WILSONS ADVISORY

Date 6 May 2025

Theme Company Update

Sector Healthcare

Company

Immutep Limited (IMM)

17.6m OS in PD-L1 negative mHNSCC

We maintain our OVERWEIGHT rating and PT of $1.05/sh on Immutep. Yesterday, Immutep provided an update on their Efti/KEYTRUDA combination, treating first line metastatic head and neck cancer (mHNSCC) patients with PD-L1 negative (CPS <1) tumours. Demonstrating a median overall survival (mOS) of 17.6 months, this is an impressive +6.3 month improvement over the KEYTRUDA/chemo combo which serves as the current SoC in USA. Immutep has moved swiftly to request a meeting with FDA to plot pathways to an approval. Given the astounding apparent efficacy and safety benefits, an accelerated approval (AA) ought to be one discussion point at that meeting, with a confirmatory Phase III in mind. The usual caveats still apply here: TACTI-003-B was a non-randomised, 'small n' study. Cohort B patients had better performance status and some other differences (from Cohort A) but none significant enough to explain the strength of these responses.

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	$1.05
Share price @ 5-May-25 (AUD)	$0.30
Forecast 12-mth capital return	250.0%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**250.0%**

Market cap ($m)	435.8
Enterprise value ($m)	253.9
Shares on issue (m)	1,453
Sold short (%)	2.0
ASX All Ords weight (%)	0.0
Median turnover/day ($m)	0.5

Key Points

TACTI-003-B updated results. Today's mature mOS result (17.6 months) and complete response (CR) rate (13%) are what investors (and regulators) should be focusing on. In the treatment of 1st line mHNSCC patients who are PD-L1 negative (CPS < 1), the combination of Efti and KEYTRUDA was associated with a +6.3 month separation on mOS and 4-fold more complete responses (CRs) than seen in KEYNOTE-048, the most relevant comparator study (specifically, the arm treating with KEYTRUDA+ chemotherapy (a platinum and 5-fluorouracil [5-FU]). Although this component of TACTI-003 was non-randomised, its results position the Efti + KEYTRUDA combo with potentially superior efficacy and safety vs the current SOC in a population with high unmet need. The Efti + KEYTRUDA combo OS was also +6.9 months ahead of the ERBITUX/platinum/5-FU combo (in KEYNOTE-048) which is SOC in parts of the world where KEYTRUDA/chemo is not approved for CPS < 1 mHNSCC patients (e.g. Europe).

A worthy development option targeting US$450M peak sales in CPS<1 mHNSCC. MSD's further involvement in Phase III will be welcomed but is contingent on striking a new agreement with Immutep. MSD's enthusiasm for mHNSCC is impossible to predict and could take various forms; from 'opting-in' to a full blown campaign (e.g. taking TACTI-004 as a template, remembering the efficacy in the 2L (covered here) and considering prospects for future expansion into locally advanced disease and even neoadjuvant HNSCC settings, where Efti is mechanistically appealing); or 'opting-out', happy to 'do no harm' as a passive beneficiary of KEYTRUDA upside, stemming from Immutep's targeted success in the CPS<1s. It is important to reiterate that independent commercialisation should be and is the base case on which mHNSCC contributes to our Immutep forecasts and valuation. Last December, in anticipation of these results, we reviewed Immutep's organisational and technical preparedness for a briefer path to first commercial revenue, if that's where TACTI-003-B leads them. That research is provided here.

Valuation. Maintain O/W. SOTP valuation of $1.05/sh comprises: a) Efti 1L NSCLC ($0.75/sh); b) Efti in mBC ($0.21/share); and c) Efti in HNSCC ($0.09/sh). Unrisked $6.57/sh. An accelerated approval in HNSCC would elevate HNSCC component to $0.21/sh (Efti launch drawn forward two years; p [success] 52%→100%). Group PT would move to $1.25/sh with early revenue obviating capital demand from FY27e.

