WILSONS

Date 8 November 2022

Theme Company Update

Sector Healthcare

Company

Immutep Limited (IMM)

Durable responses in 1L NSCLC with Efti

We maintain our OVERWEIGHT recommendation and $0.91 per share risked price target on Immutep. This morning we have seen release of the 2022 SITC abstracts (held in Boston over the next few days) of which Immutep are presenting three, including a key oral presentation. Importantly we have seen updated data from their Phase II TACTI-002 trial in 1st line (1L) Non-small cell lung cancer (NSCLC). This data is a more mature read from the latest June readout and highlights a consistent benefit of Efti when added to pembrolizumab (Keytruda) standard of care (SoC) across all PD-L1 tumor subgroups. Importantly this benefit includes the hard-to-treat PD-L1 negative tumors where default treatment is chemotherapy. On a LFL basis (TPS ≥ 1%) Efti adds 3.9 months progression free survival (PFS) versus Keytruda SoC (noting caveats with cross trial comparisons). ORR continues to incrementally improve with each data read, now at 39.5% on an all comers basis (vs 27% for Keytruda alone). For the first time we have Durability of Response (DoR) data of 21.6 months, putting the Efti combo slightly ahead of Keytruda (20.2 months) and well ahead of Keytruda/chemo combos (~8 months DoR). The Efti combo continues to be well tolerated with <10% discontinuing due to related side effects. We also have a first look at INSIGHT-003 trial data with a triple chemo combination. The data presented at SITC continues to support Phase III progression of Efti in the important 1L NSCLC setting.

Key Points

Data consistency and durability positive. Once again, we have seen a consistent, superior, and importantly durable response from the Efti + pembrolizumab combination in 1L NSCLC patients – with the SITC data released supporting the prior June ASCO trial data readout. The consistency of the overall response rate (ORR) across the data readouts (2021, May, June, Nov 2022) being 36%, 37%, 38.6% and 39.5% on an all-comers basis generates more confidence in the effect translatability into a larger Phase III cohort. The lack of overall survival (OS) data continues to read positively for Efti durability and study progression, noting that the final patient was enrolled in November of last year, and that median OS for pembrolizumab alone in pivotal Phase III trials resides ~17 months in a PD-L1$^+$ population (~12 months with chemotherapy).

Benchmarking brings confidence in Efti. Benchmarking of Efti's response in 1L NSCLC compared to approved SoC regimens continues to highlight a superiority of efficacy particularly in the lower PD-L1 expression cohorts (TPS <50%), where chemotherapy tends to be employed more often as a 1L option (bringing with it a significant side effect profile). ORR comparisons to prior benchmark trials (i.e. KEYNOTE-001) highlights >1.5-fold benefits in ORR for the PD-L1 low/negative expressing tumours with no added toxicity, which is an impressive stat to support expansion of Keytruda's addressable market to a PD-L1 all-comers basis (+35% of current label addressable market in USA and +70% of current label in EU) in this indication.

Valuation. Our SOTP risked valuation of $0.91/share comprised of a) Efti NSCLC licensing ($0.53/sh); b) Efti in HR$^+$/HER2$^-$ breast cancer ($0.30/share); and c) Efti in HNSCC ($0.09/sh). Our unrisked PT remains at $2.33 per share, with a potential >$2B acquisition valuation assessed based on predicate transactions in the oncology sector.

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	$0.91
Share price @ 8-Nov-22 (AUD)	$0.32
Forecast 12-mth capital return	184.4%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**184.4%**
Market cap ($m)	272.3
Enterprise value ($m)	192.3
Shares on issue (m)	850.9
Sold short (%)	0.7
ASX All Ords weight (%)	0.0
Median turnover/day ($m)	0.4

Dr Melissa Benson
melissa.benson@wilsonsadvisory.com.au
Tel. +61 2 8247 6639

Dr Shane Storey
shane.storey@wilsonsadvisory.com.au
Tel. +61 7 3212 1351

Madeleine Williams
madeleine.williams@wilsonsadvisory.com.au
Tel. +61 3 9640 3834

12-mth price performance ($)

	1-mth	6-mth	12-mth
Abs return (%)	18.5	(8.6)	(51.9)
Rel return (%)	16.6	(3.7)	(47.2)

Financial summary (Y/E Jun, AUD)	FY21A	FY22A	FY23E	FY24E	FY25E
Sales ($m)	0.0	0.0	0.0	0.0	0.0
EBITDA norm ($m)	(27.9)	(30.3)	86.1	(36.0)	(21.2)
Consensus EBITDA ($m)			(8.0)	(26.4)	(17.2)
EPS norm (cents)	(5.0)	(3.8)	9.8	(4.3)	(2.7)

