Biotechnology

4 April 2023 22:40 BST



COMPANY NOTE

Immutep Limited (IMM-AU)

Potential standard of care in lung and other cancers

KEY TAKEAWAY

Final TACTI-002 Phase II data of efti with pembrolizumab in 2nd line non-small cell lung cancer ("NSCLC") presented at ESMO 2023 further demonstrates the potential of efti as standard of care ("SoC"). While, as highlighted by the recent failure of Merck's anti-TiGIT vibostolimab, few drugs to date appear to have safe and meaningful synergy with PD-1/PD-L1 immune checkpoint inhibitors ("ICIs"), efti continues to generate positive combination data. This includes not only NSCLC, but also head and neck cancer ("HNSCC"). Data indicates that not only might efti provide a safer longer acting substitute for chemotherapy in ICI combinations, but also potential for synergy with chemo itself. While data from the INSIGHT-003 trial already indicates an efti-pembrolizumab-chemotherapy may be well tolerated, Phase 2 data in metastatic breast cancer indicates potential benefits of combination with chemo alone. With an impending phase III trial expected to follow on from TACTI-002, we believe efti to be on course to reach market for NSCLC by 2025E and reach a peak sales of almost \$6.5bn from NSCLC alone. Given this potential and observing comparable companies in the immuno-oncology space, we believe Immutep to be significantly undervalued. With a phase II / III in metastatic breast cancer ("mBC") confirmed and plans for expansion of TACTI-002 to phase III in NSCLC, we reiterate our OUTPERFORM recommendation with our sum of the parts ("SoTP") valuation of Immutep's share price increasing to A \$2.88 per share.

Efti extends efficacy without compromising safety: ICI combination with chemotherapy offers a unique synergy yet to be demonstrated by other late-stage drugs yet, however its harsh tolerability is a concern for poorly patients, thus monotherapy often suffices for some patients with high PD-L1 to avoid chemotherapy regimens. TACTI-002 (Part A) data

of efti with pembrolizumab compared to pembrolizumab monotherapy in 1st line NSCLC shows an increased duration of response for both PD-L1 low (TPS 1-49%) and negative (TPS <1%) patients which are classically treated with ICI + chemotherapy combination. Efti therefore demonstrates a tolerable, prolonged response which likely can replace the current SoC.

Efti's tolerability allows it to access the most difficult-to-treat population: Patients with negative PD-L1 expression are notoriously difficult to target with existing approved

therapies. Recent data from the TACTI-002 (Part B) phase IIB trial in 2nd NSCLC at ELCC 2023 show efti with pembro can revert resistance to PD-1 / PD-L1 therapy with 83.3% of patients showing tumour shrinkage or tumour growth deceleration in a majority PD-L1 low- and negative-expressing cohort.

Efti-pembro-chemo triple therapy extends treatable population: Given efti does little to exacerbate tolerability and building from synergy shown in the efti + chemotherapy AIPAC trial in mBC, the INSIGHT-003 trial in NSCLC shows efti-pembrolizumab-chemotherapy is a tolerable triple therapy that shows conceptual synergy and promising early data, with a response rate of 72.7% and disease control rate of 90.9%, potentially further extending the current pembro-chemo SoC to expand the treatable patient population.

NTSC opportunity in excess of \$6bn: The bulk of Merck's \$20.9bn pembro revenues come from NSCLC. With increased penetration from the substitution for chemo and triple therapy, we estimate that global peak revenues in NSCLC could reach \$6.5bn.

Immutep is still significantly undervalued: With a phase III-ready candidate with tangible potential to partner ICIs in a future SoC combination, Immutep has thus far gone under the radar of investors. Similar companies in the immuno-oncology space that have recently been acquired have fetched premium valuations; given the continued success of efti from multiple trials, we expect Immutep's valuation to rise significantly. Given the variation of trial collaborators in the established ICI space (MSD, Pfizer, Merck KGaA), it is clear big pharma are aware of Immutep's programmes, an acquisition may occur.

OUTPERFORM

Target Price AUD2.880 Current Price AUD0.240

FINANCIAL SUMMARY	
Net Cash/Debt (M):	20.00
MARKET DATA	
Current Price:	AUD0.240
Target Price:	AUD2.880
52 Week Range:	AUD0.435 - AUD0.230

 52 Week Range:
 AUDU.435 - AUDU.230

 Total Enterprise Value:
 161

 Market Cap (M):
 211

 Shares Out (M):
 879.3

 Float (M):
 838.6

 Average Daily Volume:
 746,509

EQUITY RESEARCH

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PRICE PERFORMANCE Immutep Limited 0.5 0.45 0.4 0.35 0.3 0.25 0.2 04/22 07/22 10/22 01/23 04/23

Source: Factset

-IMM-AU

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Company overview

Listed on the ASX ("IMM") and with ADR's traded on NASDAQ ("IMMP"), Immutep is uniquely focused on the development of cancer and immunotherapies utilising LAG-3 ("Lymphocyte Activation Gene-3"). With its HQ in Sydney, Australia and operations in Germany, France and the USA, Immutep has established a pipeline of in-house and large-pharma-out-licensed programmes which utilise LAG-3's dual role as both an activator and inhibitor of the adaptive / innate immune system (FIGURE 1).

The company's lead in-house programme is a first-in-class soluble LAG-3 fusion protein, eftilagimod alpha ("efti" or "IMP321"), that exploits the protein's ability to stimulate the immune response through the activation of antigen presenting cells ("APCs").

