n=62), ORR of 34.5% for Efti + Keytruda vs 33.3% for Keytruda mono., noting KEYNOTE-048 trial saw Keytruda mono. only deliver 14.5% ORR. CPS ≥20 (n=56) saw the strongest performance with ORR of 31.0% for Efti + Keytruda vs 18.5% for Keytruda mono. Part B. No additional formal data release. Management qualitatively noted a material increase in ORR since early data release in April. Taken with the ~34% ORR including all expression levels, implies ORR of >35% in CPS <1 patients – which remains biggest opportunity for Immutep. Safety data was limited but saw no new concerns.

Implications and next steps. We did not expect IMM to be in a position to provide details regarding AA pathway possibilities. We do acknowledge that the weaker result in the CPS 1-19 cohort (based more so on materially higher ORR in Keytruda monotherapy) does make the probability of AA less clear. To note, regardless of whether AA is granted, Immutep are of course required to conduct a Phase III (AA just allows Phase III to run alongside initial commercialisation).

Forecasts. No changes. To note, we do not forecast commercialisation of Efti in HNSCC until FY28E and already bake in A$35M associated with a Phase III trial. Removing the AA portion in our ROV would see a <1% change to valuation, given these factors (i.e. the opportunity was already over-risked; as we did not forecast earlier revenues associated with AA).

Valuation. Maintain O/W. No change to risked SOTP valuation. $1.13/sh comprises: a) Efti 1L NSCLC ($0.74/sh); b) Efti in mBC ($0.21/share); and c) Efti in HNSCC ($0.17/sh). Unrisked valuation $6.54/sh.

Financial summary (Y/E Jun, AUD)	FY22A	FY23A	FY24E	FY25E	FY26E
Sales ($m)	0.0	0.0	0.0	0.0	0.0
EBITDA norm ($m)	(34.7)	(40.8)	(43.1)	(51.9)	(45.0)
Consensus EBITDA ($m)			(46.5)	(53.0)	(60.4)
EPS norm (cents)	(4.3)	(4.7)	(3.6)	(4.5)	(2.8)

Source: Company data, Wilsons Advisory estimate, Refinitiv, IRESS.
All amounts are in Australian Dollar (A$) unless otherwise stated.

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	$1.13
Share price @ 27-Jun-24 (AUD)	$0.34
Forecast 12-mth capital return	237.3%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**237.3%**
Market cap ($m)	486.6
Enterprise value ($m)	363.2
Shares on issue (m)	1,453
Sold short (%)	0.3
ASX All Ords weight (%)	0.0
Median turnover/day ($m)	1.0

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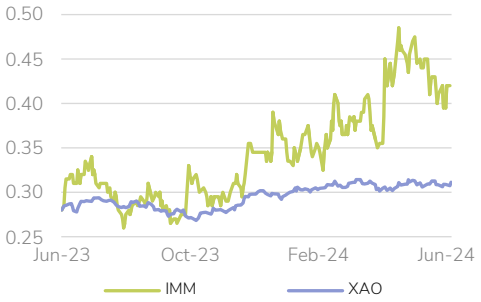
12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	(5.6)	21.7	50.0
Rel return (%)	(6.5)	16.5	35.3

Key changes		27-Jun	After	Var %
EBITDA	FY24E	(43.1)	(43.1)	0%
norm	FY25E	(51.9)	(51.9)	0%
($m)	FY26E	(45.0)	(45.0)	0%
EPS	FY24E	(3.6)	(3.6)	0%
norm	FY25E	(4.5)	(4.5)	0%
(cents)	FY26E	(2.8)	(2.8)	0%
Price target		1.13	1.13	0%
Rating		O/W	O/W	

Business Description

Immutep (IMM:ASX) is a clinical stage Australian biopharma operating in the immuno-oncology (IO) sector with their portfolio of LAG-3 directed biologics. Immutep have four assets under development, all with strong IP protection; two of which are out-licensed (LAG525 - Novartis, IMP731 - GSK) with attached milestone and royalty revenue optionality, with the remaining two (Efti and IMP761) being developed in-house for a range of oncology (incl. HNSCC, NSCLC, mBC) and autoimmune indications.

Catalysts

a) achievement of clinical trial endpoints; b) partnership opportunities; c) regulatory approvals (including IND approvals); d) corporate activity.