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12-mth price performance ($)

	1-mth	6-mth	12-mth
Abs return (%)	17.6	7.1	(31.0)
Rel return (%)	9.2	6.3	(35.6)

Financial summary (Y/E Jun, AUD)	FY23A	FY24A	FY25E	FY26E	FY27E
Sales ($m)	0.0	0.0	0.0	0.0	0.0
EBITDA norm ($m)	(38.8)	(44.2)	(50.9)	(45.0)	(35.0)
Consensus EBITDA ($m)			(59.6)	(78.1)	(77.9)
EPS norm (cents)	(4.5)	(3.6)	(4.3)	(2.7)	(2.1)

Key changes		16-Dec	After	Var %
EBITDA	FY25E	(50.9)	(50.9)	0%
norm	FY26E	(45.0)	(45.0)	0%
($m)	FY27E	(35.0)	(35.0)	0%
EPS	FY25E	(4.3)	(4.3)	0%
norm	FY26E	(2.7)	(2.7)	0%
(cents)	FY27E	(2.1)	(2.1)	0%
Price target		**1.05**	**1.05**	**0%**
Rating		**O/W**	**O/W**	

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

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 rating and PT of $1.05/sh on Immutep. The prospect of an accelerated approval (AA) for Efti in combination with KEYTRUDA, treating first line metastatic head and neck cancer (mHNSCC) with PD-L1 negative tumours took a step forward this week with the TACTI-003-B update. Median overall survival (mOS) of 17.6 months, superior to previous trials and on a path to become the new SOC.

Risks

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

P&L ($m)	FY23A	FY24A	FY25E	FY26E	FY27E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(38.8)	(44.2)	(50.9)	(45.0)	(35.0)
EBIT norm	(40.8)	(46.4)	(53.6)	(48.0)	(38.3)
PBT norm	(39.9)	(42.7)	(51.9)	(46.8)	(36.9)
NPAT norm	(39.9)	(42.7)	(51.9)	(32.7)	(25.8)
NPAT reported	(39.9)	(43.5)	(51.9)	(32.7)	(25.8)
EPS norm (cents)	(4.5)	(3.6)	(4.3)	(2.7)	(2.1)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Growth (%)	FY23A	FY24A	FY25E	FY26E	FY27E
Sales	n/m	n/m	n/m	n/m	n/m
EBITDA norm	18.6	14.0	15.3	(11.6)	(22.2)
NPAT norm	15.3	7.1	21.6	(37.0)	(21.1)
EPS norm (cents)	9.8	(20.4)	20.2	(37.0)	(21.1)
DPS (cents)	n/m	n/m	n/m	n/m	n/m

Margins and returns (%)	FY23A	FY24A	FY25E	FY26E	FY27E

Interims ($m)	2H23A	1H24A	2H24A	1H25E	2H25E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(18.8)	(22.2)	(22.0)	(25.4)	(25.5)
EBIT norm	(19.9)	(23.2)	(23.2)	(26.8)	(26.9)
PBT norm	(19.3)	(21.2)	(21.5)	(25.9)	(26.1)
NPAT norm	(19.3)	(21.2)	(21.5)	(25.9)	(26.1)
NPAT reported	(19.3)	(21.2)	(22.3)	(25.9)	(26.1)
EPS norm (cents)	(2.2)	(1.8)	(1.8)	(2.1)	(2.1)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Stock specific	FY23A	FY24A	FY25E	FY26E	FY27E
R&D expense (m)	(34.4)	(39.6)	(50.0)	(25.0)	(35.0)
Licensing revenue (m)	0.0	0.0	0.0	0.0	0.0

Balance sheet ($m)	FY23A	FY24A	FY25E	FY26E	FY27E
Cash & equivalents	123.4	181.9	132.3	147.8	122.8
Current receivables	8.0	7.4	5.0	0.0	0.0
Current inventory	0.0	0.0	0.0	0.0	0.0
PPE	0.1	0.1	0.1	0.1	0.1
Intangibles	9.5	8.2	8.2	8.2	8.2
Other assets	6.5	4.0	5.7	3.4	4.9
Total assets	147.4	201.6	151.3	159.6	136.0
Current payables	9.0	9.6	9.5	6.6	6.6
Total debt	0.0	0.0	0.0	0.0	0.0
Other liabilities	1.8	2.3	2.0	2.6	1.6
Total liabilities	11.0	12.1	11.7	9.4	8.4
Minorities	0.0	0.0	0.0	0.0	0.0
Shareholders equity	136.5	189.5	139.6	150.2	127.6

Cash flow ($m)	FY23A	FY24A	FY25E	FY26E	FY27E
Operating cash flow	(35.4)	(34.8)	(49.4)	(31.3)	(24.8)
Maintenance capex	(0.1)	(0.0)	(0.0)	(0.0)	(0.0)
Free cash flow	(35.4)	(34.9)	(49.4)	(31.3)	(24.9)
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	(1.2)	(7.0)	(0.2)	(3.2)	(0.2)
Cash flow pre-financing	(36.6)	(41.8)	(49.6)	(34.5)	(25.0)
Funded by equity	80.1	100.3	0.0	50.0	0.0
Funded by cash/debt	(123.5)	(158.7)	49.6	(65.5)	25.0