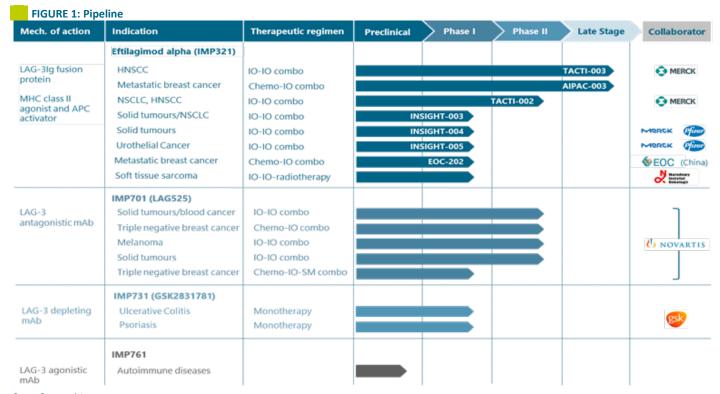
Recent data presented at SITC 2022 from Part A of the Two ACTive Immunotherapies-002 (TACTI-002) Phase II trial in 1st line non-small cell lung cancer ("NSCLC") has shown that combination of efti with pembrolizumab ("pembro"), a PD-1 inhibitor, elicits an overall response rate ("ORR") of 40.4% that is approximately double the 21.3% ORR of pembro alone across the all-comer PD-L1 patient population. This includes ORRs of 44.7% and 31.3% with efti + pembro as compared to ORRs of 16.8% and 10.7% with pembro alone in the difficult-to-treat PD-L1 low (TPS 1% - 49%) and PD-L1 negative (TPS <1%) expressing patients, respectively. Data from the ELCC 2023 from Part B of TACTI-002 in 2nd line NSCLC also shows efti combination with pembro reverts previous resistance to PD-1 / PD-L1 therapy with 83.3% patients showing either tumour shrinkage or tumour growth deceleration. Given the patients' resistance to previous PD-1 / PD-L1 therapy, it is extremely promising to see an ORR of 8.3%, with a disease control rate ("DCR") of 33% and 6-month progression free survival ("PFS") of 25%. Further preliminary data from Part C of the TACTI-002 trial evaluating the chemotherapy-free combination of efti + pembro in 2nd line head and neck cancer ("HNSCC") has shown an ORR (29.7%) that is double that of anti-PD-1 monotherapy (14.6%), with more data expected this year. Additionally, initial positive efficacy and safety data from the first-in-human triple combination of efti+pembro+chemo therapy in the INSIGHT-003 trial in 1st line NSCLC was presented at SITC 2022. The INSIGHT-003 trial recently expanded its trial cohort to 50 (from 20), and more data is expected this year following promising early signals.

As a first-in-class soluble LAG-3 protein targeting MHC Class II ligands on antigen-presenting cells ("APC"), efti is also uniquely positioned to improve clinical outcomes from SoC chemotherapy. Its activation of APCs (e.g., dendritic cells, monocytes) triggers a broad immune response that includes significant increases in cytotoxic CD8+ T cells armed with chemo-induced tumour antigens to target cancer. This synergy was demonstrated in combination with paclitaxel in metastatic breast cancer ("mBC") in a Phase IIb trial that showed encouraging efficacy and safety, including a +2.9-month median overall survival ("mOS") improvement, statistically significant mOS improvements between 4.2 to 19.6 months across three pre-specified subgroups, a statistically significant increase in cytotoxic CD8 T cells that correlated with improved OS, a higher 46% ORR (vs 38% for chemo alone), and a superior Quality of Life preservation. On the strength of these results, Immutep recently launched AIPAC-003 (Active Immunotherapy, Eftilagimod Alpha, and PAClitaxel), an integrated Phase II / III trial in mBC that incorporates feedback from the US Food and Drug Administration ("FDA") and European Medicines Agency ("EMA") and will help inform a Biologics License Application ("BLA") and support a Marketing Authorisation Application ("MAA").

With FDA Fast Track Designation for efti in combination with pembro for 1st line NSCLC, Immutep is planning a late-stage NSCLC trial based on the strong Phase II data from TACTI-002 (Part A). Efti also has FDA Fast Track Designation in 1st line HNSCC that is being studied in combination with pembrolizumab in the randomised TACTI-003 trial, which is expected to reach full enrolment in mid-2023E and have a top-line readout this year.

Led by experienced CEO Marc Voigt, Immutep has a strong cash position of A\$68.38m. Now financed to the end of FY2024E, the company is in a position to progress the late-stage clinical development of efti. This includes the ongoing randomised / controlled TACTI-003 Phase IIb trial in 1st line HNSCC, the recent initiation of the Phase II / III AIPAC-003 trial in mBC, and the future initiation of a registrational Phase II / III trial in $1^{\rm st}$ line NSCLC. The company will use clinical data from trials to assess partnering options during the course of the next 12 - 18 months.





Source: Company data

Substantial in expansion of NSCLC treatment responsive population



Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations.

Investment thesis

Efti is one of the only proprietary drugs to safely demonstrate robust synergy with PD-1 / PD-L1 immune checkpoint inhibitors ("ICIs"). As highlighted by Merck's recent anti-TIGIT vibostolimab-pembro disappoinment, effective combination of proprietary drugs with PD-1 / PD-L1 has been notoriously difficult. In contrast, efti has demonstrated efficacy in combination with ICIs across a broad range of cancers, as well as with chemotherapy. Data presented at ASCO and SITC confirms the synergy between efti and PD-1 / PD-L1 ICIs in 1st line NSCLC and efti was recently awarded Fast Track designation by the FDA in this indication. With pembro biosimilars set to arrive in 2028E and the largest portion of the \$20.9bn pembro sales coming from NSCLC, there is already a substantial value in a drug capable of safely strengthening and extending ICI efficacy in NSCLC. With strong TACTI-002 Phase II data and FDA fast track designation for efti+pembro in HNSCC and NSCLC, the recent initiation of a pivotal Phase II / III in combination with chemotherapy in mBC, and plans for a Phase II / III NSCLC trial in H2/2023E, our peak revenue estimates for efti approach \$8bn.

Immutep continues to generate powerful data for efti in a range of solid cancers, including NSCLC, HNSCC and mBC. It has shown to be effective, well tolerated, and has apparent synergy with both existing PD-1 / PD-L1 ICIs and conventional therapies such as chemo. No approved drug has demonstrated acting in synergy with ICIs in NSCLC bar chemo, meaning an efti combination treatment could offer a chemo-free and effective alternative for patients without the chemo-associated toxicities. Notably, the use of doublet chemo with pembro has led to a large decline in Duration of Response ("DoR") as compared to pembro monotherapy. This phenomenon is not seen with efti + pembro, which conversely has actually led to an increase in DoR as compared to pembro monotherapy as shown in the TACTI-002 trial. This differentiated DoR could also spur additional attention to this powerful chemo-free combination. Our peak sales for efti in NSCLC alone total >\$6.4bn alone and are over \$7.9bn for all indications curently in development (FIGURE 2).

With >A\$68m in cash Immutep is well-placed to progress efti into late-stage clinical development. Immutep will prioritise the Phase II / III trial in NSCLC for efti combined with pembro, but will also push forward with a Phase II / III in mBC. The TACTI-002 Phase II trial data was an all-comer trial with no PD-L1 pre-selection, yet the data obtained with the chemo-free efti + pembro combination still competes with data that dictates the current standard of care (anti-PD-(L)1 + chemotherapy). Immutep is exploring the opportunity to further broaden NSCLC patients' potential to respond to treatment using a triple combination of efti+pembro+chemo in the the INSIGHT-003 Phase I trial.

