WILSONS

Date	Theme	Sector
6 June 2022	Company Update	Healthcare

Company

Immutep Limited (IMM)

ASCO data lays the path to Phase III

We maintain our OVERWEIGHT recommendation and $0.91 per share risked price target on Immutep. Data from Immutep's Phase II TACTI-002 trial in non-small cell lung cancer (NSCLC) has been presented at a major US oncology conference, ASCO, over the weekend. As an update to the n=75 patient data released in late May, we have seen data from an expanded patient dataset to n=114 patients. The data remains consistent and demonstrates apparent efficacy of an Efti + pembrolizumab (Keytruda®) combination in 1st line metastatic NSCLC patients – importantly on an all-comers basis (no PD-L1 expression exclusions). PFS benefit of ~3 months on a LFL basis versus current standard of care is compelling. As we have outlined previously, the fact that Efti has demonstrated efficacy in patients with PD-L1 low (TPS 1-49%) or absent (TPS <1%) expression expands the potential addressable market for Keytruda in a 1st line setting by ≥ 35%. We continue to view this as a key driver of corporate appeal, as pharma look to insulate their IO portfolios, and in particular anti-PD-1 assets – several of which have near term (3-6 year) patent exclusivity cutoffs. The TACTI-002 data presented supports progression into later stage (e.g. Phase III) trials, opening up exciting opportunities for Immutep.

Key Points

Data consistency a positive hallmark for efficacy. Once again, we have seen a consistent and superior response from the Efti + Keytruda combination in 1st line NSCLC patients with the n=114 patient data released at ASCO on June 3rd. The consistency of the overall response rate (ORR) across the data readouts (n=36 in 2021, n=75 in May, n=114 here) being 36%, 37% and 39% on an all-comers basis generates more confidence in the effect translatability into a larger Phase III cohort. The data presented this week at ASCO supports progression to later stage trials.

Efti combination continues to demonstrate TAM expansion potential in the all-important PD-L1 negative cohort. Competitively, the cohorts with low (TPS 1-49%) or nil (TPS ≤1%) PD-L1 expression are where Immutep's data shines. These patients are currently either a) not well managed with anti-PD-1/L1 monotherapy approaches – i.e. low response; or b) are not eligible for anti-PD-1 monotherapy and proceed straight to chemotherapy in mNSCLC. These cohorts which each represent 30-35% of the total mNSCLC patient cohort are where the greatest opportunity lies, where treatments are limited and competitively there is nothing much on the radar that has shown efficacy. These are also the cohorts where current oncology pharma heavyweights (including MSD) struggle and need to innovate to capture more of the patient population.

Recent M&A highlights importance of blockbuster insulation & addressing refractory patient segments. We have started to see IO M&A really pick up in the past quarter with several large deals highlighting the focus of oncology players – that is to insulate their existing IO blockbusters either through novel combinations or expansion of their addressable TAM (i.e. refractory patients). Regeneron and BMS each making acquisitions, with MSD a surefire contender in the near term.

Valuation. We maintain our $0.91/share SOTP risked PT 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 takeout valuation assessed.

Financial summary (Y/E Jun, AUD)	FY20A	FY21A	FY22E	FY23E	FY24E
Sales ($m)	0.0	0.0	0.0	0.0	0.0
EBITDA norm ($m)	(13.0)	(27.9)	(32.8)	80.2	(41.9)
EPS norm (cents)	(3.6)	(4.3)	(4.0)	9.2	(5.0)
Consensus EBITDA ($m)			(34.8)	(8.1)	(23.1)

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

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	$0.91
Share price @ 3-Jun-22 (AUD)	$0.43
Forecast 12-mth capital return	111.6%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**111.6%**
Market cap ($m)	372.5
Enterprise value ($m)	311.9
Shares on issue (m)	866.2
Sold short (%)	1.3
ASX All Ords weight (%)	0.0
Median turnover/day ($m)	0.7

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12-mth price performance ($)

	1-mth	6-mth	12-mth
Abs return (%)	30.3	(7.5)	(38.6)
Rel return (%)	33.6	(5.7)	(37.7)