Investment Thesis

We maintain our OVERWEIGHT recommendation and risked PT of $1.13/sh on IMM. Release of topline data from the Phase IIb TACTI-003 trial in 1L metastatic head and neck cancer (HNSCC) overall was solid – with the combination of Efti and Keytruda demonstrating superior objective response rates (ORR) to Keytruda alone (monotherapy), across all PD-L1 expression levels. Whilst CPS 1-19 cohort did not dazzle, the biggest opportunity for IMM remains in CPS <1, where ORR looks to be>35%.

Risks

a) adverse clinical trial outcomes; b) negative regulator interactions; c) competitive intensity of immuno-oncology field; d) available capital.

P&L ($m)	FY22A	FY23A	FY24E	FY25E	FY26E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(34.7)	(40.8)	(43.1)	(51.9)	(45.0)
EBIT norm	(36.8)	(42.9)	(45.1)	(54.1)	(47.5)
PBT norm	(36.7)	(42.0)	(42.6)	(53.4)	(47.2)
NPAT norm	(36.7)	(42.0)	(42.6)	(53.4)	(33.1)
NPAT reported	(36.7)	(42.0)	(42.6)	(53.4)	(33.1)
EPS norm (cents)	(4.3)	(4.7)	(3.6)	(4.5)	(2.8)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Growth (%)	FY22A	FY23A	FY24E	FY25E	FY26E
Sales	n/m	n/m	n/m	n/m	n/m
EBITDA norm	24.4	17.5	5.5	20.5	(13.3)
NPAT norm	22.6	14.4	1.5	25.4	(38.1)
EPS norm (cents)	(14.2)	9.0	(23.6)	25.4	(38.1)
DPS (cents)	n/m	n/m	n/m	n/m	n/m

Margins and returns (%)	FY22A	FY23A	FY24E	FY25E	FY26E

Interims ($m)	1H23A	2H23A	1H24A	2H24E	1H25E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(20.9)	(19.9)	(22.2)	(20.8)	(25.9)
EBIT norm	(21.8)	(21.0)	(23.2)	(21.9)	(27.0)
PBT norm	(21.6)	(20.4)	(21.2)	(21.4)	(26.6)
NPAT norm	(21.6)	(20.4)	(21.2)	(21.4)	(26.6)
NPAT reported	(21.6)	(20.4)	(21.2)	(21.4)	(26.6)
EPS norm (cents)	(2.5)	(2.3)	(1.8)	(1.8)	(2.2)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Stock specific	FY22A	FY23A	FY24E	FY25E	FY26E
R&D expense (m)	(31.3)	(36.3)	(40.4)	(50.0)	(25.0)
Licensing revenue (m)	0.2	0.0	0.0	0.0	0.0

Balance sheet ($m)	FY22A	FY23A	FY24E	FY25E	FY26E
Cash & equivalents	80.0	123.4	85.6	33.7	48.6
Current receivables	8.4	8.0	5.0	5.0	0.0
Current inventory	0.0	0.0	0.0	0.0	0.0
PPE	0.0	0.1	0.1	0.1	0.1
Intangibles	10.6	9.5	9.5	9.5	9.5
Other assets	3.2	6.5	4.9	5.7	3.4
Total assets	102.2	147.4	105.2	53.9	61.6
Current payables	5.8	9.0	8.2	9.9	6.6
Total debt	0.0	0.0	0.0	0.0	0.0
Other liabilities	2.2	1.8	2.1	2.1	2.6
Total liabilities	8.1	11.0	10.5	12.2	9.4
Minorities	0.0	0.0	0.0	0.0	0.0
Shareholders equity	94.1	136.5	94.7	41.8	52.2

Cash flow ($m)	FY22A	FY23A	FY24E	FY25E	FY26E
Operating cash flow	(30.2)	(35.4)	(36.4)	(51.7)	(31.8)
Maintenance capex	(0.0)	(0.1)	(0.0)	(0.0)	(0.0)
Free cash flow	(30.3)	(35.4)	(36.4)	(51.8)	(31.9)
Growth capex	0.0	0.0	0.0	0.0	0.0
Acquisitions/disposals	0.0	0.0	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other cash flow	(3.3)	(1.2)	(1.3)	(0.2)	(3.2)
Cash flow pre-financing	(33.6)	(36.6)	(37.8)	(52.0)	(35.1)
Funded by equity	53.0	80.1	0.0	0.0	50.0
Funded by cash/debt	(72.4)	(123.5)	37.8	52.0	(64.9)

