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Date	Theme	Sector
23 October 2023	Company Update	Healthcare

Company

Immutep Limited (IMM)

Just double it! Survival that is

We maintain our OVERWEIGHT recommendation and risked PT of $0.90/sh. Further to last week's ESMO abstract release, we have seen more mature data released over the weekend at the ESMO conference presentation. The updated data from Part A (1st line metastatic non-small cell lung cancer; 1L mNSCLC) of Immutep's Phase II TACTI-002 trial continues to stun, showing marked increases in tumour response and survival when their lead agent, Efti (soluble LAG-3), is added to standard of care (SoC) therapy - in this instance Merck's top selling Keytruda. This latest data readout demonstrates an >18-month benefit over Keytruda alone (and other SoC) for the same patient cohort (PD-L1 TPS ≥1%) that Immutep will recruit in their randomised, registrational, Phase III trial currently in preparation (TACTI-004). This, to our knowledge, is the greatest demonstrated benefit over current SoC, in the absence of added toxicity we have seen, and clearly sets IMM up well for their Phase III progression. This represents a doubling (!) in the overall survival (OS) compared to current standard of care (35.5 months vs 16.7 months in PD-L1 ≥1%), clearly demonstrating a material synergistic benefit in dual immune modulation (via LAG-3 & PD-1). It is also important to remember, that unlike some other oncology biotechs' focused in more niche indications, IMM are taking on a mega-indication here in 1L mNSCLC - an indication that is alone responsible for >US$4B in Keytruda sales annually. With each continuing data read out we de-risk the TACTI-004 program in our minds, noting that we will get to a big de-risking point in mHNSCC sooner with the TACTI-003 program due for topline data in <6 months.

Key Points

New data from ESMO presentation. Following last week's abstract release in which we saw PD-L1 subtype data (from Mar 2023 cut off), for the first time – we now have comprehensive subtype information from a more mature data read (Aug 2023 cut off). 35.5 months OS is the key number here, from the PD-L1 TPS ≥1% cohort (ORR: 48.3%; mPFS: 11.2months) representing an ≥18-month survival benefit over pembrolizumab monotherapy (mOS 16.7months). Importantly safety remains with no new signals, and responses are durable (mDOR 24.2months). More detail on p3.

Strategic relevance. The kinds of survival extensions that Efti is producing force the attention of IO heavyweights (MSD, BMS, Roche) as they plan how to best insulate their own blockbuster portfolios that are nearing patent cliffs, or losing share to peers. Subcutaneous formulations of these blockbusters are big pharma's latest patent extension trick, with Roche's Tecentriq the first to win UK approval in August (+ under FDA review). MSD are following with Keytruda, whilst BMS is also working on Opdivo subcutaneous formulations with their Phase III equivalence trial just reporting success (lining up filings). Efti is already administered as a subcutaneous formulation – we will leave it to investors to draw the line as to how this may enhance its attractiveness for future combination therapy development.

Forecasts. Changes reflect FY23 result update only. No changes to modelling or forecasts.

Valuation. SOTP risked $0.90/sh PT comprises: a) Efti 1L NSCLC ($0.61/sh); b) Efti in mBC ($0.22/share); and c) Efti in HNSCC ($0.06/sh). Unrisked valuation $5.57/sh. We continue to see TACTI-003 HNSCC topline success in the next 6 months as a key de-risking point to valuation (+6%) but more importantly as a catalyst for major strategic interest.

