TAYLOR COLLISON

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Immutep (IMM)

10 June 2022

Speculative Investment

Recommendation: Outperform

Lung may jump breast cancer in trial queue

Our View

IMM reported positive headline data from its expanded TACTI-002 part A trial in first line (1L) non small cell lung cancer (NSCLC) at ASCO last week. The overall response rate (ORR) among all 114 subjects treated with the efti/Keytruda combo edged higher to 38.6% vs 36.1% in the first 36 at ASCO 2021. Consistent with the trends seen in the different PD-L1 tumour biomarker subgroups in the first 36 patients last year, the greatest of the benefit of efti was seen in the PD-L1^{low} (TPS 1-49%) group, and to a lesser extent in PD-L1^{negative} patients. There was little apparent benefit in the PD-L1^{high} group in terms of ORR, although the progression free survival of 11.8 months looks encouraging.

The response rate and progression free survival in the PD-L1^{low} group, which were both around double that reported for Keytruda monotherapy, are strongly supportive of late stage clinical development in this setting. We view a pivotal trial of the efti/Keytruda combo in PD-L1^{low} first line NSCLC as a better option than IMM's proposed Phase III trial of efti+chemo in breast cancer. Management has indicated that it will evaluate its options based on this substantial new data set in NSCLC, and we would welcome a change in strategy.

The key value driver for IMM continues to be the randomised TACTI-003 trial of efti plus Keytruda in first line head and neck cancer (HNSCC), which is expected to read out **topline results in H2CY23**. Our valuation is unchanged at $1,158m, $1.31/sh fully diluted or $1.36/sh undiluted. Maintain Outperform.

Key Points

A window of opportunity in PD-L1^{low} 1L NSCLC
Based on the updated TACTI-002 Part A results we believe that the best prospects for the efti combo to demonstrate superior efficacy to Keytruda monotherapy in 1L NSCLC would be in patients with low or negative PD-L1 expression (TPS<50%). However, Keytruda monotherapy for 1L NSCLC is only approved in the US for patients with PD-L1≥1%. In our view this creates a window of opportunity to compare efti+Keytruda vs Keytruda monotherapy in a pivotal trial in PD-L1^{low} (TPS 1-49%) patients.

While the influential NCCN clinical practice guidelines in the US recommend Keytruda/chemo combo as the preferred therapy in this patient population, it recommends Keytruda monotherapy in patients who cannot tolerate or refuse chemotherapy. The efti combo could be compared to Keytruda in these patients.

Even though under this scenario the clinical trial would be conducted in patients who were unsuitable for or refuse Keytruda/chemo combo therapy, we would expect efti combo therapy to be approved for use in all PD-L1^{low} patients if it demonstrates superior efficacy in the pivotal trial.

Given the good tolerability reported for the efti combo therapy to date, if efti gains FDA approval for use in combination with Keytruda in PD-L1^{low} 1L NSCLC patients, we would expect it to take meaningful market share from the more toxic chemo/Keytruda combo which is the current preferred therapy.

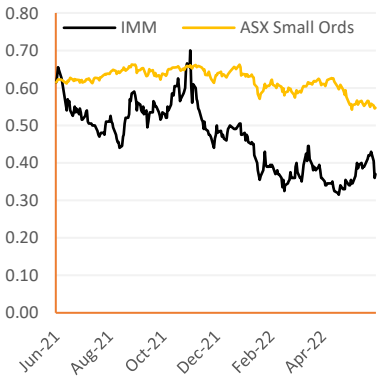
Different response patterns in NSCLC vs head and neck cancer (HNSCC). In NSCLC patients most of the benefit was seen in PD-L1^{low} and PD-L1^{negative} patients, whereas in HNSCC patients in TACTI-002 part C the greatest benefit was seen in PDL-1^{high} patients. Management suggested that this may be because NSCLC tends to be an immunologically "hot" tumour whereas HNSCC can be considered more "tepid". This may just be chance variation, or it may mean that there are particular patient populations that are most suited to benefit from antigen presenting cell activation by efti to stimulate immune responses.