Liquidity	FY22A	FY23A	FY24E	FY25E	FY26E
Cash conversion (%)	87.4	88.9	90.4	101.1	102.8
Net debt ($m)	(80.0)	(123.4)	(85.6)	(33.7)	(48.6)
Net debt / EBITDA (x)	2.3	3.0	2.0	0.6	1.1
ND / ND + Equity (%)	(568.1)	(945.6)	(947.3)	(416.5)	n/m
EBIT / Interest expense (x)	n/m	46.7	18.0	74.0	n/m

Valuation	FY22A	FY23A	FY24E	FY25E	FY26E
EV / Sales (x)	n/m	n/m	n/m	n/m	n/m
EV / EBITDA (x)	n/m	n/m	n/m	n/m	n/m
EV / EBIT (x)	n/m	n/m	n/m	n/m	n/m
P / E (x)	n/m	n/m	n/m	n/m	n/m
P / BV (x)	3.8	3.7	5.3		
FCF yield (%)	(8.4)	(7.1)	(7.3)		
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0
Payout ratio (%)	0.0	0.0	0.0	0.0	0.0
Weighted shares (m)	849.9	892.5	1,186	1,186	1,186

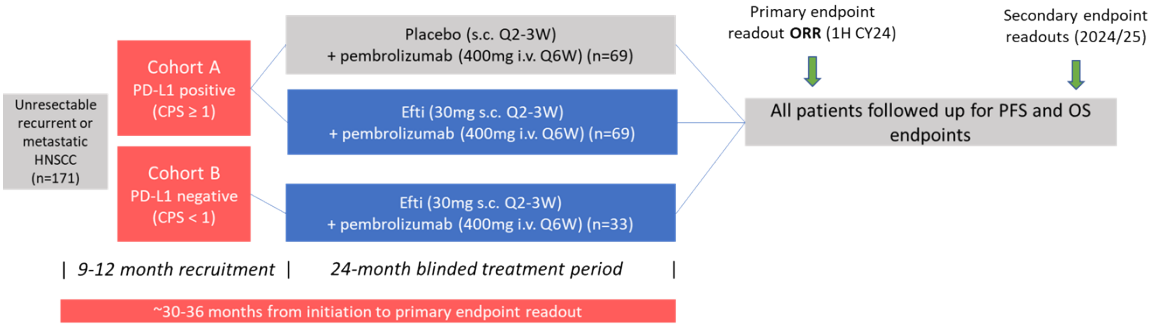
Source: Company data, Wilsons Advisory estimate, Refinitiv, IRESS.
All amounts are in Australian Dollar (A$) unless otherwise stated.

TACTI-003 data review

Trial refresher and competitive landscape

Figure 1 below shows the design for Immutep's Phase IIb TACTI-003 trial in first line (1L) metastatic head and neck squamous cell carcinoma (mHNSCC), completed in collaboration with Merck (MSD). The trial was divided into the randomised Part A subset (n=138) consisting of those expressing Keytruda's (pembrolizumab) target PD-L1 reflected by PD-L1 combined positive score (CPS) of ≥ 1, and the non-randomised Part B subset (n=33) including only patients with 'cold' tumours with no PD-L1 expression (PD-L1 CPS <1). Objective response rate (ORR) is the primary endpoint of this study, with progression free survival (PFS) and overall survival (OS) both secondary endpoint measures that will be reported in due course.

Figure 1: Overview of TACTI-003 trial design



Source: Immutep, Wilsons Advisory.

Current Keytruda approvals limited. As a reminder, there are a material number of 1L mHNSCC patients that cannot access Keytruda (pembrolizumab) as an approved treatment option based on their expression of PD-L1. The relative estimated proportions of HNSCC patients and their PD-L1 expression is challenging to define with published studies providing wide estimate ranges of the proportion of PD-L1 negative patients (CPS <1) within HNSCC (16 – 58%)[1,2] and the balance being PD-L1 positive (CPS≥1). We settle on 30% as a relevant mid-range, noting IMM have typically quoted ~20%. Those with 'cold' tumours only have access to Keytruda via a combination with chemotherapy in the US market (and no access in Europe). This patient population (CPS<1) remain the most significant opportunity in the space given the dearth of options available to them and the dearth of assets in development focused on this group of patients.