The increasing volume of data supporting efti's synergy with PD-1 / PD-L1 ICIs is making the company an attractive partner for licensing and co-develoment programmes. Immutep looks increasingly valuable



and is an attractive potential acquisition target. MSD's Q4/2022 revenue highlighted pembro as their top selling product, generating \$20.9bn last year. Several key patents for pembro will expire over the coming years and without a combination product such as efti, will fail to maintain a proprietry edge. While MSD already has a clear interest in efti with its participation in the TACTI-002 / 003 studies, Merck KGaA and Pfizer have also indicated interest with the announcement of clinical collaboration combining avelumab with efti for the treatment of metastatic urothelial cancer. This jointly-funded INSIGHT-005 trial follows the encouraging data from INSIGHT-004 in which the addition of efti to an anti-PD-L1 therapy, avelumab, led to deep, durable responses in PD-L1 low / negative expressing patients with advanced cancers that are typically insensitive to ICI therapy.

Immutep's share price fell 40% over the course of 2022 as a result of the market's flight from risk. With a stream of positive news flow, the shares are now a significant investment opportunity for investors, in our view. Given the recent NSCLC data and with PD-1 / PD-L1 biosimilars on the horizon, along with the pending final data in the randomised $1^{\rm st}$ line HNSCC TACTI-003 trial this year, we believe that Immutep will become an increasingly attractive acquisition target for large pharma. On the basis of our revenue, our SoTP ("Sum of the Parts") valuation indicates a valuation of A\$2.5bn or A\$2.88 per share. While this is clearly not reflected in the current market valuation, financed till end of 2024E, Immutep is well placed to ride out current market turbulence and potentially assess an efti licence.

News flow

We anticipate positive newsflow throughout 2023E (FIGURE 3), as further data becomes available across several indications including $1^{\rm st}$ line NSCLC, $2^{\rm nd}$ line HNSCC, $2^{\rm nd}$ line PD-X refractory NSCLC, mBC, and $1^{\rm st}$ line HNSCC. We expect Immutep to extend TACTI-002 Part A in $1^{\rm st}$ line NSCLC into a Phase II / III in NSCLC, and also expect more data from INSIGHT-003 triple therapy. In March 2023, Immutep announced the initiation of a Phase II / III AIPAC-003 trial in mBC. We can expect to hear announcements of investigator-led trials from various ICI's in combination with efti over the next year as companies look to Immutep to strengthening their portfolios.

Upcoming key trials to reveal efti as a potential blockbuster drug

FIGURE 3: Exp	pected news flow for Immutep in 2023E
TACTI-002	Expansion to phase 3 study – design feedback expected H1 2023E and trial commencement in H2 2023E
AIPAC-003	Commencement of phase 2/3 study in metastatic breast cancer Q2 2023
TACTI-003	Ongoing patient recruitment & updates for phase 2b 1st line HNSCC
INSIGHT-003	Further results expected to evaluate success of efti-pembro-chemo triple therapy in phase 1
Source: Company data	



Efti to further expand the ICI repertoire

Unique immune activator for combination

Immune checkpoint inhibitors have transformed the treatment of a number of major cancers. Broad extension of their benefits into other cancers and beyond specific patient populations has been slow. Despite titanic efforts, the development of additional immune modulators or synergistic combinations has been largely unsuccessful. Positive Phase II data from the TACTI-002 studies in NSCLC and HNSCC indicate that efti may be the first drug, aside from chemotherapy, capable of extending the benefits of PD-1 / PD-L1 ICIs. Safe and well tolerated, efti promises to be ideal for combination.

While there has been a steady stream of me-too approvals since the first CTLA-4, PD-1, and PD-L1 ICIs were approved in 2011, 2014, and 2016 respectively, development of additional classes of ICIs disappointed. It was only with regulatory approval of the first LAG-3 targeted therapy (relatlimab) in combination with an anti-PD-1 therapy (nivolumab) in 2022, that we've seen expansion of the ICI class.



Source: goetzpartners Research

Efti provides an alternative to chemo for extending ICI benefits

Although large numbers of clinical trials have been performed to assess how combination with other drugs could extend or enhance the efficacy of PD-1 / PD-L1 ICIs, until the development of LAG-3-targeted antibodies it was essentially only chemo and a selection of kinase inhibitors that have shown synergy. There is an urgent need for new drugs capable of extending the benefits of immunotherapy whilst minimising side-effects.

The current focus is on NSCLC, efti has also been shown to enhance the action of the anti-PD-1 antibody pembro in HNSCC where pembro monotherapy is poorly effective; Immutep has clinical trials ongoing in a range of other solid tumours. Data from the TACTI-002 study indicates that the efti-pembro combination delivers superior efficacy across the total 1st line NSCLC patient population, regardless of PD-L1 expression, with a far superior DoR to pembro-chemo, and without additional safety and tolerability concerns compared to pembro monotherapy. The data illustrates how efti could extend the benefits of ICIs in NSCLC and potentially other cancers as well.



Efti combination set to transform NSCLC therapy

The current status of NSCLC treatment

NSCLC is one of the most prevalent cancers over 2m cases per annum globally. Oncogene mutations are present in around 60% of cases, often via EGFR mutations and ALK fusions, and are treated with chemotherapy and TKI inhibitors. Non-oncogenic-driven NSCLC often have higher rates of mutation and are therefore treatable with immune checkpoint inhibitors ("ICIs") in latter-stage disease. Patients with a high level of PD-L1 expression (TPS ≥50%) respond to ICI monotherapy, but patients with low levels of PD-L1 (TPS 1% - 49%) or negative PD-L1 (TPS <1%) often require an ICI-chemotherapy combination regimen. Some patients do not respond at all to ICI treatment and resistance to ICIs may occur in some cases. ICI combinations, particularly dual ICI treatment in the case of nivolumab plus ipilimumab, sacrifice tolerability for increased efficacy; increasing the frequency of immune-related adverse events when compared to nivolumab monotherapy. Effective combination alternatives are needed for patients unable to withstand aggressive treatment regimens.