Key changes		15-Mar	After	Var %
EBITDA	FY22E		(32.8)	
norm	FY23E		80.2	
($m)	FY24E		(41.9)	
EPS	FY22E		(4.0)	
norm	FY23E		9.2	
(cents)	FY24E		(5.0)	
Price target			0.91	
Rating			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 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. We see a valuation disconnect between IMM and their opportunities in these markets with significant TAMs in metastatic cancers (breast $2.3B, head & neck $2.2B, lung $8B) where unmet need is high and partnership with existing blockbusters (Keytruda) sets them up for an immediacy of adoption with future

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)	FY20A	FY21A	FY22E	FY23E	FY24E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(13.0)	(27.9)	(32.8)	80.2	(41.9)
EBIT norm	(15.1)	(30.0)	(34.7)	78.2	(44.2)
PBT norm	(14.9)	(29.9)	(34.1)	78.9	(42.7)
NPAT norm	(14.9)	(29.9)	(34.1)	78.9	(42.7)
NPAT reported	(14.8)	(30.5)	(34.6)	78.9	(42.7)
EPS norm (cents)	(3.6)	(4.3)	(4.0)	9.2	(5.0)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Growth (%)	FY20A	FY21A	FY22E	FY23E	FY24E
Sales	n/m	n/m	n/m	n/m	n/m
EBITDA norm	(25.0)	115.0	17.6	(344.4)	(152.3)
NPAT norm	(20.8)	100.9	14.1	(331.3)	(154.2)
EPS norm (cents)	(22.1)	19.0	(7.5)	(331.3)	(154.2)
DPS (cents)	n/m	n/m	n/m	n/m	n/m

Margins and returns (%)	FY20A	FY21A	FY22E	FY23E	FY24E
ROA	n/m	n/m	n/m	43.8	n/m
ROIC	n/m	n/m	n/m	557.6	n/m
ROE	n/m	n/m	n/m	46.1	n/m

Interims ($m)	1H21A	2H21A	1H22A	2H22E	1H23E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(18.8)	(9.1)	(15.4)	(17.4)	(18.3)
EBIT norm	(19.9)	(10.1)	(16.4)	(18.3)	(19.3)
PBT norm	(19.8)	(10.1)	(16.3)	(17.8)	(18.9)
NPAT norm	(19.8)	(10.1)	(16.3)	(17.8)	(18.9)
NPAT reported	(20.5)	(10.0)	(16.8)	(17.8)	(18.9)
EPS norm (cents)	(3.7)	(1.2)	(1.9)	(2.1)	(2.2)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Stock specific	FY20A	FY21A	FY22E	FY23E	FY24E
R&D expense (m)	(20.4)	(17.2)	(28.6)	(33.0)	(35.0)
Licensing revenue/milestor	7.5	0.0	0.0	120.0	0.0

Balance sheet ($m)	FY20A	FY21A	FY22E	FY23E	FY24E
Cash & equivalents	26.3	60.6	77.6	157.0	113.7
Current receivables	3.3	6.1	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	15.2	12.8	12.8	12.8	12.8
Other assets	1.7	2.4	2.9	3.5	3.0
Total assets	46.6	82.0	98.3	178.4	134.6
Current payables	2.9	4.8	3.0	3.7	3.2
Total debt	0.0	0.0	0.0	0.0	0.0
Other liabilities	10.2	3.8	3.9	3.4	3.4
Total liabilities	13.3	8.8	7.2	7.3	6.9
Minorities	0.0	0.0	0.0	0.0	0.0
Shareholders equity	33.3	73.3	91.2	171.1	127.7

Cash flow ($m)	FY20A	FY21A	FY22E	FY23E	FY24E
Operating cash flow	(10.8)	(17.6)	(33.8)	79.6	(43.2)
Maintenance capex	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Free cash flow	(10.9)	(17.7)	(33.8)	79.6	(43.2)
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	(1.4)	(3.1)	(2.2)	(0.1)	(0.1)
Cash flow pre-financing	(12.3)	(20.8)	(36.0)	79.5	(43.3)
Funded by equity	22.0	55.0	53.0	0.0	0.0
Funded by cash/debt	(31.8)	(89.3)	(70.0)	(79.5)	43.3

Liquidity	FY20A	FY21A	FY22E	FY23E	FY24E
Cash conversion (%)	84.9	63.5	104.9	98.3	106.5
Net debt ($m)	(26.3)	(60.6)	(77.6)	(157.0)	(113.7)
Net debt / EBITDA (x)	2.0	2.2	2.4	(2.0)	2.7
ND / ND + Equity (%)	(377.3)	(477.9)	(570.7)	n/m	(811.0)
EBIT / Interest expense (x)	79.7	n/m	55.9	n/m	30.4