Key changes		6-Jun	After	Var %
EBITDA	FY23E	80.2	86.1	7%
norm	FY24E	(41.9)	(36.0)	14%
($m)	FY25E	(27.2)	(21.2)	22%
EPS	FY23E	9.2	9.8	6%
norm	FY24E	(5.0)	(4.3)	14%
(cents)	FY25E	(3.4)	(2.7)	21%
Price target		**0.91**	**0.91**	**0%**
Rating		**O/W**	**O/W**	

Source: Company data, Wilsons 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 and autoimmune indications.

Investment Thesis

IMM's clinical assets focus on the newest approved immuno-oncology (IO) target, LAG-3. Their lead product Efti aims to enhance and extend IO blockbusters including Merck's Keytruda, with latest data continuing to support this thesis. We see a valuation disconnect between IMM and their opportunities in these markets with significant TAMs (breast $2.3B, head & neck $2.2B, lung $8B) where unmet need is high and combination with existing blockbusters sets up an immediacy of adoption

Catalysts

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

Risks

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

P&L ($m)	FY21A	FY22A	FY23E	FY24E	FY25E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(27.9)	(30.3)	86.1	(36.0)	(21.2)
EBIT norm	(30.0)	(32.3)	83.7	(38.7)	(24.1)
PBT norm	(29.9)	(32.2)	84.4	(37.1)	(22.9)
NPAT norm	(29.9)	(32.2)	84.4	(37.1)	(22.9)
NPAT reported	(30.5)	(33.1)	84.4	(37.1)	(22.9)
EPS norm (cents)	(5.0)	(3.8)	9.8	(4.3)	(2.7)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Growth (%)	FY21A	FY22A	FY23E	FY24E	FY25E
Sales	n/m	n/m	n/m	n/m	n/m
EBITDA norm	115.0	8.4	(384.3)	(141.8)	(41.1)
NPAT norm	100.9	7.7	(362.1)	(144.0)	(38.3)
EPS norm (cents)	38.6	(24.7)	(358.5)	(144.0)	(38.3)
DPS (cents)	n/m	n/m	n/m	n/m	n/m

Margins and returns (%)	FY21A	FY22A	FY23E	FY24E	FY25E
ROA	n/m	n/m	45.4	n/m	n/m
ROIC	n/m	n/m	628.4	n/m	n/m
ROE	n/m	n/m	47.2	n/m	n/m

Interims ($m)	2H21A	1H22A	2H22A	1H23E	2H23E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(9.1)	(15.4)	(14.8)	(15.4)	101.5
EBIT norm	(10.1)	(16.4)	(16.0)	(16.6)	100.3
PBT norm	(10.1)	(16.3)	(15.9)	(16.2)	100.6
NPAT norm	(10.1)	(16.3)	(15.9)	(16.2)	100.6
NPAT reported	(10.0)	(16.8)	(16.4)	(16.2)	100.6
EPS norm (cents)	(1.2)	(1.9)	(1.9)	(1.9)	11.7
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Stock specific	FY21A	FY22A	FY23E	FY24E	FY25E
R&D expense (m)	(17.2)	(31.3)	(33.0)	(35.0)	(20.0)
Licensing revenue/milestor	0.0	0.2	120.0	0.0	0.0

Balance sheet ($m)	FY21A	FY22A	FY23E	FY24E	FY25E
Cash & equivalents	60.6	80.0	165.4	127.7	103.9
Current receivables	6.1	8.4	5.0	5.0	5.0
Current inventory	0.0	0.0	0.0	0.0	0.0
PPE	0.0	0.0	0.0	0.0	0.0
Intangibles	12.8	10.6	10.6	10.6	10.6
Other assets	2.4	3.2	3.5	3.0	2.3
Total assets	82.0	102.2	184.5	146.3	121.7
Current payables	4.8	5.8	3.5	3.0	2.2
Total debt	0.0	0.0	0.0	0.0	0.0
Other liabilities	3.8	2.2	2.1	2.1	2.1
Total liabilities	8.8	8.1	5.7	5.3	4.5
Minorities	0.0	0.0	0.0	0.0	0.0
Shareholders equity	73.3	94.1	178.7	141.1	117.3