Recommendation	OVERWEIGHT
12-mth target price (AUD)	$0.90
Share price @ 23-Oct-23 (AUD)	$0.28
Forecast 12-mth capital return	227.3%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**227.3%**

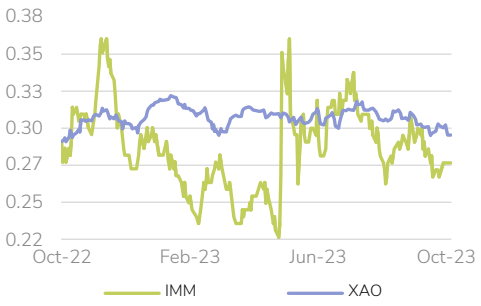
Market cap ($m)	326.9
Enterprise value ($m)	203.5
Shares on issue (m)	1,189
Sold short (%)	0.2
ASX All Ords weight (%)	0.0
Median turnover/day ($m)	0.4

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 (%)	(8.3)	9.5	(3.7)
Rel return (%)	(6.0)	16.2	(6.7)

Financial summary (Y/E Jun, AUD)	FY22A	FY23A	FY24E	FY25E	FY26E
Sales ($m)	0.0	0.0	0.0	0.0	26.1
EBITDA norm ($m)	(30.3)	(38.8)	(42.7)	(38.0)	(25.6)
Consensus EBITDA ($m)			(47.8)	(43.0)	88.9
EPS norm (cents)	(3.8)	(4.5)	(3.7)	(3.4)	(1.7)

Key changes		13-Jun	After	Var %
EBITDA	FY24E	(45.3)	(42.7)	6%
norm	FY25E	(40.5)	(38.0)	6%
($m)	FY26E		(25.6)	
EPS	FY24E	(3.9)	(3.7)	6%
norm	FY25E	(3.6)	(3.4)	7%
(cents)	FY26E		(1.7)	
Price target		**0.90**	**0.90**	**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 (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 stay OVERWEIGHT with our risked PT of $0.90/sh. This latest data readout demonstrates an >18-month benefit over Keytruda alone. This, to our knowledge, is the greatest demonstrated benefit over current SoC, in the absence of added toxicity we have seen, and clearly sets IMM up well for their Phase III progression. With each continuing data read out we de-risk the TACTI-004 program in our minds, noting we get to a big de-risking point in TACTI-003 sooner, due for topline data in <6 months.

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	26.1
EBITDA norm	(30.3)	(38.8)	(42.7)	(38.0)	(25.6)
EBIT norm	(32.3)	(40.8)	(45.1)	(40.6)	(28.6)
PBT norm	(32.2)	(39.9)	(44.0)	(40.0)	(28.2)
NPAT norm	(32.2)	(39.9)	(44.0)	(40.0)	(19.8)
NPAT reported	(32.2)	(39.9)	(44.0)	(40.0)	(19.8)
EPS norm (cents)	(3.8)	(4.5)	(3.7)	(3.4)	(1.7)
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	8.4	28.0	10.2	(11.1)	(32.5)
NPAT norm	7.7	23.9	10.2	(9.1)	(50.5)
EPS norm (cents)	(24.7)	17.9	(17.1)	(9.1)	(50.5)
DPS (cents)	n/m	n/m	n/m	n/m	n/m

Margins and returns (%)	FY22A	FY23A	FY24E	FY25E	FY26E
EBITDA margin	n/m	n/m	n/m	n/m	(98.3)
EBIT margin	n/m	n/m	n/m	n/m	(109.6)
PBT margin	n/m	n/m	n/m	n/m	(108.2)
NPAT margin	n/m	n/m	n/m	n/m	(75.8)

Interims ($m)	2H22A	1H23A	2H23A	1H24E	2H24E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(14.8)	(18.3)	(20.4)	(21.3)	(21.4)
EBIT norm	(16.0)	(19.3)	(21.6)	(22.5)	(22.6)
PBT norm	(15.9)	(19.0)	(20.9)	(21.9)	(22.1)
NPAT norm	(15.9)	(19.0)	(20.9)	(21.9)	(22.1)
NPAT reported	(15.9)	(19.0)	(20.9)	(21.9)	(22.1)
EPS norm (cents)	(1.9)	(2.3)	(2.3)	(1.8)	(1.9)
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)	(34.2)	(40.0)	(35.0)	(20.0)
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	81.4	38.1	20.8
Current receivables	8.4	8.0	5.0	5.0	5.1
Current inventory	0.0	0.0	0.0	0.0	0.2
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	5.9	4.4	4.4
Total assets	102.2	147.4	101.9	57.1	40.2
Current payables	5.8	9.0	8.1	4.9	8.9
Total debt	0.0	0.0	0.0	0.0	0.0
Other liabilities	2.2	1.8	1.7	1.7	2.7
Total liabilities	8.1	11.0	10.0	6.7	11.8
Minorities	0.0	0.0	0.0	0.0	0.0
Shareholders equity	94.1	136.5	91.9	50.3	28.4