Valuation	FY20A	FY21A	FY22E	FY23E	FY24E
EV / Sales (x)	n/m	n/m	n/m	n/m	n/m
EV / EBITDA (x)	(26.6)	(11.2)	(9.0)	2.7	(6.2)
EV / EBIT (x)	(23.0)	(10.4)	(8.5)	2.8	(5.9)
P / E (x)	(11.8)	(10.0)	(10.8)	4.7	(8.6)
P / BV (x)	6.3	4.4	4.0	2.1	2.9
FCF yield (%)	(5.2)	(5.5)	(9.2)	21.7	(11.8)
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)	410.1	692.6	854.1	854.1	854.1

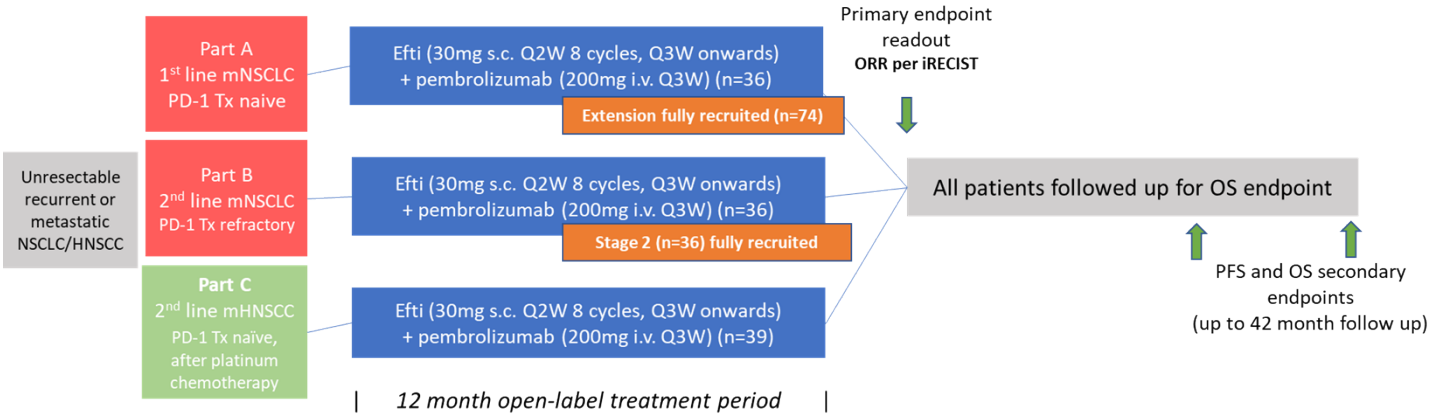
Source: Company data, Wilsons estimate, Refinitiv.
All amounts are in Australian Dollar (A$) unless otherwise stated.

ASCO data update

TACTI-002 refresher

TACTI-002 trial summary. TACTI-002 is a non-randomised Phase II, open-label trial being conducted across 19 study site locations across the USA, UK, Europe and Australia. **Figure 1** below summarises the trial design, with Part A being the focus of today's note (1st line NSCLC patients).

Figure 1. TACTI-002 trial design



Source: Immutep, clinicaltrials.gov, Wilsons.

Data from expanded cohort (n=114) continues to show superior efficacy of Efti combination

As we recently outlined, the updated TACTI-002 data (n=75) continued to show superior efficacy when comparing Efti in combination with pembrolizumab and pembrolizumab monotherapy (from published studies). The additional ASCO data announced over the weekend continues to support this same conclusion. Updated data from n=114 patients (Part A plus extension) are summarised in **Table 1** in comparison to the pivotal Phase III studies used to support current standard of care IO therapies in the mNSCLC indication. Importantly Efti combination responses remain consistent, with respect to the primary endpoint – overall response rate (ORR) – when comparing across the interim data readouts (36%, 37% and 39% ORR from 2021, Jan '22 and April '22 data cutoffs). Consistent in primary endpoint as the trial sample size (n) increases provides more confidence in the translatability of this effect in larger (i.e. Phase III) randomised controlled trials.