Current NSCLC treatment options are failing patients expressing low PD-L1

Efti-Pembro; an additional chemo-free treatment option with high ORR/PFS, a differentiated DoR, and a favourable safety profile, across all PD-L1 expression levels

FIGURE 5: Current status of approved ICI regimes for NSCLC

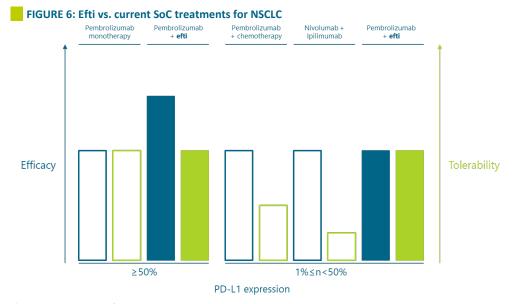


Source: goetzpartners Research

Efi demonstrates superior benefits to current SoC

Synergy has been shown between efti and PD-1 ICI in TACTI-002 (efti with pembro in 1^{st} line NSCLC, 2^{nd} line PD-X refractory NSCLC, and 2^{nd} line HNSCC), and we look forward to seeing the randomised data from the TACTI-003 trial (efti with pembro in 1^{st} line HNSCC). Data suggests efti is a superior partner for combination with PD-1 inhibitors compared to chemotherapy, increasing median progression free survival to 9.3 months from 8.2 months in patients with TPS \geq 1%. Importantly efti+pembro treatment extended the mDoR to 21.6 months compared to mDoR of 8.8 months for SoC (anti-PD-(L)1 + doublet chemo) in PD-L1 all comers in NSCLC. As shown in Figure 6,

Efti more than doubles the mDoR compared to SoC treatment



Source: goetzpartners Research



PD-1 ICI combination with efti improves efficacy in high PD-L1 expressing patients without decreasing tolerability and maintains efficacy in low PD-L1 expressing patients. Efti can provide a sustainable treatment option for non-oncogenic NSCLC patients with low PD-L1 without the side effects associated with chemo or dual ICI (nivolumab plus ipilimumab).

The efti-pembro-chemo triple threat

Data from the metastatic breast cancer AIPAC Phase IIb trial revealed potential synergy between efti and chemotherapy, providing rationale for efti as a triple therapy combination with an ICI and chemotherapy. Additionally, as opposed to other IO-IO combinations that target ICIs on the same T cell, efti engages APCs while ICIs focus on the T cells themselves.

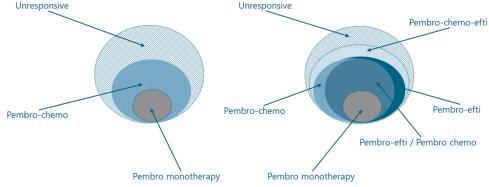
Further rationale for the triple combo comes down to the role each therapy plays in the anti-cancer immune response. Chemo will create a supply of tumour antigens from cancer cell death which the efti-activated dendritic cells can present to T cells, while pembro will ensure that the resulting T cell attack on the tumour is not dampened down, culminating in an aggressive anti-cancer response. Triple therapy could thus further expand the population of NSCLC patients responsive to therapy.

The INSIGHT-003 trial in NSCLC combines efti with pembro and doublet chemotherapy. Positive interim data suggests this triple therapy is safe and efficacious, with a response rate of 72.7% and disease control rate of 90.9%. Most of the cohort express low levels of PD-L1, which could indicate efti as a future improvement to the current SoC regimen for low PD-L1 expression which has limited efficacy. Improved efficacy may also allow patients who do not respond effectively to the current SoC to continue treatment, further extending the addressable patient population in the NSCLC market.

Importantly, tolerability is increased across all combination groups

Early data from the triple therapy combo shows 72.7% response rate and well tolerated

FIGURE 7: Efti broadens the treatable population for NSCLC



Source: goetzpartners Research

NSCLC therapeutics development pipeline

Influx of PD-1/PD-L1 copycats

For non-oncogenic driven NSCLC, chemotherapy and ICIs comprise the current market. More ICIs targeting PD-1 and PD-L1 are seeking approvals to treat NSCLC with chemotherapy such as avelumab (Merck KGaA & Pfizer) and cosibelimab (Checkpoint Therapeutics), however these will likely not provide significant patient benefit beyond current approved regimens and will struggle to gain a share of the established PD-1 / PD-L1 ICI market. Efti is uniquely placed in the NSCLC therapeutic development pipeline, engaging with an additional target, and complementing or potentially replacing these current SoC regimens.

Additional PD-1 / PD-L1 ICI's will likely provide no further patient benefit

NSCLC vaccines; a novel approach

Ose Immuno Therapeutics' peptide vaccine Tedopi® is an encouraging candidate consisting of nine optimised neoepitopes from five tumour antigens and a further T-cell activating epitope. It is currently in Phase III as a monotherapy and in Phase II as a combination with nivolumab, both for NSCLC. The monotherapy trial, for patients that have been unresponsive to ICIs following sequential ICI-chemotherapy treatment had improved OS and safety compared the chemotherapy SoC arm (13.5 months vs. 10.6 months; HR=0.71). BioNTech's expertise in mRNA vaccines has led to development of BNT116, which encodes several common NSCLC neoepitopes and is in Phase I, as well as an antibody immunomodulator treatment BNT311 in Phase II with pembro which has proven safe and efficacious in a previous Phase I trial.

Novel approaches and targets will yield highest patient benefit



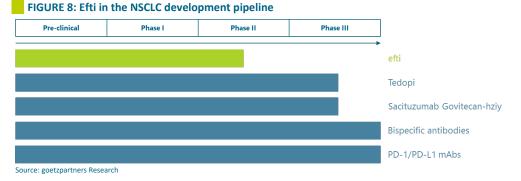
New targets for NSCLC

Sacituzumab Govitecan-hziy (Gilead) is already approved for monotherapy triple negative breast cancer ("TNBC") and bladder cancer. It is a TROP-2-targeting / topoisomerase inhibitor ADC in Phase III for NSCLC following platinum-based chemotherapy or PD-1 / PD-L1 immunotherapy. A further Phase III trial in TNBC with pembro could show synergy with an ICI that could be replicable in the upcoming Phase III trial in NSCLC with pembro that is currently in the recruitment stage. Oleclumab (AstraZeneca); a CD-73-targeting monoclonal antibody ("mAb") in Phase III trial in NSCLC as combination with durvalumab, shows promising efficacy data, however dual mAb treatment could render tolerability an issue.

Dual targeting with bispecific antibodies

Two bispecific antibodies, ivonescimab (Akeso) and KN046 (Jiangsu Alphamab) targeting PD-1 / VEGF and PDL1 / CTLA-4 respectively are also both in Phase III for NSCLC. Invonescimab was particularly efficacious for patients with a PD-L1 TPS >50%, with an ORR of 76.9% and a disease control rate of 100%, however it was less effective against lower expression of PD-L1, the ORR / DCR of low PD-L1 being 50.0% / 95.5%, and less efficacious still against negative PD-L1, with an ORR of 60% and DCR of just 1%. Currently there are no approved bispecifics targeting immune checkpoints, however their advantageous safety profile compared to double mAb therapy could improve the SoC, although efti also demonstrates this benefit whilst complementing the SoC. Another barrier for these bispecifics is the FDA's recent reluctance to accept Chinese-only run trials as a suitable proxy for the US population, and as the ICI bispecifics market is dominated by Chinese players, these candidates may struggle to make immediate impacts for Western patient populations.