Our conflicts of interests are disclosed on the last page of this report.

Summary (AUD)

Market Capitalisation	**$316M**
Share price	**$0.365**
52 week low	$0.305
52 week high	$0.71
Cash as at 31 March 2022	$87.2m

Share price graph (AUD)



Key Financials (AUD)

	FY21A	FY22E	FY23E
Revenue ($m)	3.9	6.1	3.9
R&D ($m)	(17.2)	(27.0)	(42.0)
SG&A ($m)	(14.6)	(7.9)	(8.2)
EBITDA ($m)	(27.9)	(28.8)	(46.3)
Reported NPAT ($m)	(29.9)	(30.3)	(47.6)
NPAT Adj. ($m)	(29.9)	(30.3)	(47.6)
EPS Adj. (c)	(5.0)	(3.8)	(5.6)
PE ratio (x)	n/a	n/a	n/a
DPS (c)	0.0	0.0	0.0
EV/Sales	n/a	n/a	n/a
EV/EBITDA (x)	n/a	n/a	n/a
ROE	n/a	n/a	n/a

Immutep - Summary of Forecasts — IMM $ 0.365

PROFIT & LOSS SUMMARY (A$m)

Year end June	FY20A	FY21A	FY22E	FY23E
Sales, royalties, milestones	7.5	0.0	2.2	0.0
Other (includes R&D tax rebate	8.5	3.9	3.9	3.9
Total Revenue	**16.0**	**3.9**	**6.1**	**3.9**
Growth (pcp)	141.8%	-75.8%	57.2%	-36.1%
R&D Expenses	(20.4)	(17.2)	(27.0)	(42.0)
SG&A expenses	(7.5)	(14.6)	(7.9)	(8.2)
EBITDA	**(11.9)**	**(27.9)**	**(28.8)**	**(46.3)**
Dep'n/Other Amort'n	(2.1)	(2.1)	(2.1)	(2.1)
EBIT	(14.0)	(30.0)	(30.9)	(48.4)
Net Interest	0.2	0.1	0.6	0.8
Pre-Tax Profit	(13.5)	(29.9)	(30.3)	(47.6)
Tax Expense	(0.0)	(0.0)	0.0	0.0
Minorities	0.0	0.0	0.0	0.0
NPAT Adj.	**(13.5)**	**(29.9)**	**(30.3)**	**(47.6)**
Growth (pcp)	n/a	n/a	n/a	n/a
Adjustments	0.0	0.0	0.0	0.0
NPAT Reported	(13.5)	(29.9)	(30.3)	(47.6)

PER SHARE DATA

Year end June	FY20A	FY21A	FY22E	FY23E
EPS (c) - Reported	**(3.4)**	**(5.0)**	**(3.8)**	**(5.6)**
Growth (pcp)	n/a	n/a	n/a	n/a
EPS (c) - Adjusted	(3.4)	(5.0)	(3.8)	(5.6)
Growth (pcp)	n/a	n/a	n/a	n/a
Dividend (c)	0.0	0.0	0.0	0.0
Franking	0.0	0.0	0.0	0.0
Gross CF per share (c)	(2.7)	(3.0)	(3.4)	(5.2)
NTA per share (c)	3.7	8.0	9.6	4.3

KEY RATIOS

Year end June	FY20A	FY21A	FY22E	FY23E
Net Debt : Equity (%)	-78.3%	-82.3%	-88.1%	-80.5%
Net Debt: EBITDA (x)	2.2	2.2	2.8	0.8
Current ratio (x)	9.3	12.8	16.8	8.5
ROE (%)	-46.7%	-56.1%	-36.5%	-68.4%
ROIC (%)	n/a	n/a	n/a	n/a
Dividend Payout Ratio (%)	n/a	n/a	n/a	n/a

VALUATION MULTIPLES

Year end June	FY20A	FY21A	FY22E	FY23E
PE Ratio (x)	**n/a**	**n/a**	**n/a**	**n/a**
Dividend Yield (%)	**0.0%**	**0.0%**	**0.0%**	**0.0%**
EV/Sales (x)	n/a	n/a	n/a	n/a
EV/EBITDA (x)	n/a	n/a	n/a	n/a
EV/EBIT (x)	n/a	n/a	n/a	n/a