Cash flow ($m)	FY21A	FY22A	FY23E	FY24E	FY25E
Operating cash flow	(17.6)	(30.2)	85.5	(37.6)	(23.7)
Maintenance capex	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Free cash flow	(17.7)	(30.3)	85.5	(37.6)	(23.7)
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	(3.1)	(3.3)	(0.1)	(0.1)	(0.1)
Cash flow pre-financing	(20.8)	(33.6)	85.4	(37.7)	(23.8)
Funded by equity	55.0	53.0	0.0	0.0	0.0
Funded by cash/debt	(89.3)	(72.4)	(85.4)	37.7	23.8

Liquidity	FY21A	FY22A	FY23E	FY24E	FY25E
Cash conversion (%)	63.5	100.3	98.5	108.7	117.7
Net debt ($m)	(60.6)	(80.0)	(165.4)	(127.7)	(103.9)
Net debt / EBITDA (x)	2.2	2.6	(1.9)	3.5	4.9
ND / ND + Equity (%)	(477.9)	(568.1)	n/m	(957.6)	(776.0)
EBIT / Interest expense (x)	n/m	n/m	n/m	24.9	19.8

Valuation	FY21A	FY22A	FY23E	FY24E	FY25E
EV / Sales (x)	n/m	n/m	n/m	n/m	n/m
EV / EBITDA (x)	n/m	n/m	1.2	n/m	n/m
EV / EBIT (x)	n/m	n/m	1.3	n/m	n/m
P / E (x)	n/m	n/m	3.3	n/m	n/m
P / BV (x)	3.3	2.9	1.5	1.9	
FCF yield (%)	(7.4)	(11.1)	31.3	(13.8)	
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)	594.5	849.9	861.7	861.7	861.7

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

TACTI-002 data update

We would refer readers to our note at the ASCO data release in June for TACTI-002 design reminders; see here.

Data is consistent: Efficacy benefit with comparative tolerability

Updated data published in the SITC abstract from n=114 patients (extended Part A cohort) are summarised in **Figure 1,** in comparison to the prior data readout (June ASCO). We also include several relevant benchmarking pivotal trials (not comprehensive) in this figure and recent benchmarking by Immutep shown in **Figure 2**. We continue to see a consistent ORR on an all-comers basis (39.5% vs 38.6% at June readout), with an interim median progression free survival (mPFS) of 6.9 months in line with prior data readouts. Importantly however the PD-L1 subgroup response benefits have continued to incrementally strengthen with respect to ORR (**Figure 3 overleaf**) and median PFS demonstrating a consistency/durability of response.

New information presented includes duration of response (DoR) at 21.6 months for the Efti + pembrolizumab combo, which sits well versus pembrolizumab alone (20.2 months) and other IO/IO, IO/chemo combinations (~8 months for chemo regimens). The safety and tolerability of Immutep's combination also continues to track favourably versus SoC, in particular versus chemotherapy 1L options with 9.6% of discontinuations only related to drug treatment.

Overall survival (OS) data still forthcoming. Immutep are yet to present median OS data from TACTI-002 noting that the first patient with enrolled in 2019, and the last patient in November 2021 (recalling a 12-month treatment period). We anticipate potential first OS data in 1H 2023.

Efti combo superior when on a LFL basis to PD-L1 positive populations. There continues to be significant caveats with cross-trial comparisons which we are acutely aware of, however in this instance, these remain our best way of relative efficacy benchmarking. The median PFS of 5.4 months achieved with pembrolizumab alone in the pivotal KEYNOTE-042 trial excludes PD-L1 negative (TPS <1%) tumours. Updated TACTI-002 data presented demonstrates a mPFS of 9.3 months for the PD-L1 TPS ≥1% population (LFL-basis to KEYNOTE-042) – representing a continued 3.9-month benefit over current monotherapy SoC with comparative tolerability, which is a clinically meaningful benefit.