Approved NSCLC treatments in are unable to replicate efti's safety and synergy with PD-1 / PD-L1 ICIs



Immutep's Efti well placed to take significant share of NSCLC market

Immutep has the agility that its lead candidate has the potential to be used across multiple indications. Currently, NSCLC and HNSCC are their priorties followed closely by mBC. Based on the quality of the current data and the potential of efti combinations to expand the responsive NSCLC population, we have increased the market penetrations to 35% of the US and 25% of the European markets. This yields peak sales of over \$7.9bn. This seems reasonable given that pembro is currently generating \$20.9bn in annual sales and in large part from NSCLC. Also, while pembro faces competing products with the same MoA, there are no other products with the MoA of efti at this current time. Other emerging therapies fail to offer such attractive combination prospects as efti regarding safety and efficacy, highlighted by Merck's recent anti-TIGIT vibostolimab-pembro combination disappoinment, thus we believe efti to be well placed to capitalise on the future NSCLC market.

An essential combo immunotherapy will be in demand from market leaders looking to extend shelf-life

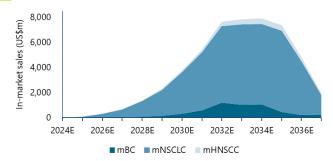


Financial forecasts

Product sales

Although Immutep is expected to receive revenue from it's other partnered programmes most immediately from LAG525, in the absence of direct competition efti is clearly the most significant revenue driver. We estimated peak efti revenues of around \$7.9bn generating royalties of \$2.8bn (FIGURE 9).

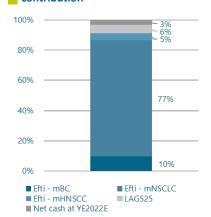
FIGURE 9: Efti revenue forecasts



Source: goetzpartners Research estimates.

Warning Note: Forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations

FIGURE 10: Relative product value contribution



Source: goetzpartners Research.

Warning Note: Forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations.

Sum of the parts (SoTP) valuation

Our SoTP valuation yields a fair value of A\$2.88 / share with NSCLC accounting for 77% of the value (FIGURE 10). This indicates substantial upside from current levels (FIGURE 11) based on risk-adjusted net present values ("rNPVs") for efti in mBC, lung and head & neck cancer, LAG525 in multiple tumours, (all discounted using a WACC of 14%) and net cash at YE2022E). Now funded until the end of FY2024E and with the expectation of efti moving into Phase II / III for NSCLC and additional data, we believe that the company has a strong chance of out-licensing efti or being potentially acquired, in our view. While in the light of the recent data, we have decreased our probability of success of efti in mBC to 20% (from 40%), the positive TACTI-002 trial has allowed us to increase the probablity to 22% (from 10%). (FIGURE 13).

FIGURE 11: Immutep sum-of-the-parts valuation

			Peak sales		NPV		Adj. NPV	NPV/sh
Product	Indications	Stage	(\$m)	Year	(A\$m)	Prob.	(A\$m)	(A\$)
Eftilagimod alpha	mBC	Phase IIb	1,177	2032E	408	60%	245	0.282
Eftilagimod alpha	mNSCLC	Phase II	6,483	2035E	3,177	60%	1,906	2.201
Eftilagimod alpha	mHNSCC	Phase II	443	2035E	267	45%	120	0.138
LAG525	Cancer	Phase II	4,000	2033E	214	65%	139	0.161
Net cash at YE2022E					80	100%	80	0.092
Fair value					4,146		2,490	2.875
Current share price ((A\$)	•	•					0.250
Unside								1050%

Source: goetzpartners Research estimates.

Warning Note: Forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations

Immutep is significantly under valued compared to peers

Immutep looks significantly undervalued based on the acquistion values and market caps of its oncology peers. The immune-oncology space is dominated by big pharma players. Small and medium-size companies have been consistently acquired by larger players. For the purposes of modelling we have assumed out-licensing, but a potential acquisition is probably more likely, in our view. Immutep's clinical collaboration with MSD makes it an obvious choice for acquisiton but Pfizer and Merck KGaA have also indicacted interest in efti in their recent investigator led trials.

Immutep against sector comparables

Figure 12 is a selection of recent oncology transactions and can be taken as a guide for potential Immutep acquisition values. Amgen's 2021 acquisition of Five Prime Therapeutics is a suitable comparable, like efti, their lead candidate bemarituzumab was Phase III-ready at the time of acquisition, with shares bought out for approximately \$1.9bn. The main indication of bemarituzumab is in gastric cancer, which is now in Phase III with chemotherapy and nivolumab, and there are also Phase I trials in



bladder and NSCLC. Comparisons can be drawn between Immutep and Turning Point Therapeutics, acquired by BMS in June 2022 for \$4.1bn, given the focus on their NSCLC (albeit targeting oncogenic drivers ROS-1 and NTRK) therapeutics with differentiated DoR from early-stage trial data which efti similarly shows in chemo-free efti+pembro trials in NSCLC. In contrast, Takeda's \$525m acquisition of Maverick Therapeutics has limited applicability despite its Phase I / II trial, given the limited expandability of the lead candidate (an EGFR-CD-3 T-cell engager) across multiple indications, which is a major advantage of efti. With few big pharma immuno-oncology acquisition targets for Phase III-onwards assets, Immutep could be a uniquely high-value target for large pharma suitors to acquire.

FIGURE 12	: Valua	ations of compa	rative M	&As				
Target company	Location	Acquiring Company	Location	Value (milestones)	Date	Type of deal	Lead asset	Stage at time of deal
FivePrime ⁻		AMGEN		\$1.9bn	March 2021	Full company acquisition	bemarituzumab (FGFR2b antibody)	Phase III ready (positive phase II data)
VELOSBIO		MERCK		\$2.75bn	November 2020	Full company acquisition	VLS-101 (ROR1 ADC)	Phase II
ARVINAS		Pfizer		\$1bn (+\$1.4bn)	July 2021	Single asset commercial rights	Arv-471 (ER degrader)/Arv- 110 (AR degrader)	Phase II
immun•gen.		Lilly		\$13m (\$1.7bn)	February 2022	Multi asset commercial rights	Camptothecin ADCs	-
TRILLIUM	+	P fizer		\$2.26bn	August 2021	Full company acquisition	2x SIRPα-Fc fusion proteins	Phase I/II
Turning Point		ullı Bristol Myers Squibb		\$4.1bn	June 2022	Full company acquisition	Repotrectinib (tyrosine kinase inhibitor)	Phase I/II
MAVERICK (Takeda	•	\$525m	March 2021	Full company acquisition	TAK-186 (EGFR-CD-3 T- cell engager)	Phase I/II
SEVEN		GILEAD		\$4.9bn	March 2020	Full company acquisition	magrolimab (CD-47 antibody)	Phase II ready (positive phase Ib data)