CAPITAL RAISING ASSUMPTIONS

Year end June	FY20A	FY21A	FY22E	FY23E
Shares Issued (m)	143.8	154.1	98.6	0.0
Issue Price (A$)	0.15	0.35	0.5	0.0
Gross Cash Raised (A$m)	22.0	53.7	51.3	0.0

BALANCE SHEET SUMMARY

Year end June	FY20A	FY21A	FY22E	FY23E
Cash	26.3	60.6	82.1	37.6
Receivables	3.3	6.1	6.1	6.1
Inventories	0.0	0.0	0.0	0.0
Other	1.5	1.7	1.7	1.7
Total Current Assets	31.2	68.4	89.9	45.4
Inventories	0.0	0.0	0.0	0.0
Property Plant & Equip	0.0	0.0	(0.1)	(0.2)
Intangibles	15.4	13.6	11.7	9.8
Other	0.0	0.0	0.0	0.0
Total Current Assets	15.4	13.6	11.6	9.7
TOTAL ASSETS	**46.6**	**82.0**	**101.5**	**55.1**
Accounts Payable	2.9	4.8	4.8	4.8
Borrowings	0.1	0.2	0.2	0.2
Provisions	0.3	0.4	0.4	0.4
Other	0.0	0.0	0.0	0.0
Total Current Liab	3.4	5.3	5.3	5.3
Borrowings	0.1	0.1	0.1	0.1
Provisions	0.1	0.1	0.1	0.1
Other	10.1	3.6	5.5	7.4
Total Non-Current Liab	9.9	3.4	5.3	7.3
TOTAL LIABILITIES	**13.3**	**8.8**	**10.7**	**12.6**
TOTAL EQUITY	**33.3**	**73.3**	**90.9**	**42.5**

CASH FLOW SUMMARY

Year end June	FY20A	FY21A	FY22E	FY23E
EBIT (excl Abs/Extr)	**(14.0)**	**(30.0)**	**(30.9)**	**(48.4)**
Add: Dep'n & Amort'n	2.1	2.1	2.1	2.1
Other non-cash items	(7.4)	(11.7)	(6.4)	(6.9)
Less: Tax paid	0.0	0.0	0.0	0.0
Net Interest	0.2	0.1	0.6	0.8
Change in Rec.	1.9	(2.8)	0.0	0.0
Change in Inv.	0.0	0.0	0.0	0.0
Gross Cashflows	(10.8)	(17.6)	(27.2)	(44.4)
Capex	(0.0)	(0.0)	(0.1)	(0.1)
Free Cashflows	(10.9)	(17.7)	(27.3)	(44.5)
Share Issue Proceeds	20.6	52.9	48.7	0.0
Other	0.1	(1.0)	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0
Net Cashflows	**9.8**	**34.3**	**21.5**	**(44.5)**
FX Effect on Cash	0.1	(0.8)	0.0	0.0

IMM base case valuation summary (undiluted)

	Probability (%)	Valuation (A$m)	Value A$/share
efti/ICI NSC lung cancer	20%	188.5	0.22
efti/ICI head & neck cancer	50%	341.1	0.40
efti/ICI melanoma	20%	22.2	0.03
efti/chemo breast cancer	10%	64.0	0.07
efti milestones - partner after TACTI-003	30-45%	439.9	0.52
LAG525 solid tumours (lung cancer)	25%	62.1	0.07
SG&A	-	(38.3)	(0.04)
Portfolio total	-	1,079.3	1.26
Net cash end FY22e (incl conv note face value)	-	78.6	0.09
Total Valuation	-	1,158.0	1.36

Data from additional cohorts in TACTI-002 presented at SITC

IMM presented data from all 114 1L NSCLC patients subjects in the expanded TACTI-002 Part A trial in an oral presentation at the American Society for Clinical Oncology (ASCO) on 3 June. The patients were all treated with its cancer immunotherapy drug efti combined with the immune checkpoint inhibitor Keytruda (pembrolizumab).