Table 1. Comparison of Efti vs other checkpoint inhibitors vs SOC in 1st line metastatic NSCLC^

	Efti + pembrolizumab	Pembrolizumab	Atezolizumab	Pembro+ chemo	Nivolumab + ipilimumab
Targets	APC activator + Anti-PD-1	Anti-PD-1	Anti-PD-L1	Anti-PD-1+ chemo	Anti-PD-1+ Anti-CTLA-4
FDA approval	-	April 2019	May 2020	Oct 2018	May 2020
Study	TACTI-002 Part A extension	Keynote-042	IMpower110	Keynote-407	Checkmate-227
Phase	II	III	III	III	III
Therapy Line	1st	1st	1st	1st	1st
n	114	637	277	278	583
PD-L1 TPS <1%	28%	nil	nil	34%	32%
TPS 1-49%	32%	53%	61%	37%	33%
TPS ≥50%	17%	47%	39%	26%	35%
Median PFS	6.9 m	5.4 m	5.7 m	6.4 m	7.2 m
HR (for progression)	interim (NR)	1.07, p>0.05	0.77	0.56, p<0.001	0.79
Median OS (months)	Not yet reached	16.7m	17.5 m	15.9 m	17.1 m
HR (for death)	-	0.81, p=0.0018	0.83, p>0.05	0.64, p<0.001	0.73
DoR median	Not yet reached	20.2 m	not estimatable	7.7 m	19.6 m
ORR	39%	27%	29%	58%	33%
Response criteria	iRECIST	RECIST v1.1	RECIST v1.1	RECIST v1.1	RECIST v1.1
Adverse Events (AEs)					
Discontinuation AEs	10%	8%	6%	23%	18%

^Note this is not an exhaustive list of all approved IO combinations and drugs ; simply a summary of interesting trial predicates and comparisons.

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.

NR = not reported. # total TACTI-002 population (includes HNSCC).

Source: Immutep, clinicaltrials.gov, Wilsons.

PFS. An incremental update included was progression free survival (PFS) was reported as 6.9 months on an all-comers basis. It is important to note this is not a like-for-like comparison to the 5.4 month PFS achieved in KEYNOTE-042 with pembrolizumab monotherapy as this 5.4 month PFS was achieved in a PD-L1 positive population (TPS ≥ 1%). On a LFL basis the Efti + pembro combination in TPS ≥ 1% patients is currently 8.4 months (a 3 month benefit vs pembrolizumab alone). Similar outcomes are seen when comparing to Roche's anti-PD-L1 atezolizumab (achieving 5.7 month PFS in TPS ≥ 1% cohort).

The addition of Efti has a clear benefit thus in terms of ORR and PFS when comparing on a LFL basis across anti-PD-1/PD-L1 approved monotherapies in mNSCLC, of course noting the caveats with cross-trial comparisons.

Low and negative PD-L1 cohorts (~65% total population) are key target for Efti. As we have noted previously, these two cohorts, as opposed to high PD-L1 expression (TPS ≥ 50%) patients (which typically have good responses to pembrolizumab monotherapy) are where Efti's competitive edge lies in the 1st line metastatic NSCLC setting. NSCLC is a busy indication with all major oncology players attempting to improve upon current standard of care. The comparison between Efti combo responses (from the n=114 data just released) versus pembrolizumab monotherapy (KEYNOTE-001 trial[1]) clearly shows superiority in ORR in the PD-L1 negative and low expression patients (28% vs 11% and 42% vs 17% respectively for Efti combo vs pembro monotherapy). Given that PD-L1 negative patients are currently ineligible for pembrolizumab monotherapy (US & EU), which represent ~30-35% of all mNSCLC, this 2.5x response rate (to 28%) is a meaningful improvement and could support expansion of the pembrolizumab label to include PD-L1 negative patients. The same could be said for PD-L1 low (TPS 1-49%) patients which are also ineligible in Europe for pembrolizumab monotherapy. The data here (**Table 2**) show the potential for Efti to expand the eligible mNSCLC population for pembrolizumab treatment by 30-65%. This continues to be, in our view, the most significant driver of corporate/licensing interest in Efti given the size of the NSCLC opportunity, particularly for MSD that currently dominate this indication with pembrolizumab sales.