Source: goetzpartners Research

Comparison against listed peers also indicates Immutep's undervaluation (FIGURE 13). Immunocore is a leading player in the bispecifics market, with their candidate Kimmtrak (tebantefusp) being the third bispecific and T-cell engager to be approved in January 2022 (FDA) and April 2022 (EMA). Arvinas represents an interesting player, with two PROTACs (proteolysis targeting chimeras) against the oestrogen and androgen receptors in Phase II, with rights to Arv-471 acquired by Pfizer for potentially \$2.4bn if milestones are reached, including a guaranteed \$300m equity investment, however trial results have been mixed. Although Arcus Biosciences anti-TIGIT antibody candidate domvanalimab has shown positive data in its Phase II trial, comparatively it did not outperform Roche's leading TIGIT programme tiragolumab which later failed two Phase III trials, casting doubts for investors in the TIGIT space, thus potentially reducing promise in Arcus's programme.

Immutep is currently significantly undervalued compared to its competitors

FIGURE 40 M. L			
FIGURE 13: Valuations of	t comparative	. bubliciv listed	companies

Company	Location	Market Cap (local)	Market Cap (USD)	Lead asset	Phase of development
immutep®	816 218	AUD 0.24bn	\$0.16bn	Eftilagimod alpha – LAG-3-Fc fusion protein	Phase II (positive data)
IMMUNOCORE		USD 2.50bn	\$2.50bn	Kimmtrak (GP-100- CD-3 T-cell engager)	Approved Jan 2022 ('22 revenue: \$140m)
ARVINAS		USD 1.66bn	\$1.66bn	Arv-471 (ER degrader)/Arv-110 (AR degrader)	Phase II
ARCUS BIOSCIENCES		USD 1.32bn	\$1.32bn	Domvanalimab (TIGIT antibody)	Phase III
immun•gen.		USD 0.94bn	\$0.94bn	Mirvetuximab soravtansine-gynx (FRα/DM4 ADC)	Marketed Nov 2022 ('22 revenue: \$2.6m)
ımmatics		USD 0.67bn	\$0.67bn	IMA203 (autologous T-cell therapies)	Phase Ib
F-star THERAPEUTICS		USD 0.14bn	\$0.14bn	FS-118 (PD-L1/LAG-3 bispecific antibody)	Phase I/II
OSE IMMUNO ()		EUR 0.10bn	\$0.11bn	Tedopi (multi-neo- epitope NSCLC vaccine)	Phase II (positive data)

Source: goetzpartners Research



Profit & Loss Statement	2022A	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Jun YE (A\$k except EPS)	30-Jun-22	30-Jun-23	30-Jun-24	30-Jun-25	30-Jun-26	30-Jun-27	30-Jun-28	30-Jun-29	30-Jun-30
Revenue	6,758	7,978	71,656	47,812	229,517	311,176	424,024	943,184	1,345,243
growth	70%	18%	798%	(33%)	380%	36%	36%	122%	43%
License income	170	-	64,518	40,324	227,689	304,926	412,909	934,513	1,321,346
% sales	3%	0%	90%	84%	99%	98%	97%	99%	98%
growth	_	(100%)		(37%)	465%	34%	35%	126%	41%
Other income	6,588	7,978	7,138	7,488	1,829	6,251	11,115	8,671	23,897
% sales	97%	100%	10%	16%	1%	2%	3%	1%	2%
growth	66%	21%	(11%)	5%	(76%)	242%	78%	(22%)	176%
R&D and intellectual property	(31,342)	(39,403)	(41,346)	(5,721)	(33,091)	(63,213)	(47,640)	(142,495)	(202,824)
% sales	464%	494%	58%	12%	14%	20%	11%	15%	15%
growth	82%	26%	5%	(86%)	478%	91%	(25%)	199%	42%
Corporate administrative expenses	(7,210)	(13,570)	(12,049)	(2,986)	(13,231)	(25,514)	(21,834)	(76, 100)	(135,182)
% sales	107%	170%	17%	6%	6%	8%	5%	8%	10%
growth	15%	88%	(11%)	(75%)	343%	93%	(14%)	249%	78%
D&A expenses	(2,063)	(1,102)	(1,189)	(1,217)	(1,148)	(1,153)	(1,199)	(1,298)	(1,646)
% sales	31%	14%	2%	3%	1%	0%	0%	0%	0%
growth	(0%)	(47%)	8%	2%	(6%)	0%	4%	8%	27%
Other external expenses	536	(11,914)	(2,005)	(2,306)	17,678	-	-	-	-
% sales	(8%)	149%	3%	5%	(8%)	0%	0%	0%	0%
growth	(106%)	(2325%)	(83%)	15%	(867%)	(100%)			
Total costs & operating expenses	(40,080)	(65,990)	(56,589)	(12,231)	(29,792)	(89,880)	(70,673)	(219,892)	(339,653)
EBIT	(33,322)	(58,012)	15,067	35,581	199,725	221,296	353,352	723,292	1,005,591
Interest expenses	-	-	-	-	-	-	-	-	-
Profit/Loss before tax	(33,322)	(58,012)	15,067	35,581	199,725	221,296	353,352	723,292	1,005,591
growth	11%	74%	(126%)	136%	461%	11%	60%	105%	39%
% sales	(493%)	(727%)	21%	74%	87%	71%	83%	77%	75%
Income tax	-	-	(1,507)	(7,116)	(59,917)	(66,389)	(106,005)	(216,988)	(301,677)
Tax rate	0%	0%	10%	20%	30%	30%	30%	30%	30%
Net income/loss	(33,322)	(58,012)	13,560	28,465	139,807	154,907	247,346	506,304	703,913
Earnings per Share (Basic)	(0.038)	(0.067)	0.016	0.033	0.161	0.179	0.286	0.584	0.813

Source: Company data, goetzpartners Research estimates.

Warning Note: Past performance and forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations.



