goetzpartners SECURITIES

FLASH NOTE

Immutep Limited (IMM-AU)

Changing the game in lung cancer survival

OUTPERFORM

Target Price AUD2.880
Current Price AUD0.320

KEY TAKEAWAY

Immutep's LAG-3-based immune activator efti has already generated impressive late-stage data in a range of major cancers; including lung, breast, head, and neck. A safe and well-tolerated upstream activator of antigen presenting cells, efti has already showed potential in combination therapies with PD-1 / L1 inhibitors such as pembrolizumab (pembro) and chemotherapy. Data presented from its NSCLC (non-small cell lung cancer) Phase 2 trials at the recent ESMO meeting confirmed efti's potential benefit across the full spectrum of late-stage NSCLC patients. Data from TACTI-002 efti-pembro indicated unprecedented improvements in duration of response and overall survival; potentially removing the need for chemo for the bulk of 1st line ("1L") patients. Impressive ORR and PFS data from INSIGHT-003 indicate that a triple efti-pembro-chemo combination could extend benefits to harder to treat poorly or non-responsive patients. With positive feedback from the FDA on TACTI-004 registrational trial and Fast Track designation, we believe efti to be on course to reach market for NSCLC by 2026E and reach a peak sales of almost $6.5bn from NSCLC alone. With a Phase 2 / 3 in metastatic breast cancer ("mBC") now underway and FDA Fast Track Designation in 1L HNSCC currently in Phase 2b, we reiterate our OUTPERFORM recommendation with our SoTP valuation at a TP A$2.88 per share.

Efti at ESMO - life changing data presented: Immutep presented data updates for TACTI-002 and INSIGHT-003 at ESMO congress 2023. The highlight was the remarkable Phase 2 efti-pembro combo achieving a mOS benefit of 35.5 months in 1L NSCLC patients with PD-L1 TPS ≥1% (the population for which efti holds FDA Fast Track). With the mOS data for PD-L1 TPS ≥50% group still not yet reached; we can expect it to come in anywhere north of 40 months. Efti-pembro combo far exceeds all SoC treatments in 1L NSCLC which at best have a mOS of c.23 months in the TPS ≥1%.

Superior, safe, and inclusive for all PD-L1 expression levels: Patients with low and negative PD-L1 expression are notoriously difficult to target with existing approved therapies, yet they make up c.70% of 1L NSCLC patients. The Phase 2 TACTI-002 of efti + pembro treatment 1L NSCLC has continued to generate outstanding efficacy data across all PD-L1 expression levels while maintaining the safety profile. Efti + pembro generated robust ORR, PFS and DoR across the PD-L1 spectrum, with high DoR accredited to the chemo-free regimen. With superior 3-year OS rates at 45.6%, 31%, and 63.6% in TPS ≥1%, TPS 1-49% and TPS ≥50% respectively. Efti continues to generate robust data in these difficult to treat patient cohorts, providing a superior alternative to the SoC.

The INSIGHT-003 triple threat to NSCLC: Data from the first cohort of 21 patients in the INSIGHT-003 Phase 1 trial in 1L NSCLC shows the triplet efti-pembro-chemo is well tolerated and showing promising efficacy in this difficult to treat patient group with 81% of patients in this trial having PD-L1 TPS <50%. The triple therapy has led to an ORR of 64% and mPFS of 10.9 months in the low and negative PD-L1 expressers. Which bodes well when compared to ORR of 40.8% for the same patient cohort treated with anti-PD-1 + chemo reported from a registrational trial. The triple therapy looks to extend the current pembro-chemo SoC, expanding the treatable patient population without increasing toxicities.

Efti - in the LAG-3 asset class but nothing like the others: Unlike the LAG-3 assets currently in pharma pipelines which work by blocking LAG-3 on T-cells, efti's unique MOA switches on antigen presenting cells which then drive the anti-cancer response. We have seen promising efficacy data for efti in combination with pembro alone, chemo alone, and pembro + chemo. With further rational for efti's combination with radiotherapy being explored in the EFTISARC-NEO trial, efti is positioned to become a mainstay in cancer treatment, strengthened by its robust safety and tolerability.

EQUITY RESEARCH

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COMPANY DESCRIPTION

Immutep 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-in-class antigen presenting cell ("APC") activator being investigated in combination with chemotherapy / immune therapy / radiotherapy. 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; 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 $37bn in 2022 and is expected to be worth nearly $150bn by 2030, 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

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Companies Mentioned in this report

- (BIOTECHNOLOGY)
- Immutep Limited (IMM-AU)

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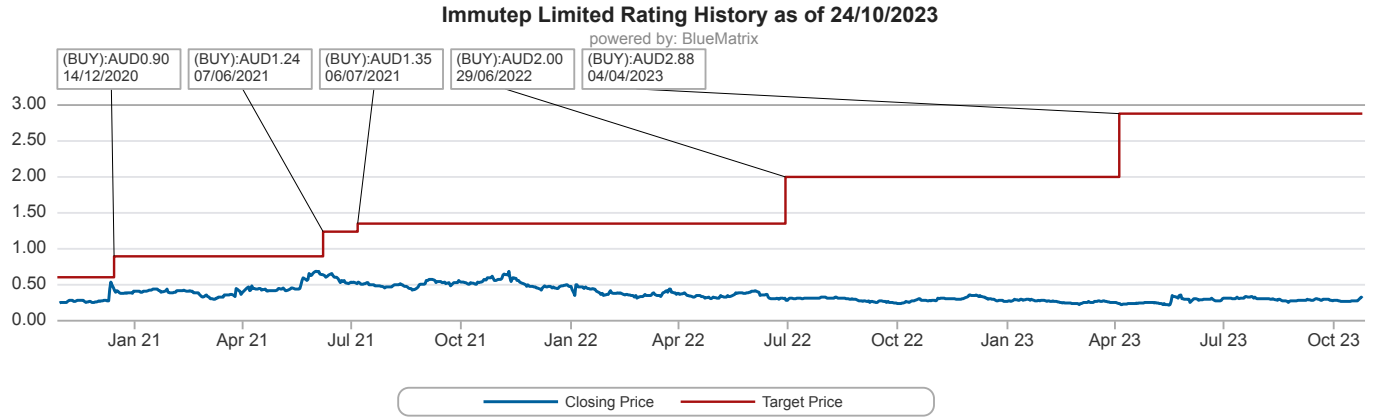

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IMM-AU
AUD2.880 | Company Update
30 October 2023

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