Liquidity	FY23A	FY24A	FY25E	FY26E	FY27E
Cash conversion (%)	93.6	87.2	100.3	103.4	106.6
Net debt ($m)	(123.4)	(181.9)	(132.3)	(147.8)	(122.8)
Net debt / EBITDA (x)	3.2	4.1	2.6	3.3	3.5
ND / ND + Equity (%)	(945.6)	n/m	n/m	n/m	n/m
EBIT / Interest expense (x)	44.4	12.5	31.5	38.5	27.0

Valuation	FY23A	FY24A	FY25E	FY26E	FY27E
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)	2.6	1.9			
FCF yield (%)	(9.9)	(9.8)			
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)	892.5	1,200	1,214	1,214	1,214

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

TACTI-003-B: mOS readout and other analyses

TACTI-003-B update

TACTI-003-B mOS has now been reached with an impressive 17.6 months, translating to a +6.3 month benefit when compared to SOC (KEYTRUDA+chemotherapy; as trialled in KEYNOTE-048). **Figure 1** provides cross-trial comparisons v KEYNOTE-048 on key efficacy and safety measures. Note also the indicative superiority (+6.9 month mOS benefit) to the ERBITUX (cetuximab)/chemo combination, also tested in KEYNOTE-048) which is the SOC in parts of the world where KEYTRUDA/chemo is not approved for PD-L1 negative mHNSCC.

As an aside, the mOS result in this CPS < 1 population even exceeds those achieved with KEYTRUDA/chemo in the PD-L1 positive (CPS 1-19 and CPS ≥ 20) subgroups of KEYNOTE-048 (mOS = 12.7 months[1] and 14.7 months, respectively[2]). This result also holds up against the KEYTRUDA monotherapy results established in the MSD/Esai LEAP-010 study where mOS was 17.9 months in patients with higher CPS scores (strongly PD-L1 positive) and better performance status[3] (mOS 17.9 months).

Complete response (CR) rates will also be a key consideration for regulators. CR rates of Efti + KEYTRUDA being 12.9% and ~4-fold KEYNOTE-048 in the CPS<1 subgroup being 3% (KEYTRUDA + chemotherapy). Although this was a small trial, we view these results as very encouraging and a strong candidate to replace the current SOC in (CPS <1) PD-L1 negative mHNSCC patients. Importantly, treatment continues to be well tolerated with no new safety signals reports. TACTI-003-B reports a 79% reduction in the proportion of patients with ≥ grade 3 treatment-emergent adverse events compared to SOC (15% v 72%).

Figure 1: Updated TACTI-003 data v KEYNOTE-048 in 1L mHNSCC

Comparison of relevant trial programs in 1L mHNSCC	Efti + pembrolizumab	Pembrolizumab	Pembro + chemo	Cetuximab + chemo
	IO - IO	IO monotherapy (SOC only in 'hot' tumours)	IO - Chemo (now SOC)	2L SOC or for cold tumour patients
Checkpoint target	PD-1 + LAG-3	PD-1	PD-1	NA
Study	TACTI-003 Part B	Keynote-048	Keynote-048	Keynote-048
NCT Reference	NCT04811027		NCT02358031	
Phase	IIb	III	III	III
Therapy Line	1st	1st	1st	1st
n	31	301	281	278
Demographics (% male)	74%	83%	80%	87%
HPV status (% positive)	12.9%^	21%	21%	22%
Current smoker	26%	*	*	*
Median age	64	62	61	61
PD-L1 CPS <1	100%	15%	15%	15%
CPS 1-19	0%	41%	40%	45%
CPS ≥ 20	0%	44%	45%	40%
Median PFS	5.8 months	2.1 months	4.9 months	5.2 months
HR (for progression)	N/A	NA	0.84 (p>0.05)	-
PF at 6 months	NR	25%	45%	45%
Median OS (CPS < 1)	**17.6 months**	**7.9 months**	**11.3 months**	**10.7 months**
Median Duration of response	9.3 months	2.6 months	6.7 months	4.3 months
ORR CPS <1	35.5%	5.4%	30.8%	39.5%
DCR (total)	58.1%	44% (32% for CPS<1)	64%	70%
Complete response (CPS<1)	13%	0%	3%	2%
Response criteria	RECIST v1.1	RECIST v1.1	RECIST v1.1	RECIST v1.1
Treatment-related Adverse Events (AEs)				
Discontinuation AEs	9%	0%	8%	9%
Grade ≥3 AEs	15%	17%	72%	69%
AEs leading to death	0%	1%	4%	3%

^in patients with oropharyngeal tumours only. * only current + former smoker stats reported combined
N/A - not applicable; NR - not reported; PFS - progression free survivial; OS - overall survival
CPS - combined positive score (PD-L1 expression status).