Table 2. Efficacy responses by PD-L1 subgroup (1L NSCLC)

	Efti + pembrolizumab (TACTI-002)		Pembrolizumab (KEYNOTE-001)
PD-L1 subgroup	Proportion of cohort	ORR	ORR
n		114	147
All (unselected)	100%	38.6%	24.8%
<1% TPS (negative)	28%	28.1%	10.7%
1-49% TPS (low)	32%	41.7%	16.5%
≥50% TPS (high)	17%	52.6%	50.0%

Source: Immutep, Kang et al.

M&A within Immuno-oncology (IO) heats up

Recent M&A highlights importance of blockbuster insulation & addressing refractory patient segments. Several recent pharma deals highlight the focus of oncology players – that is to insulate their existing IO blockbusters either through novel combinations (i.e. with LAG-3 or other targets) and/or via expansion of their addressable TAM (i.e. assets that address refractory patient subsets). These deals also demonstrate that the pharma M&A market is very much alive and active with big pharma finally digging into their deep pockets following some bumper COVID sales years.

Sanofi deal focused on combinatorial flexibility. Regeneron (NASDAQ:REGN) have been busy with a buyout of Sanofi's stake in Libtayo® (anti-PD-1 mAb) for a US$900M upfront payment (+11% sales royalty) which includes plans to further develop Regeneron's own anti-LAG-3/PD-1 combination. This is one example of deals focused on bringing novel IO combos into the pipeline. The most significant of these has been GSK's $2B deal (US$625M upfront) for iTeos Therapeutics in 2021 on the basis of their anti-TIGIT asset. This of course has been cast into doubt based on the recent flop of Roche's leading anti-TIGIT asset, tiragolumab, which has recently failed in two Phase III trials. This very much leaves the IO space looking for new targets outside of TIGIT to pair with their approved anti-PD-1 agents.

CheckMate deal focused on refractory patient subsets. This was preceded by Regeneron's April acquisition of CheckMate Pharmaceuticals (NASDAQ:CMPI) for US$250M (~335% premium), based on an asset (vidutolimod) which demonstrated efficacy in PD-1 refractory melanoma patients. This strategic acquisition by REGN highlights they are looking for assets that address the portion of the market in which their existing anti-PD-1 assets are failing. This strategy of course is the same one in which Immutep have demonstrated efficacy, in both Part A of their TACTI-002 trial (in patients with nil PD-L1 expression) and also in Part B (2nd line PD-1/PD-L1 refractory patients), showing that the addition of Efti to current standard of care (Keytruda®) can enhance and recreate clinical responses – significantly expanding the addressable mNSCLC patient pool.

Turning Point deal also focused on expanding TAM. Bristol Myers Squibb's (NYSE:BMY) acquisition of Turning Point Therapeutics (NASDAQ:TPTX) for US$4.1B (122% premium) further highlights big pharma's focus on pipeline expansion via increased addressable patient pools within indications where they already have a significant presence. BMY's anti-PD-1 agent Opdivo is a blockbuster and used in NSCLC therapy. This deal focused on acquisition of repotrectinib, a novel tyrosine kinase inhibitor (TKI), with promising data in NSCLC patient subsets with ROS1 and NTRK mutations. If approved, repotrectinib expands the pool of NSCLC patients addressable within BMY's portfolio.

Next steps

More mature TACTI-002 readouts. This was the first interim readout from the expanded Part A patient cohort (n=114). We will continue to see updated interim data readouts as the cohort progresses through their therapy, noting that overall survival (OS) data is a key readout we are yet to see for ~12 months (mid CY23), noting this is a secondary endpoint in this trial only. We will continue to received updated PFS readouts also, importantly across the three PD-L1 subgroups. We look to see PFS as maintained above pembrolizumab monotherapy – most importantly n the TPS <1% and TPS 1-49% subgroups where the greatest clinical and competitive benefit lies for Efti in the NSCLC indication.

Corporate activity/ trial progression. We anticipate a greater level of interest and awareness of the Efti NSCLC program has arisen following ASCO. We see clear advantages for MSD (and others) to bring Efti technology into their portfolios. The ability for IMM to show data from a larger Phase II dataset for discussions around Phase III partnership or licensing strengthens their value proposition. Predicting timing of any deals remains challenging.

[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.

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Recommendation structure and other definitions

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