goetzpartners SECURITIES

FLASH NOTE

Immutep Limited (IMM-AU)

Efti-combo's boost efficacy of lung cancer standard of care

OUTPERFORM

Target Price AUD2.880
Current Price AUD0.310

KEY TAKEAWAY

Current non-small cell lung cancer ("NSCLC") standard of care ("SoC") in the absence of genetic driver mutations involves the use of PD-1 / PD-L1 immune checkpoint inhibitors ("ICI") with or without simultaneous chemotherapy. As highlighted by the recent failure of Merck's anti-TiGIT vibostolimab, few drugs have shown safe and meaningful synergy with PD-1 / PD-L1 ICI. In contrast, co-administration of efti with ICI monotherapy or as a triple efti-ICI-chemo therapy substantially improves outcomes; potentially decreasing the overall number of patients receiving chemo while increasing benefits in those that do. Initial overall survival ("OS") data from TACTI-002 shows efti-pembro combination achieved a median OS of 25 months in NSCLC patients with an increased duration of response. Consistent with efti-chemo synergy in metastatic breast cancer ("mBC") Phase 2, the INSIGHT-003 trial indicates that triplet efti-pembrolizumab-chemotherapy is also well tolerated with improved efficacy. 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 2025E and reach a peak sales of almost $6.5bn from NSCLC alone. With a Phase II / III in mBC now underway and FDA Fast Track Designation in 1st line HNSCC currently in Phase 2b we reiterate our OUTPERFORM recommendation with our SoTP valuation at a TP A$2.88 per share.

Efti-pembro superior to other approved therapies: In NSCLC patients with PD-L1 TPS ≥1% (the population for which efti holds FDA Fast Track), efti-pembro combo achieved median OS of 25 months, compared to just 16 months for pembro monotherapy and 15.8 - 23.3 months for anti-PD1 plus chemo. Coupled with the superior safety and duration of response profile, efti-pembro is poised to be the preferred treatment over the current SoC.

Efti's tolerability allows it to access the most difficult-to-treat population: Patients with low and negative PD-L1 expression are notoriously difficult to target with existing approved therapies, yet they make up c.70% of 1st line NSCLC patients. Efficacy data from TACTI-002 Phase 2 1st line NSCLC shows efti + pembro generated ORRs of 44.7% and 31.3% compared to pembro alone ORRs of 16.8% and 10.7% in low PD-L1 (TPS 1-49%) and PD-L1 negative (TPS <1%) expressing patients respectively. Efti continues to generate robust data in these difficult to treat patient cohorts.

Efti-pembro-chemo triple therapy extends treatable population: Data from INSIGHT-003 Phase 1 trial in 1st line NSCLC shows the triplet efti-pembro-chemo is safe and well tolerated, prompting study expansion to 50 patients. Promising efficacy data demonstrates the triple combo elicited an ORR of 65% in patients with PD-L1 TPS <50% compared to an 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 by offering both chemo or chemo-free combos.

NSCLC opportunity in excess of $6bn: The bulk of MSD's $20.9bn pembro revenues come from NSCLC and with key patents due to expire on pembro, MSD is under pressure for a new combination product for patent extension after the failure of their anti-TIGIT. With increased penetration from the substitution for chemo and triple therapy, we estimate that global peak revenues for efti in NSCLC could reach $6.5bn.

Immutep is still significantly undervalued by investors: With a Phase III ready candidate and FDA fast track designation in two indications, Immutep has slipped under investors radars. Companies in the immuno-oncology space at a similar stage have recently been acquired and fetched premium valuations; given the continued success of efti across multiple trials, we expect Immutep's valuation to rise significantly. With a number of clinical trial collaborations with established ICI players (MSD, Pfizer, Merck KGaA), it is clear big pharma are keeping a close eye on efti.

EQUITY RESEARCH

DR. CHRIS REDHEAD
Research Analyst
T +44 (0) 203 859 7725
chris.redhead@goetzpartners.com

ALEXANDRA WALSH
Junior Equity Research Analyst
T +44 (0) 203 859 7725
alexandra.walsh@goetzpartners.com

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-in-class 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 $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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- (PFIZER INC)
- (MSD)
- (MERCK KGAA)
- Immutep Limited (IMM-AU)

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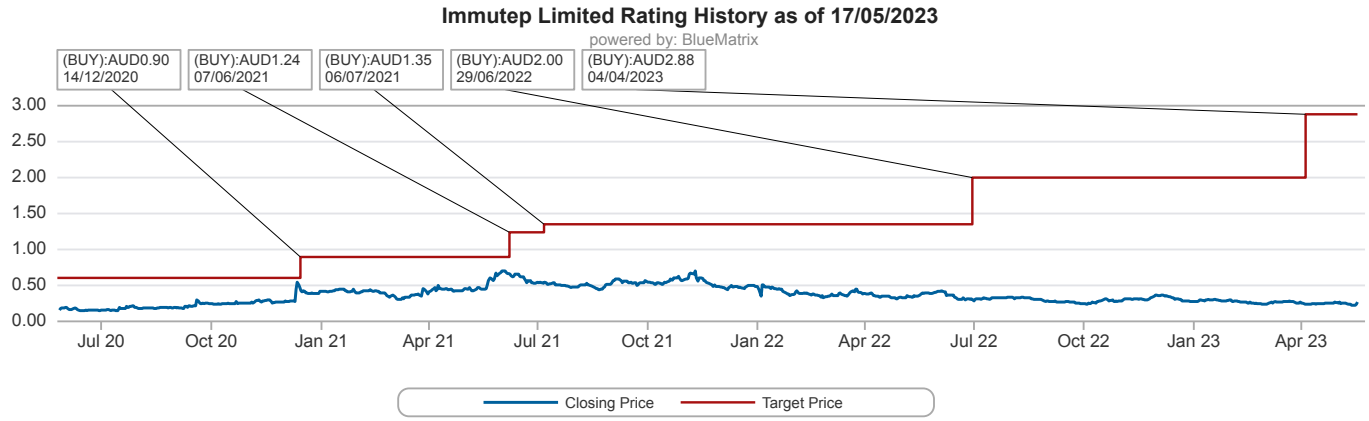

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goetzpartners securities Limited

The Stanley Building, 7 Pancras Square, London, N1C 4AG, England, UK.

Tel: +44 (0)203 859 7725

www.goetzpartnerssecurities.com