CPS<1 patients the market expansion opportunity. Per **Figure 2**, in the US market Keytruda monotherapy is approved for PD-L1 CPS ≥1 cohorts, however in Europe only those with TPS ≥50% have access to Keytruda monotherapy in 1L HNSCC. This represents ~one third of US patients and ~two thirds of European patients that do not have access to chemotherapy free options in 1L HNSCC. For those with PD-L1 negative tumours current SoC in HNSCC continues to be a chemotherapy-based regimen – either Keytruda + chemotherapy or cetuximab (an epidermal growth factor inhibitor) in combination with platinum-based chemotherapy. Both treatment paradigms carry significant side effects and dose-limited toxicities making tolerability a challenge. The search for enhanced efficacy (and survival), with an improved side effect profile continues to be the primary focus in HNSCC drug development, particularly in PD-L1 negative patients.

Figure 2: Current approvals of Keytruda in 1L mHNSCC

Market	PD-L1 approved cohorts	Required combination	Representative of total population	Chemotherapy free option (proportion of population)
US	All	Chemotherapy	100%	70%
	CPS ≥1	None (monotherapy)	70%	
EU	CPS ≥1	Chemotherapy	70%	40%
	TPS ≥50%	None (monotherapy)	≤40%	

Source: FDA, EMA, company data.

Challenging to treat cancer. mHNSCC is a highly challenging to treat indication with very limited treatment options for patients. We have past examples of MSD working in collaboration with pharma/drug assets to enhance Keytruda response. In the case of their Eisai collaboration (and their TKI drug, LENVIMA), the Phase III LEAP-010 trial sadly had a positive improvement in both ORR and PFS that was significant however at the second planned interim analysis the combo failed to show any significant OS benefit over Keytruda alone (+placebo). The study was terminated early. There is an ongoing triple combination Phase II program (Keytruda + LENVIMA + chemotherapy) in the LEAP-009 trial that is anticipated to readout data mid-2025 that continues the Eisai and MSD collaboration – but yet again demonstrates the challenge in mHNSCC and in providing an effective chemotherapy-free regimen.

[1] Yang *et al*. 2018. The prognostic role of PD-L1 expression for survival in head and neck squamous cell carcinoma: A systematic review and meta-analysis. *Oral Oncology*. 86: 81-90.
[2] Lu et al. 2023. PD-L1 expression in recurrent or metastatic head and neck squamous cell carcinoma in China (EXCEED study): a multicentre retrospective study. *J Clinical Pathology*. doi: 10.1136/jcp-2023-209059

Merus – an early competitor - only in PD-L1 positive cohorts. Whilst early, we have seen promising initial efficacy from Merus Therapeutics with their EGFR and LGR5 targeted bispecific antibody, petosemtamab. In their Phase I/II trial (NCT03526835), data from n=24 in 'hot' tumours (CPS≥1) demonstrated an ORR of 67% (compared to 23% and 43% for Keytruda alone or Keytruda + chemo respectively). This is a promising avenue, noting that the addition of this agent to Keytruda monotherapy did more than double the toxicity profile of the combination – albeit with a marked initial efficacy uplift to show for it. The big caveat here is that data is from a very small cohort of patients (n=24 data thus far) and hence we appreciate it is early. The most important key point, yet again CPS <1 patients are excluded from this program, leaving Efti as the only asset in development for this cohort of patients, with the highest unmet need.

Part A data (PD-L1 CPS ≥1)

Summary. In the randomised, controlled Cohort A (N=138; 118 evaluable) comprised of 1L HNSCC patients with any PD-L1 expression (CPS >1), Efti demonstrated results as summarised in **Figure 3** below.

Figure 3: Overall response rates based on PD-L1 expression level

	Efti + pembrolizumab	Pembrolizumab monotherapy
High PD-L1 expression (CPS ≥20)	31.0% (n=29)	18.5% (n=27)
Low PD-L1 expression (CPS 1-19)	34.5% (n=29)	33.3% (n=33)
Any PD-L1 expression (CPS ≥ 1)	32.8% (n=58)	26.7% (n=60)

Source: Immutep.