Efti (eftilagimod alpha or IMP321) is a LAG-3 Ig fusion protein that activates antigen presenting cells (APCs) to stimulate the initial steps of the immune response. TACTI-002 is an open label, single arm study, with no placebo control group.

Exhibit 1 shows that the overall response rate (ORR) among all 114 subjects treated with the efti/Keytruda combo was 38.6% when assessed using iRECIST[1] on an intention to treat (ITT) basis (ie, including all enrolled subjects, regardless of whether they have undergone any scans to assess tumour response). The ITT ORR was slightly higher than the 36.1% reported for the first 36 subjects at ASCO 2021. There is the potential for the response rates to increase further with longer patient follow-up.

Response rates in TACTI-002 Part A assessed according to RECIST 1.1[2] criteria, which is the measure most frequently cited in scientific journal articles, were comparable to the iRECIST response rates.

To date, 80% (35/44) of the responses have been confirmed at a subsequent scan. A further 5 patients are pending a confirmatory scan, so the proportion of responses that are confirmed could potentially reach as high as 91% (40/44).

The efti combo continues to be safe and well tolerated, with a safety profile consistent with that previously reported for studies of pembrolizumab monotherapy.

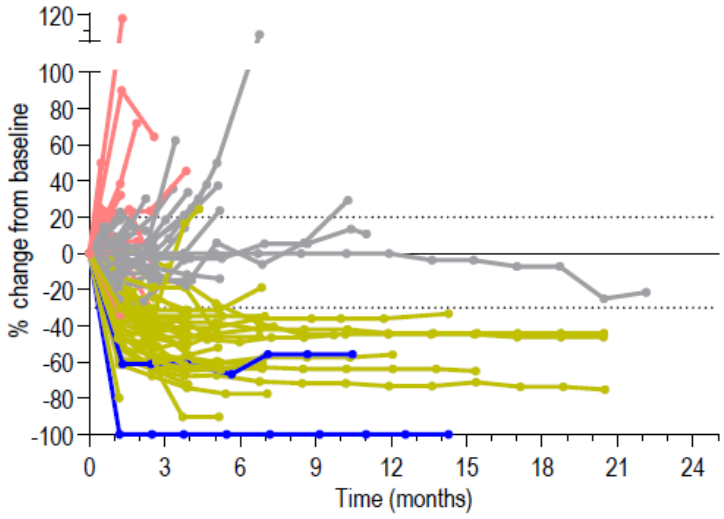
Exhibit 1: TACTI-002 Part A response rates by iRECIST and RECIST 1.1 are comparable

Response	iRECIST n (%)	RECIST 1.1 n (%)
N	114	114
Complete Response	2 (1.8)	2 (1.8)
Partial Response	42 (36.8)	41 (36.0)
Not Evaluable	11 (9.6)	11 (9.6)
ORR (ITT=114)	44 (38.6)	43 (37.7)
ORR (Evaluable=103)	44 (42.7)	43 (41.8)

Source: Immutep, Taylor Collison research

The spider plot in Exhibit 2 shows the changes in tumour burden for the individual patients over time. The plot shows that the tumour responses are long lasting, with only 8.6% of confirmed responders progressing within 6 months. The median duration of response has not yet been reached.

Exhibit 2: Spider plot showing individual patient tumour responses in first line NSCLC in TACTI-002