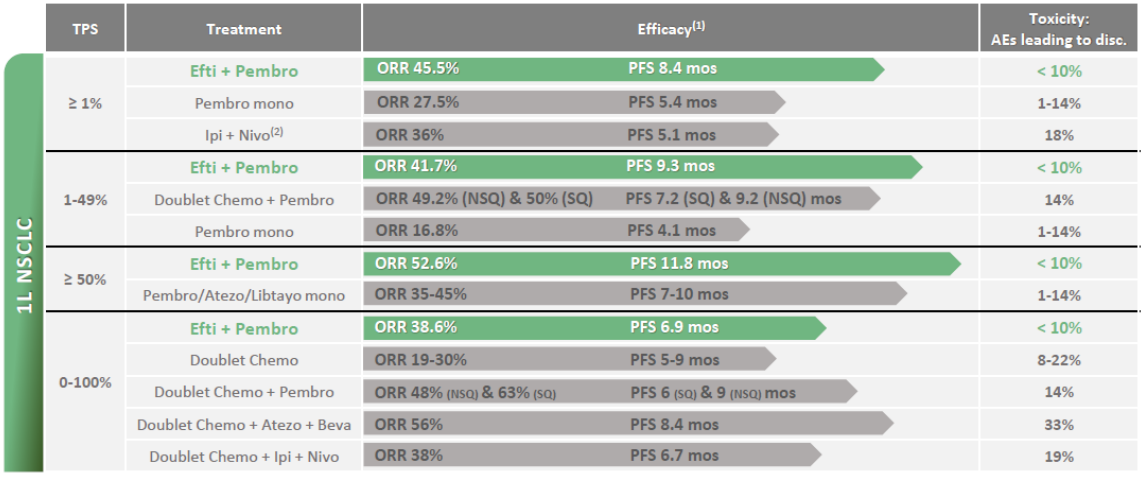
Figure 1: Updated TACTI-002 data readout shows consistency to prior data reads. Comparison to pivotal IO studies highlights data on track to reach superiority over SoC

	Efti + pembrolizumab	Efti + pembrolizumab	Pembrolizumab	Atezolizumab + tiragolumab	Pembro+ chemo	Nivolumab + ipilimumab
Targets	APC activator + Anti-PD-1	APC activator + Anti-PD-1	Anti-PD-1	Anti-PD-L1+ Anti-TIGIT	Anti-PD-1+ chemo	Anti-PD-1+ Anti-CTLA-4
FDA approval	-	-	April 2019	-	Oct 2018	May 2020
Study	TACTI-002	TACTI-002 (updated data)	Keynote-042	CITYSCAPE	Keynote-407	Checkmate-227
Phase	II	II	III	II	III	III
Therapy Line	1st	1st	1st	1st	1st	1st
n	114	114	637	67	278	583
PD-L1 TPS <1%	28%	28%	nil	57%	34%	32%
TPS 1-49%	32%	33%	53%		37%	33%
TPS ≥50%	17%	18%	47%	43%	26%	35%
Median PFS	6.9 m	6.9 m	5.4 m	5.6 m	6.4 m	7.2 m
HR (for progression)	-	-	1.07, p>0.05	0.62	0.56, p<0.001	0.79
Median OS (months)	Not yet reached	Not yet reached	16.7m	23.2m	15.9 m	17.1 m
HR (for death)	-	-	0.81, p=0.0018	0.69	0.64, p<0.001	0.73
DoR median	Not yet reached	21.6 m	20.2 m	17.6m	7.7 m	19.6 m
ORR	39%	40%	27%	39%	58%	33%
Response criteria	iRECIST	iRECIST	RECIST v1.1	RECIST v1.1	RECIST v1.1	RECIST v1.1
Adverse Events (AEs)						
Discontinuation AEs	10%	10%	8%	15%	23%	18%

For trials with PD-L1 subgroups, the most inclusive dataset is shown (i.e. all PD-L1 levels) to make most comparable to TACTI-002 data. i.e. for some IO higher OS data was found in TPS>50% groups etc.

Source: Immutep, Wilsons, trials as referenced.

Figure 2: Benchmarking of the Efti + pembrolizumab combo versus current SoC options in 1L NSCLC



Source. Immutep corporate presentation.

Low/negative PD-L1 cohorts (70% total NSCLC) continue to be important to thesis. Updated ORR data from these two PD-L1 cohorts (TPS <1% and TPS ≥1%) continue to show a profoundly superior effect of pembrolizumab when Efti is added (**Figure 3**) with 1.7- to 1.9-fold higher response rates in these cohorts (vs KEYNOTE-001). We use KEYNOTE-001 as the best benchmarking predicate study given its stage/size and inclusion of all PD-L1 subgroups, with subsequent pembrolizumab trials excluding the PD-L1 negative (TPS <1%) patients. Currently pembrolizumab monotherapy is indicated in the US for TPS ≥ 1% tumour only in NSCLC, noting that Efti addition brings the response in PD-L1 negative tumours (the balancing cohort) to ahead of pembrolizumab monotherapy.