Versus expectations. Our expectations for this study were to see benefit in one or two of the PD-L1 cohorts within Part A (PD-L1 CPS 1-19 or CPS>20) in terms of a meaningfully greater ORR response over Keytruda monotherapy – with no added safety burden. Our prior ballpark thinking was an ORR of +10% vs a historical control ballpark ORR of 20% (Keynote-048 trial ORR was 14.5%), equating to the ORR we saw in the 2L TACTI-002 trial of ~30% (of course noting differences between 1L and 2L populations). The expectation to see statistical significance was low purely based on the size of the trial and it not being adequately powered to potentially see differences.

The big difference to expectations from the readout, was the far higher ORR in the Keytruda monotherapy arm in the CPS 1-19 cohort, demonstrating a 33.3% ORR vs historical ORR of ~14.5% in the Keynote-048 Phase III trial[3]. Management noted today that the large difference of the Keytruda monotherapy versus historical results in CPS 1-19 patients may be explained by imbalances between the treatment groups, including smoker status and location of primary tumour.

How does this change the view on opportunity for Efti? The overarching premise of Efti in 1L mHNSCC is to provide an option for patients that does not require chemotherapy for the CPS 1-19 cohorts (as required in EU) and the added toxicity it brings, if an IO-IO combo (such as Keytruda + Efti) can deliver equivalent efficacy, noting that despite the aberration this has still been shown with the results released yesterday, with the caveat of Keytruda monotherapy offering stellar ORR. Further analysis still needs to be conducted on the prognostic factors that may have favoured the Keytruda monotherapy arm. Durability of response (DOR) is another key opportunity, given chemotherapy use markedly reduces duration of response in prior studies, however we await DOR data in the 2H. Enhanced efficacy of Keytruda generally to increase the proportion of responders (ORR) makes for a more compelling case to justify a new SOC.

Part B data (PD-L1 CPS<1)

Summary. Further data was not released today in regard to the Part B cohort. Qualitatively, management commented that there had been a material improvement since the initial data release in April. Management qualitatively noted a material increase in ORR since early data release in April. Taken with the ~34% ORR including all expression levels, implies ORR of >35% in CPS <1 patients – which remains biggest opportunity for Immutep.

Versus expectations. An earlier readout (May 24) from this cohort demonstrated the combination of Efti + Keytruda in comparable CPS<1 1L patients was 26.9% (based on 26 of 33 patients total) as an interim readout. This was accompanied by a disease control rate (DCR) of 57.7% in the absence of any chemotherapy being used which is impressive. Historical data from CPS <1 patient cohorts demonstrated ORR levels of between 4.5-5.4% and DCR of 40.5% from the Keynote-048 Phase III trial in 1L mHNSCC. Prior to the May data we had low expectations in this cohort, simply given how challenging these patients are to treat and therefore a 4-5x uplift in response rate has superseded our initial expectations. Potential updates to data in the coming weeks that would show this number lifting to >35% ORR should see a lot more focus on what Efti can offer specifically in this cohort, given the dearth of current treatment options, and, clinical trials which include this cohort.

[3]Burtness, B. et al. Pembrolizumab Alone or With Chemotherapy for Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma in KEYNOTE-048: Subgroup Analysis by Programmed Death Ligand-1 Combined Positive Score. Journal of Clinical Oncology 2022 40:21, 2321-2332

Outcomes/implications. Anti-PD-L1 monotherapy is not approved for use in 1L mHNSCC for those with CPS<1 (accounting for ~30% of the total population) in the US. In Europe, no PD-L1 negative patients are able to access Keytruda (even with chemotherapy). Given that HNSCC prevalence rates in Europe are almost 4x higher than the US (43 cases per 100,000 vs 11.2 cases per 100,000), this presents an attractive opportunity for a blockbuster PD-L1 to crack into that new market expanding its major market TAM by ~25% on a patient population basis and shouldn't be underestimated.

In summary – the main opportunity for Efti is to expand the current addressable market for Keytruda in Europe to PD-L1 negative (CPS<1) patients, with recent competitive updates (included in **Figure 4**), yet to offer an option in this cohort. We of course still see the opportunity for Efti to also remove the need for combination with chemotherapy (that brings tolerability challenges) in HNSCC, increasing market uptake/reach for anti-PD-L1 therapy (i.e. Keytruda).