Cash flow ($m)	FY22A	FY23A	FY24E	FY25E	FY26E
Operating cash flow	(30.2)	(35.4)	(41.8)	(43.2)	(17.1)
Maintenance capex	(0.0)	(0.1)	(0.0)	(0.0)	(0.0)
Free cash flow	(30.3)	(35.4)	(41.9)	(43.2)	(17.1)
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)	(0.1)	(0.1)	(0.1)
Cash flow pre-financing	(33.6)	(36.6)	(42.0)	(43.3)	(17.3)
Funded by equity	53.0	80.1	0.0	0.0	0.0
Funded by cash/debt	(72.4)	(123.5)	42.0	43.3	17.3

Liquidity	FY22A	FY23A	FY24E	FY25E	FY26E
Cash conversion (%)	100.3	93.6	100.7	115.6	101.2
Net debt ($m)	(80.0)	(123.4)	(81.4)	(38.1)	(20.8)
Net debt / EBITDA (x)	2.6	3.2	1.9	1.0	0.8
ND / ND + Equity (%)	(568.1)	(945.6)	(775.1)	(311.4)	(273.3)
EBIT / Interest expense (x)	n/m	44.4	39.7	59.3	82.8

Valuation	FY22A	FY23A	FY24E	FY25E	FY26E
EV / Sales (x)	n/m	n/m	n/m	n/m	11.7
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)	2.5	2.4	3.6		
FCF yield (%)	(12.9)	(10.9)	(12.8)		
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)	849.9	892.5	1,187	1,187	1,187

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

Updated 1L NSCLC data

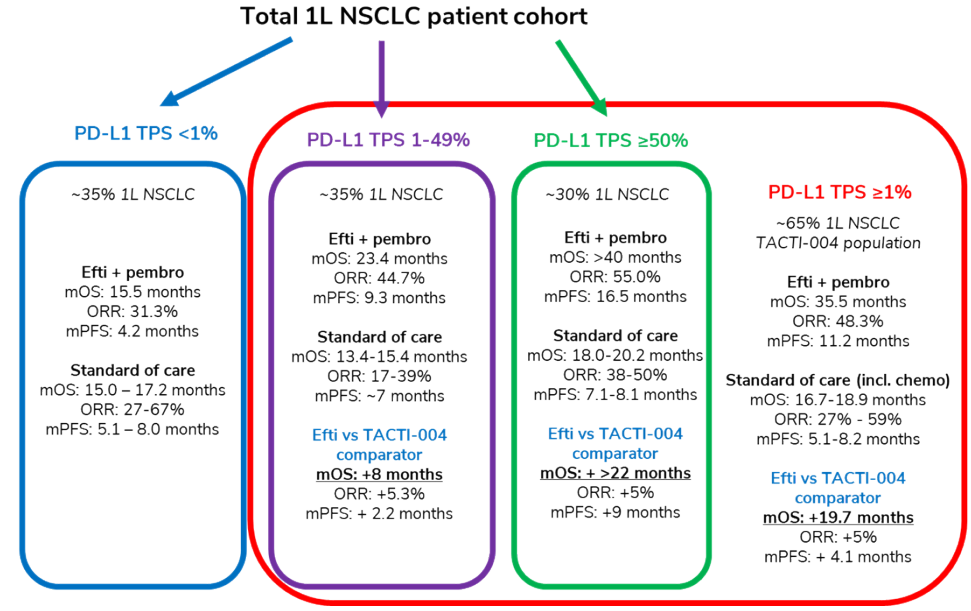
More mature data impresses – again...