FIGURE 15: Immutep balance sheet model									
Balance Sheet	2022A	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Jun YE (A\$k)	30-Jun-22	30-Jun-23	30-Jun-24	30-Jun-25	30-Jun-26	30-Jun-27	30-Jun-28	30-Jun-29	30-Jun-30
ASSETS									
CURRENT ASSETS	90,812	30,896	44,285	62,436	173,311	316,754	552,113	1,043,926	1,731,681
Cash and cash equivalents	79,995	19,863	33,032	50,957	161,603	304,812	539,931	1,031,501	1,719,007
GST receivable	-	-	-	-	-	-	-	-	-
Grant and other receivables	8,374	8,541	8,712	8,886	9,064	9,245	9,430	9,619	9,811
Other current assets	2,443	2,492	2,542	2,593	2,644	2,697	2,751	2,806	2,862
FIXED ASSETS	11,358	11,743	12,046	11,372	11,443	11,924	12,932	16,445	21,630
Tangible assets, net	38	72	110	151	196	246	302	362	429
Plant & Equipment Computer									
Furniture and fittings Goodwill	-	-	_	_	-	-	_	_	_
Intangible assets, net	10,824	11,670	11,937	11,221	11,247	11,678	12,630	16,083	21,201
Patents	-	-	-	-	, -	-	-	-	-
Intellectual property	10,824	11,670	11,937	11,221	11,247	11,678	12,630	16,083	21,201
Total goodwill & Other intangible assets	12,593	11,670	11,937	11,221	11,247	11,678	12,630	16,083	21,201
as % of revenue	2	1	0	0	0	0	0	0	0
Net investment	(2,034)	(923)	266	(716)	25	431	952	3,453	5,118
Amortization	(1,312)	(1,082)	(1,167)	(1,194)	(1,122)	(1,125)	(1,168)	(1,263)	(1,608)
as % of prior year's total goodwill & intangible assets	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%
Gross investment as % of revenue	135 2.0%	160 2.0%	1,433 2.0%	478 1.0%	1,148 0.5%	1,556 0.5%	2,120 0.5%	4,716 0.5%	6,726 0.5%
Other TOTAL ASSETS	496 102,170	42,638	56,331	73,808	184,754	328,678	565,044	1,060,371	
LIABILITIES									
CURRENT LIABILITIES	6,414	6,408	17,660	17,791	17,924	18,060	18,199	18,341	18,485
Trade payables	5,752	5,867	5,985	6,104	6,226	6,351	6,478	6,607	6,740
Borrowings	-	-	-	-	-	-	-	-	-
Current tax payable	-	-	- 271	-	-	204	402	410	410
Employee benefits	357 173	364 177	371	379	386 188	394 101	402 195	410	418 203
Other payables Deferred revenue	1/3	-	180	184 11,124		191 11,124		199 11,124	
Warrant liability	132	-	11,124 -	- 11,124	11,124 -	- 11,124	11,124	- 11,124	11,124 -
NON-CURRENT LIABILITIES	1,678	13,596	4,482	(4,331)	(33,128)	(44,247)	(55,366)	(66,485)	(77,603)
Convertible note liability	1,453	13,367	15,372	17,678	-	-	-	-	-
Warrant liability	-	-	-	-	-				-
Employee benefits	225	229	234	239	243	248	253	258	263
Deferred tax liability and other	-	-	-	-	-	-	-	-	-
Deferred revenue, less of current portion	-	-	(11,124)	(22,248)	(33,371)	(44,495)	(55,619)	(66,743)	(77,867)
TOTAL LIABILITIES	8,092	20,005	22,142	13,460	(15,204)	(26,187)	(37,167)	(48,144)	(59,118)
EQUITY									
SHAREHOLDERS EQUITY	94,077	21,206	32,761	58,920	198,530	353,437	600,783	1,107,087	1,811.001
Contributed equity	367,408	352,548	350,543	348,237	348,039	348,039	348,039	348,039	348,039
Reserves	29,005	29,005	29,005	29,005	29,005	29,005	29,005	29,005	29,005
Accumulated losses	(302,335)	(360,347)	(346,787)	(318,322)	(178,514)	(23,607)	223,739	730,043	1,433,957

TOTAL LIABILITIES & SHAREHOLDERS' EQUITY

Source: Company data, goetzpartners Research estimates.

Warning Note: Past performance and forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations.

41,210

54,903

72,380 183,326 327,250 563,616 1,058,943 1,751,882

102,170



Cash Flow Statement	2022A	2023E	2024E	2025E	2026E	2027E	2028E	2029E	20301
Jun YE (A\$k)	30-Jun-22	30-Jun-23	30-Jun-24	30-Jun-25	30-Jun-26	30-Jun-27	30-Jun-28	30-Jun-29	30-Jun-30
OPERATING CASH FLOW									
Payments to suppliers and employees	(33,839)	(64,974)	(55,488)	(22,227)	(39,859)	(99,944)	(80,692)	(229,815)	(349, 229)
License income	88	-	64,518	40,324	227,689	304,926	412,909	934,513	1,321,346
Interest received	225	229	234	238	243	248	253	258	263
Tax received / paid	(0)	-	(1,507)	(7,116)	(59,917)	(66, 389)	(106,005)	(216,988)	(301,677
Miscellaneous income	(5)	709	744	781	821	862	905	950	997
Grant income	3,302	7,040	6,160	6,468	765	5,141	9,958	7,463	22,636
NET CASH USED IN OPERATING ACTIVITIES	(30,230)	(56,996)	14,661	18,469	129,740	144,843	237,326	496,381	694,337
CASH FLOW FROM INVESTING									
Payments for held-to-maturity investments	-	-	-	-	-	-	-	_	_
Proceeds from held-to-maturity investments	_	-	-	-	-	-	-	_	_
Payments for P&E and intangibles	(23)	(213)	(1,492)	(543)	(1,219)	(1,634)	(2,207)	(4,811)	(6,831)
Proceeds from disposal of P&E	-	-	-	-	-	-	-	_	_
Acquisitions, net of cash acquired	-	-	-	-	=	-	-	_	_
Net cash provided by investing activities	(23)	(213)	(1,492)	(543)	(1,219)	(1,634)	(2,207)	(4,811)	(6,831)
CASH FLOW FROM FINANCING									
Proceeds from issue of shares / options / warrants	52,975	_	_	_	_	_	_	_	_
Proceeds from borrowings	-	_	-	_	_	-	_	_	_
Repayment of borrowings	(200)	(2,945)	_	_	(17,876)	_	_	_	_
Transaction costs	(2,427)	-	_	_	-	_	_	_	_
Net cash provided by financing activities	50,348	(2,945)	-	-	(17,876)	-	-	-	-
	•		•						
Net change in cash and cash equivalents	20,096	(60,155)	13,169	17,926	110,645	143,209	235,120	491,570	687,506
Effect of exchange rate on cash and cash equivalents	(671)	-	-		-	-			-
Cash and cash equivalents, beginning of period	60,593	80,018	19,863	33,032	50,957	161,603	304,812	539,931	1,031,501
						<u>.</u>			

13,169

17,926

128,521

143,209

235,120

491,570

687,506

Cash generation/(burn)
Source: Company data, goetzpartners Research estimates.