Figure 4: Summary of TACTI-003 data with relevant historical control studies (and new Merus data)

Comparison of relevant trial programs in 1L mHNSCC

	Efti + pembrolizumab	Efti + pembrolizumab	Pembrolizumab	Pembrolizumab	Pembro+ chemo	Cetuximab + chemo	Petosemtamab + pembro
	IO - IO	IO - IO	IO - IO	IO monotherapy (SOC only in 'hot' tumours)	IO - Chemo (now SOC)	2L SOC or for cold tumour patients	IO - EGFR/LGR5 bispecific
Checkpoint target	PD-1 + LAG-3	PD-1 + LAG-3	PD-1 + LAG-3	PD-1	PD-1	NA	NA
Study	TACTI-003 Part B	TACTI-003 Part A	TACTI-003 Part A	Keynote-048	Keynote-048	Keynote-048	NCT03526835
Phase	IIb	IIb	IIb	III	III	III	I/II
Therapy Line	1st	1st	1st	1st	1st	1st	1st
n	33	69	68	301	281	278	24
Demographics (% male)	NR	79%	70%	83%	80%	87%	78%
Median age	NR	NR	NR	62	61	61	64
PD-L1 CPS <1	100%	0%	0%	15%	15%	15%	0%
CPS 1-19	0%	50%	55%	41%	40%	45%	42%
CPS ≥20		50%	45%	44%	45%	40%	56%
Median PFS	NR	NR	NR	2.3 months	4.9 months	5.2 months	NR
HR (for progression)	-	-	-	p>0.05	0.84 (p>0.05)	-	-
PF at 6 months	-	-	-	25%	45%	45%	-
Median OS	NR	NR	NR	11.6 months	13.0 months	10.7 months	NR
HR (for death)	-	-	-	0.83 (p=0.02)	0.77 (p=0.034)	-	-
Median Duration of response	-	-	-	22.6 months	6.7 months	4.3 months	-
ORR (total)	26.9%	34%	26.7%	**16.9%**	**36.0%**	**36.0%**	67.0%
ORR CPS <1	26.9%	-	-	4.5%	30.8%	39.5%	-
ORR CPS ≥1	-	32.8%	26.70%	19.0%	36.0%	36.0%	67.0%
ORR CPS 1-19	-	34.5%	33.3%	14.5%	29.3%	33.6%	60.0%
ORR CPS ≥20	-	31.0%	18.5%	23.0%	38.0%	43.0%	71.0%
DCR (total)	57.7%	75.9%	59.3%				87.5%
Response criteria	RECIST v1.1	RECIST v1.1	RECIST v1.1	RECIST v1.1	RECIST v1.1	RECIST v1.1	RECIST v1.1
Treatment-related Adverse Events (AEs)							
Discontinuation AEs†	7.8%	7.8*%	5.9%	0%	8%	9%	4%

^NR - not reported quantitatively. Qualitatively noted DoR greater in nivo group vs SOC

*PD-L1 ≥1%. Remainder of group of were not quantifiable in their PD-L1 expression levels.

†Discontinuations based on combined Cohort A+B

Source: Company data, referenced, trials.

Outlook and implications

TACTI-003 derisked & next steps

As we previously flagged, we have already derisked TACTI-003 success in our valuation at the early April data. Given the superior ORR vs Keytruda monotherapy across all expression levels, we maintain this decision, noting that Immutep will present updated Part B data on July 11th 2024 at an ESMO plenary session.

Await further updates regarding Accelerated Approval (AA) discussions. We are unable to make any further assessments currently regarding AA, noting today's results do not provide a clear indication of whether AA is feasible. As we pointed out in our note yesterday, we have built our base case on IMM valuation that we would not see an Accelerated approval (AA) from FDA for mHNSCC for Efti, recognising that AA is challenging to predict given there are less clear predicate benchmarks for what would constitute data that is supportive of this.

As an exercise, given we have already included A$35M in R&D costs associated with a Phase III trial in HNSCC and do not forecast first revenues until FY28E, re-modelling our ROV associated with HNSCC, without AA would see less than 1% change in valuation (due to slightly adjusted timing). We recognise that if the possibility of AA was to be removed, it brings the issue of funding back to the forefront of investor's minds, given the most recent equity raise was of course allocated entirely to Immutep's Phase III trial in NSCLC (which is a far bigger, more lucrative opportunity).

CPS <1 cohort still yet to reveal final topline data. In the PD-L1 CPS<1 cohort we have suggested a 4-5x uplift ORR would act as a surrogate endpoint for AA ahead of OS data, which is of course yet to be reported (expected in 2025). We are therefore eager to see results in this cohort.

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Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/disclosures.

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