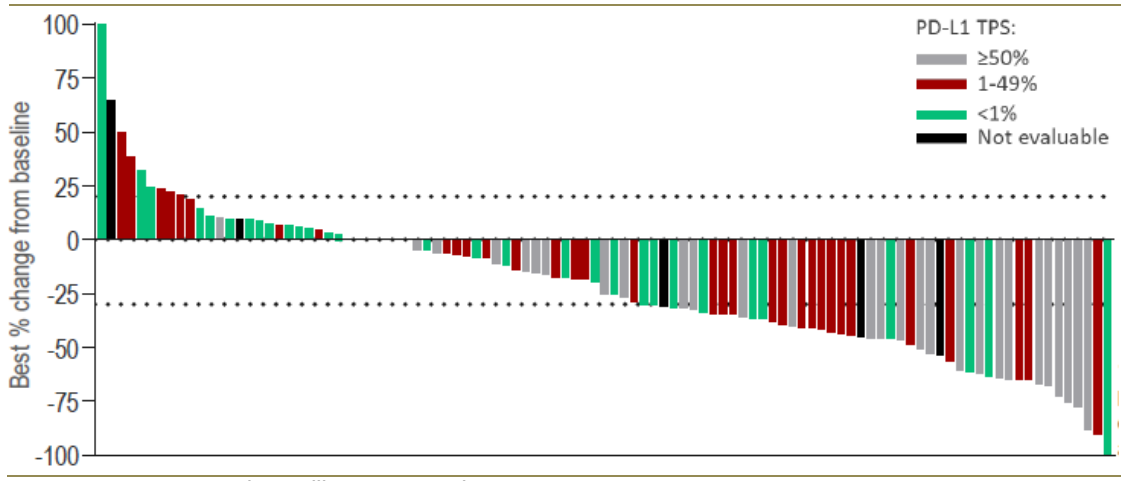


Source: Immutep, Taylor Collison Research.

[1] Immune Response Evaluation Criteria in Solid Tumours
[2] Response Evaluation Criteria in Solid Tumours version 1.1

The waterfall plot in Exhibit 3 shows that tumour responses occurred in all PD-L1 subgroups. 66% of patients with a post-baseline assessment had a decrease in target lesions.

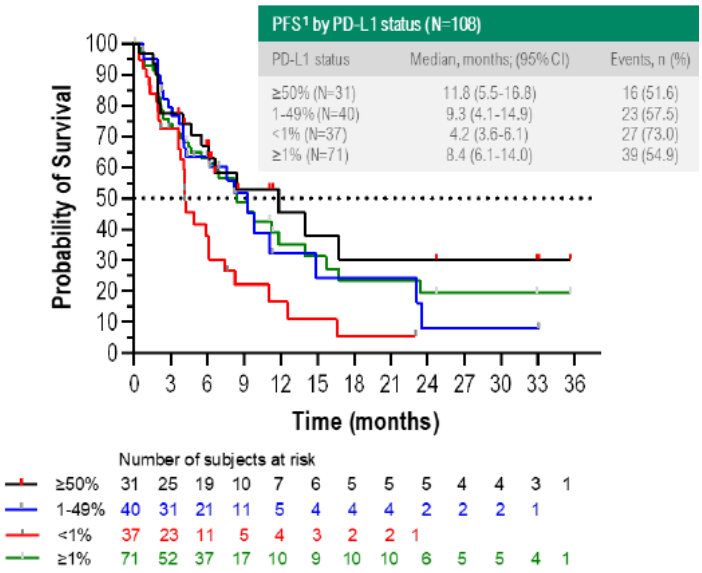
Exhibit 3: Waterfall plot best overall tumour response and PD-L1 subgroup



Source: Immutep, Taylor Collison Research.

Exhibit 4 shows that interim progression free survival (PFS) in the PD-L1^{low} group was comparable to the PD-L1^{high} group.

Exhibit 4: Progression free survival according to PD-L1 subgroup in first line NSCLC in TACTI-002



Source: Immutep, Taylor Collison Research.

Comparing ORR by PD-L1 status

The level of the PD-L1 biomarker expressed in the tumour is used to identify patients who are most likely to respond to treatment with anti PD-(L)1 checkpoint inhibitors such as Keytruda. The level of the biomarker is expressed as the tumour proportion score (TPS).

IMM was able to assess PD-L1 TPS in a central lab for 87 patients. For 21 patients, local assessment was used due to non-evaluable central assessment results. Six patients were unable to be assessed for PD-L1 expression by either method.