We have attempted to summarise and simplify the key data from IMM's latest ESMO presentation below in **Figure 1**, highlighting the benefit in each patient cohort over the current standard of care therapies.
In **Figure 1** we state:

- the three key data endpoints (median overall survival – mOS; objective response rate – ORR; median progression free survival – mPFS);
- the latest data from TACTI-002 (being **Efti + pembro**)
- a summary of the comparative **standard of care treatments** per those endpoints; and
- a benefit comparison of this latest Efti data vs the TACTI-004 comparator arm that the Efti + pembro combo will need to beat to reach a successful Phase III outcome.

As noted, the PD-L1 TPS ≥1% cohort (in red) (65% of all mNSCLC patients) is the most important and relevant for IMM at present given it is the target cohort for enrolment in their Phase III TACTI-004 trial (**Figure 2**) which will begin recruiting in early 2024. As a reminder, PD-L1 status denotes the level of PD-L1 expressed in the patient's tumours and patients are categorised and treated based on this status. Those with high (TPS≥50%) PD-L1 status have the best response to anti-PD-1 therapies like pembrolizumab (Keytruda), and those with absent (TPS <1%) PD-L1 status have limited/no response to these therapies and are typically placed on chemotherapy regimens immediately.

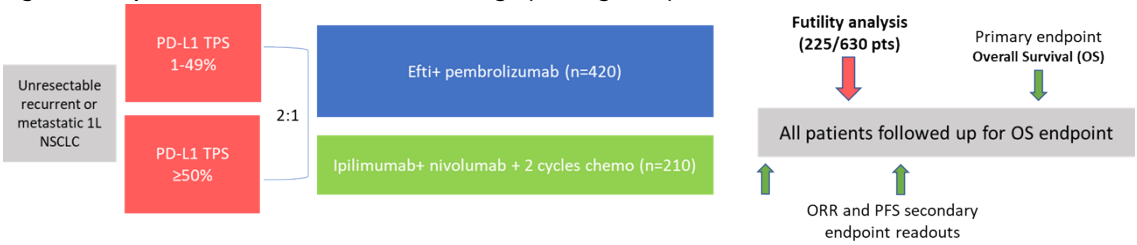
Figure 1: Summary of latest 1L mNSCLC data versus current SOC and TACTI-004 comparator



Source: Immutep, Relevant clinical trial publications (CheckMate-9LA, Keynote-042, Keynote-407, IMPower110, Checkmate-227).

What does it take to get Efti to a 1L NSCLC approval? Achieving significant superiority in overall survival (OS) when combining Efti with pembrolizumab (Keytruda) when compared to the SOC comparator arm is necessary for trial success to support FDA filing and subsequent approval. The SOC comparator arm Immutep have chosen is a triple combination of ipilimumab (an anti-CTLA-4) plus nivolumab (an anti-PD-1) plus 2 cycles of chemotherapy (**Figure 2**). This comparator appears to be chosen as the best choice to reflect a SOC relevant to both TPS 1-49% and TPS ≥50% patient cohorts (by NCCN guidelines). If TACTI-002 data is replicated at a larger scale, the ability to show superiority to this comparator arm in the Phase III appears likely. A futility analysis (after 225 patients) is anticipated in 2025. At this stage the TPS <1% cohort has failed to impress, however the low ORR in this cohort is skewing mOS, which may be better than it appears at a cohort level. We look to INSIGHT-003 outcomes (with the Efti+ pembro+ chemo triple combo) for the future path in this very difficult to treat third of NSCLC patients.

Figure 2: Simplified TACTI-004 Phase III trial design (starting 2024)



Source: IMM, Wilsons.

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