Warning Note: Past performance and forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations.

(30,253) (57,209)



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COMPANY DESCRIPTION

Immutep (known as Prima BioMed until November 2017) is an Australian clinical-stage biotechnology company that develops immunotherapies for cancer and autoimmune diseases. Immutep is the global leader in the understanding of and in developing therapeutics that modulate Lymphocyte Activation Gene-3 ("LAG-3"). LAG-3 was discovered in 1990 at the Institut Gustave Roussy by Dr Frédéric Triebel, Immutep's Chief Scientific Officer and Chief Medical Officer. The company has three assets in clinical and one asset in preclinical development. The lead product candidate is eftilagimod alpha ("efti"), a first-inclass antigen presenting cell ("APC") activator being investigated in combination with chemotherapy or immune therapy for advanced breast cancer and melanoma. Immutep is dual-listed on the Australian Stock Exchange ("IMM") and on the NASDAQ Global Market ("IMMP") in the US (American Depository Receipts), and has operations in Europe, Australia, and the US. The company has licensing deals with Novartis, GSK and EOC (China only), and clinical trial collaboration and supply agreements with Merck & Co. and Merck KGaA / Pfizer, the latter for lead asset efti.

SCENARIOS

Base Case - GP Investment Case

Immutep generates further clinical data on efti and secures an outlicensing deal over the next 12 - 18 months.

Bluesky Scenario

N/A

Downside risk

Company is unable to generate further positive data on efti and fails to achieve licensing deal.

Peer Group Analysis

SWOT

Strengths: Global leadership position in LAG-3 with 4 LAG-3 related product candidates; many active clinical trials with readouts expected 2023E; strong performance of efti alongside many FDA-approved therapies; established collaborations with big players (Merck (MSD), Merck KGaA / Pfizer, Novartis and GSK).

Weaknesses: Sales growth in China dependent on EOC Pharma collaboration; single asset (efti) accounts for most of value and does not have strong efficacy data as a monotherapy; expired composition of matter patent means efti is only protected by use and formulation patents.

Opportunities: Provide a novel class of immunotherapy for use alongside many existing approved therapies across many cancer and auto-immune indications; efti may become the first immunotherapy licensed for use in mBC; M&A activity in the immune-oncology space.

Threats: Market entry by competitors and alternative therapies may erode sales; EMA and FDA approval for immune-oncology drugs subject to stringent criteria.

INDUSTRY EXPECTATIONS

Immutep is developing immunotherapies for cancer, with a focus on the immune checkpoint LAG-3. The immune checkpoint inhibitor ("ICI") class has experienced rapid adoption since the launch of BMS's Yervoy (ipilimumab) in 2011, owing to their ability to elicit durable responses in 20 - 50% of patients for up to 10 years. The global ICI market was worth \$16.8bn in 2018 and is expected to nearly triple by 2022E, driven largely by expanding use of existing therapies both in approved and new indications. The race is on to develop novel compounds with complementary mechanisms of action for combination therapy able to augment response rate without increasing toxicity, which, if successful, are expected to enjoy rapid uptake.



Important Disclosures: Non-Independent Research

Analyst Certification

I, Dr. Chris Redhead, hereby certify that the views regarding the companies and their securities expressed in this research report are accurate and are truly held. I have not received and will not receive direct or indirect compensation in exchange for expressing specific recommendations or views in this research report.

I, Alexandra Walsh, hereby certify that the views regarding the companies and their securities expressed in this research report are accurate and are truly held. I have not received and will not receive direct or indirect compensation in exchange for expressing specific recommendations or views in this research report.

Meaning of goetzpartners Research Ratings

goetzpartners securities Limited ("GPSL") publishes investment recommendations, which reflect the analyst's assessment of a stock's potential relative return. Our research offers 4 recommendations or 'ratings':

OUTPERFORM - Describes stocks that we expect to provide a relative return (price appreciation plus yield) of 15% or more within a 12-month period.

NEUTRAL - Describes stocks that we expect to provide a relative return (price appreciation plus yield) of plus 15% or minus 10% within a 12-month period.

UNDERPERFORM - Describes stocks that we expect to provide a relative negative return (price appreciation plus yield) of 10% or more within a 12-month period.

NON-RATED – Describes stocks on which we provide general discussion and analysis of both up and downside risks but on which we do not give an investment recommendation.

Companies Mentioned in this report

- (BIOTECHNOLOGY)
- (BIOTECH)
- (MERCK)
- (MSD)
- (MERCK KGAA)
- (PFIZER)
- (EOC PHARMA)
- (NOVARTIS)
- (GLAXOSMITHKLINE)
- (CHECKPOINT THERAPEUTICS)
- (OSE IMMUNOTHERAPEUTICS)
- (BIONTECH)
- (GILEAD)
- (ASTRAZENECA)
- (AKESO INC.)
- (JIANGSU ALPHAMAB)
- (AMGEN)
- (FIVE PRIME THERAPEUTICS)
- (BRISTOL MYERS SQUIBB)
- (TURNING POINT THERAPEUTIC)
- (TAKEDA)
- (MAVERICK THERAPEUTICS)
- (VELOSBIO)
- (ARVINAS)
- (ELI LILLY)
- (IMMUNOGEN)
- (TRILLIUM THERAPEUTICS)
- (FORTY SEVEN INC.)
- (ROCHE)
- (IMMUNOCORE)
- (ARCUS BIOSCIENCES)
- (IMMATICS)
- (F-STAR THERAPEUTICS)
- Immutep Limited (IMM-AU)

Valuation Methodology

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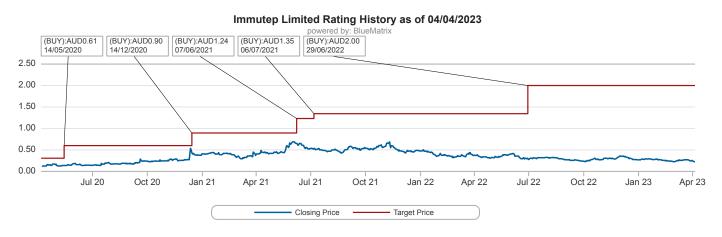
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GPSL has received compensation from Immutep Limited for the provision of research and advisory services within the previous twelve months.

IMM-AU AUD2.880 | Company Update

4 April 2023

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