Exhibit 5 shows the ORR for patients grouped by PD-L1 status according to either central assessment only, or by central plus local assessment. The ORR is reported on an ITT basis and includes both confirmed and unconfirmed responses.

In our evaluation of the PD-L1 subgroups on page 6 we focus on the combined central and local assessment because it represents a larger data set and is likely to be representative of a real-world patient population.

Exhibit 5: TACTI-002 Part A ITT response rate by PD-L1 grouping by central vs central + local assessment

Tumour response (iRECIST, ITT, unconfirmed)	PD-L1 <1%	PD-L1 1-49%	PD-L1 ≥50%	Total subjects
PD-L1 central assessment	28.1% (9/32)	41.7% (15/36)	52.6% (10/19)	87
PD-L1 central + local	24.3% (9/37)	40.0% (16/40)	51.6% (16/31)	108

Source: Immutep, Taylor Collison research

Benchmarking Keytruda monotherapy in 1L NSCLC

As there is no comparison arm in the TACTI-002 Phase II trial, we have looked at the response rates to Keytruda monotherapy in similar patient populations in historical trials. Although such cross trial comparisons have limitations, they provide a useful benchmark to compare the efti combo results to.

We based our benchmarks on data from the following three trials:

- Keynote-042[3] (KN-042) - Phase III trial compared Keytruda monotherapy with chemotherapy in 1,274 patients with 1L NSCLC and PD-L1 TPS ≥1%.
- Keynote-024[4] (KN-024) - Phase III trial compared Keytruda monotherapy with chemotherapy in 305 patients with 1L NSCLC and PD-L1 TPS ≥50%.
- Keynote-001[5] (KN-001) - Phase I trial treated 101 1L and 394 2L NSCLC patients with Keytruda monotherapy; only 8 of 101 1L patients had TPS<1%, with 6 of these evaluated for response.

Points to note:

- These publications all report confirmed response rates, ie, they only count response that have been confirmed by a follow-up scan.
- KN-024 and KN-042 report response rates on an intention to treat (ITT) basis, ie, they include all enrolled subjects, regardless of whether they have undergone any scans to assess tumour response.
- The KN-024 and KN-042 trials provide robust estimates of confirmed ITT response rates for PD-L1^{high} and PD-L1^{low} subgroups

There is very limited benchmark data for PD-L1 negative patients. KN-001 reported 1 response from 6 evaluable 1L patients (ORR 16.7%) and 3 responses from 28 evaluable 2L patients (ORR 10.7%). We average these 2 values to derive our benchmark ORR of 12.9% for Keytruda monotherapy in PD-L1^{negative} 1L NSCLC, but this estimate has low reliability.

Exhibit 6: Clinical trial data contributing to our Keytruda monotherapy benchmark response rates

PD-L1 expression category	KN-042 confirmed ITT ORR	KN-024 confirmed ITT ORR	KN-001 1L evaluable confirmed ORR	KN-001 2L evaluable confirmed ORR	Average Keytruda 1L confirmed ORR benchmark
Negative (<1%)			16.7%	9.1%	12.9%
Low (1-49%)	16.6%		19.2%	15.6%	16.6%
High (≥50%)	39.5%	44.8%	50%	43.9%	42.1%

Source: Taylor Collison research. Note: values in grey not included when calculating benchmark.

[3] Mok et al 2019. Lancet 2019; 393: 1819–30. http://dx.doi.org/10.1016/S0140-6736(18)32409-7
[4] Reck et al 2016. N Engl J Med 2016;375:1823-33. DOI: 10.1056/NEJMoa1606774
[5] Garon et al 2015. N Engl J Med 2015;372:2018-28. DOI: 10.1056/NEJMoa1501824. Supplementary appendix Table S7.

Comparing efti combo therapy with Keytruda monotherapy benchmarks in 1L NSCLC

As mentioned on above, we base our comparison between the Keytruda monotherapy benchmarks and the efti Keytruda combo on the larger data set of 108 patients who had tumour PD-L1 expression assessed either locally or by the central lab in TACTI-002 Part A.