Source: Immutep, MSD, Wilsons Advisory.

[1] Burtness, B., *et al.* (2022) 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 J. Clin. Oncol. 40:2121.

[2] Burtness, B., *et al.* (2019) *Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomised, open-label, phase 3 study* Lancet https://doi.org/10.1016/S0140-6736(19)32591-7.

[3] Licitra, L., *et al.* (2024) *Pembrolizumab with or without levatinib as first-line therapy for recurrent or metastatic heand and neck squamous cell carcinoma (R/M HNSCC): Phase III LEAP-010 Study.* Int. J. Rad. Onc. Biol. Phys.

Weighing the risks of KEYTRUDA's potential outperformance in Cohort B. Investors may remember results from TACTI-003-A, where imbalances in patient characteristics (e.g. smoking/HPV status and the location of primary tumour) were proposed as reasons why KEYTRUDA monotherapy 'outperformed' expectations in one of the PD-L1 positive subgroups. This outome deprived the Efti/KEYTRUDA of any comparative benefit in CPS 1-19 patients. As there is no data for Efti in mHNSCC as a monotherapy, the single-arm nature of TACTI-003-B demands analysis of baseline patient characteristics too, looking for any features here that could have predisposed this population to better responses. **Figure 2** reproduces that data across cohorts (A & B) and PD-L1 positive subgroups (CPS 1-19; CPS ≥ 20).

Highlighted data points in **Figure 2** for Cohort A have been called out by Immutep before. For instance, the high proportion of a) HPV+ patients (53.8% v 30.8%); and b) primary tumours located in the larynx (30.3% v 17.2%) were both raised as potential reasons why KEYTRUDA alone was seen to do better than investigators expected in CPS 1-19 patients. In Cohort B, Immutep has shared that HPV status did not heavily influence results (1/4 HPV+ and 2/7 HPV- patients were responders). The proportion of laryngeal tumours in Cohort B (32.2%) is similar to the outperforming KEYTRUDA monotherapy (1-19) group but has very low (3.2%) hypolaryngeal representation. These HNSCC cases are thought to have poor prognosis – often driven by alcohol and tobacco exposure and generally, later diagnosed. The only other characteristic of note is performance status, where Cohort B as a higher proportion of 'fitter' ECOG-1 patients. The impact of difference in smoking status seems difficult to interpret, if any.

Figure 2: TACTI-003 patient baseline characteristics across cohorts and CPS subgroups. Underlined data identify possible imbalances in characteristics that may have influenced responses

Cohort		Cohort B	Cohort A			
Subgroup (CPS status)		CPS <1	CPS 1-19		CPS ≥20	
		Efti + Pembro	Efti + Pembro	Pembro	Efti + Pembro	Pembro
Age	Median Age, Years (Range)	64 (23-83)	66 (43-80)	68 (38-86)	64 (43-87)	64 (49-85)
Sex	Female / Male	25.8 / 74.2	17.2 / 82.8	18.2 / 81.8	24.1 / 75.9	44.4 / 55.6
ECOG	ECOG 0 / ECOG 1	32.3 / 67.7	41.4 / 58.6	45.5 / 54.5	41.4 / 58.6	44.4 / 55.6
Smoking Status	Current / Ex / Never	25.8 / 61.3/ 12.9	13.8 / 65.5 / 20.7	15.2 / 78.8 / 6.1	31.0 / 51.7 / 17.2	18.5 / 63 / 18.5
HPV Status	Positive/Negative	12.9* / 22.6	30.8 / 69.2	53.8 / 46.2	27.3 / 72.7	40.7 / 59.3
Primary Tumour	Oral Cavity	29.0	20.7	18.2	31	48.1
	Oropharynx	35.5	44.8	39.4	37.9	25.9
	Hypopharynx	3.2	17.2	12.1	20.7	14.8
	Larynx	32.3	17.2	30.3	10.3	11.1
Disease Status At Study Entry	Local Only	16.1	10.3	21.2	41.4	18.5
	Local and Metastatic	22.6	37.9	21.2	10.3	37
	Metastatic Only	61.3	51.7	57.6	48.3	44.4

Source: Immutep, Wilsons Advisory

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