These data continue to support the thesis that Efti can expand the TAM for Keytruda by 35% (to include PD-L1 all comers) in addition to driving better response rates in the existing (TPS ≥1%) approved cohorts.

Figure 3: PD-L1 subgroup benchmarking to pembrolizumab monotherapy (best LFL comparator trial). Updated SITC data (Nov) shows the improvement with data maturity as well as the superiority over pembro alone

	Efti + pembrolizumab (TACTI-002)			Pembrolizumab (KEYNOTE-001)	Benchmarking
PD-L1 subgroup	**Proportion of cohort**	**ORR (June)**	**ORR (Nov)**	**ORR**	**Fold benefit**
n		114	114	147	
All (unselected)	100%	38.6%	39.5%	24.8%	0.59
<1% TPS (negative)	28%	**28.1%**	**31.1%**	**10.7%**	**1.91**
1-49% TPS (low)	33%	**41.7%**	**44.7%**	**16.5%**	**1.71**
≥50% TPS (high)	18%	52.6%	55.0%	50.0%	0.10

**24 of 114 not defined by PD-L1 subgroup*

Source: Immutep, Kang *et al* 2017[1].

Phase III the next step for Eft in 1L NSCLC. Following their recent Fast Track Designation win from the FDA in this indication and declaration that progression of this (1L NSCLC) program is a priority for the company we would expect a Phase III program is in the works and regulator discussions on design are underway. The continued positive outcomes in both ORR and PFS are encouraging given these are the likely co-primary endpoints for a pivotal trial design.

1L NSCLC pipeline activity update. First line metastatic NSCLC continues to be a large and attractive oncology indication with a lot of ongoing trial activity. As an around the grounds, with respect to IO assets, we await readout of Gilead/Arcus' Phase II with anti-TIGIT asset domvanalimab in the ARC-7 study in early CY23, with the parallel Phase III pivotal ARC-10 trial now streamlined to compare only to Keytruda monotherapy (results >2024e). Meanwhile Roche continues their anti-TIGIT tiragolumab SKYSCRAPER-01 program, despite the Phase III failure earlier this year in 1L NSCLC missing their co-primary PFS endpoint. And in LAG-3 land, we await the Phase II readout from BMY's trial in mNSCLC using a triple combination approach with their anti-LAG-3 mAb relatlimab with anti-PD1 (nivolumab) and chemotherapy (due ~1Q24). MSD also have their Phase II KEYNOTE-495 trial investigating their anti-LAG-3 mAb favezelimab in combination with pembrolizumab, with updated data being presented also at SITC this week.

[1] Kang et al. 2017. Pembrolizumab KEYNOTE-001: an adaptive study leading to accelerated approval for two indications and a companion diagnostic. Ann Oncol. 28(6): 1388-1398.

INSIGHT-003: First look at a triple combination

Efti + anti-PD-1 + chemotherapy

INSIGHT-003 is an investigator led study. As a reminder, INSIGHT-003 is focused on triple combination evaluation of Efti plus anti-PD-1 agents (i.e. nivolumab, pembrolizumab) as well as chemotherapy. This study looks at patients in 1L NSCLC with n=20 being the recruitment target. The first patient was recruited in August of 2021. 14 of the total 20 patients have been enrolled as of June this year, with 79% of enrolled patients falling into the low PD-L1 category (TPS <50%).

Safety the key concern. Initial safety reads showed two serious AEs both unrelated to Efti, with one Grade 3 insomnia event considered related to Efti. The majority of AEs being related to chemotherapy backbone treatment and typical of the AE profile anticipated with this treatment.

Initial efficacy from 10 patients. Early efficacy signals from 10 of 14 patients show ORR of 70% and Disease Control Rate (DCR) of 90% (according to RECIST 1.1), of course noting the very small patient subset evaluated (n=10). It is encouraging at this early stage only 1 of 10 patients have progressive disease.

Potential to explore triple combination in Phase III NSCLC trial. The addition of a triple combination arm into a Phase III trial of Efti in 1L NSCLC would allow for a broadened label (allowing both pembrolizumab monotherapy as well as pembrolizumab + chemotherapy backbones) however has the potential to double the required trial recruitment size (if each arm requires its own control cohort). Immutep have mentioned several times the interest in exploring a triple combo in their late stage (Phase III) progression of Efti in NSCLC – it is yet unclear if this may be in a more minor capacity as an add on exploratory arm, or as a powered trial endpoint subgroup.

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Wilsons contact

For more information please phone: 1300 655 015 or email: publications@wilsonsadvisory.com.au