The benchmark data is all based on confirmed response rates, whereas the TACTI-002 part A response rates in the PD-L1 subgroups include both confirmed and unconfirmed responses.

In TACTI-002 part A, 80% of the responses have been confirmed to date. A further 5 patients are pending a confirmatory scan, so the proportion of confirmed responses could potentially reach as high as 91% if all 5 responses are confirmed.

In order to compare the TACTI-002 data to the Keytruda benchmark data on a like for like basis, we use the 80% (current) and 91% (potential) confirmation rates to estimate the confirmed ORR for each PD-L1 subgroup in TACTI-002 part A. Note, the actual confirmed response rates in each subgroup may differ from these estimates, depending on the distribution of unconfirmed responses among the subgroups.

As Exhibit 7 shows, with 80% of responses confirmed we estimate that the response rates to the efti combo are over 50% higher than the Keytruda monotherapy benchmark in PD-L1^{negative} patients (1.51x), while the efti combo response rate is almost double the benchmark in the PD-L1^{low} group (1.93x). In the PD-L1^{high} group the estimated confirmed ORR for the efti combo is in line with the benchmark response rate.

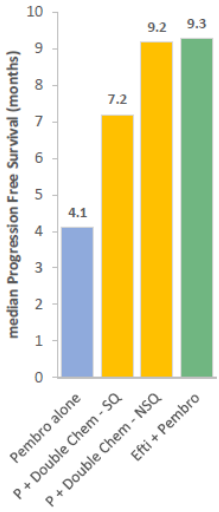
Exhibit 7: Comparing TACTI-002 Part A ORR to Keytruda monotherapy benchmarks in 1L NSCLC

PD-L1 expression category	TACTI-002 Part A BORR (unconfirmed, ITT, + local assay)	TACTI-002 estimated Confirmed ITT ORR at 91%	TACTI-002 estimated Confirmed ITT ORR at 80%	Average Keytruda 1L Confirmed ITT ORR benchmark	efti uplift factor (est. confirmed ORR @91%)	efti uplift factor (est. confirmed ORR @80%)
Negative (<1%)	24.3%	22.1%	19.5%	12.9%	1.72x	**1.51x**
Low (1-49%)	40.0%	36.4%	32.0%	16.6%	2.20x	**1.93x**
High (≥50%)	51.6%	47.0%	41.3%	42.1%	1.11x	**0.98x**

Source: Immutep, Taylor Collison research

The PFS data for the PD-L1^{low} patients in TACTI-002 Part A also compares favourably to benchmark data. In PD-L1^{low} patients the median PFS of 9.3 months for the efti/Keytruda combo is more than double that reported for Keytruda monotherapy in the KN-042 Phase III trial and is equal to or better than the PFS reported for Keytruda/chemo combos in the KN-189 and KN-407 Phase III trials (Exhibit 8).

Exhibit 8: Median PFS (months) for efti combo vs Keytruda alone or Keytruda/chemo combos in TPS 1-49% 1L NSCLC



Source: Immutep. Note: P, Pembro= Keytruda (pembrolizumab); SQ= squamous NSCLC; NSQ= non-squamous NSCLC.

Well placed to progress to a randomised late stage study of efti combo therapy in 1L NSCLC

Taken together, the high ORR and PFS data from a meaningful sample size of 40 patients support progressing the efti/Keytruda combo to late stage clinical trials in 1L NSCLC in the PD-L1^{low} patient population, in our view.

Management has indicated that it will review its strategic options in light of the NSCLC data. We view a pivotal trial of the efti/Keytruda combo in PD-L1^{low} first line NSCLC as a better option for IMM than its proposed Phase III trial of efti+chemo in breast cancer.

IMM is already enrolling subjects in the TACTI-003 registration-directed, randomised controlled Phase IIb trial of the efti/Keytruda combo vs Keytruda monotherapy in 1L HNSCC. Twenty one subjects had been recruited as at 29 April, out of the target of ~154 subjects. We expect recruitment to be completed in Q1 CY23, with results reported in H2 CY23.

With $87.2m cash at 31 March, the company is funded into CY24.

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