goetzpartners SECURITIES

FLASH NOTE

Immutep Limited (IMM-AU)

Efti lung benefits better longer versus standard of care

OUTPERFORM

Target Price AUD2.000
Current Price AUD0.320

KEY TAKEAWAY

Eftilagimod ("efti") continues to deliver across indications. Data in first line non-small cell lung cancer ("NSCLC") presented at the Society of Immunotherapy of Cancer ("SITC") show that efti-pembrolizumab ("pembro") beats chemo-pembro on progression-free survival and importantly has a much longer duration of response ("DoR"); almost double in PD-L1 all comers. Extending the durability of response while mitigating the side effects associated with SoC chemotherapy indicates potential for increased survival in first line NSCLC, substantially expanding treatment responsive populations and decreasing toxicity-linked treatment discontinuation. In initial data from Phase 1 INSIGHT-003 also presented at SITC, showed triple combination of efti-chemo-pembro is well tolerated with interim data indicating 72.7% response rate to the therapy; further extending efti's potential utility. The efti-pembro combination has already been granted Fast Track designation for patients with a PD-L1 Tumor Proportion Score ("TPS") ≥1%; streamlining phase 3 efti-pembro NSCLC trial design and approval. With NSCLC alone a $6bn opportunity, we anticipate efti total peak sales of at least $8bn; valuing the company at c.AUD 1.7bn (AUD 2.03 / share). Efti looks an attractive asset as PD-X patents expire. Financed to 2024E and with more data in the pipeline, IMM looks dramatically undervalued, in our view. We reiterate both our OUTPERFORM recommendation and our AUD $2.00 target price.

Safer and better tolerated alternative to chemo: Governed by PD-L1 status, PD-X-chemo is the current 1st line SoC for 70% of late-stage NSCLC patients. Pembro-efti combinations delivered a 48.3% overall response rate ("ORR") and 9.3-month median progression free survival ("mPFS") compared to 55% and 8.2 month with pembro-chemo SoC respectively in TPS ≥1%. Importantly pembro-efti treatment extended the mDoR to 21.6 months compared to the SoC mDoR of 8.8 months in PD-L1 all comers. Avoiding the severe acute and long-term side effects, efti could provide an alternative to chemo for the majority of NSCLC patients without degrading the immune system over time.

Triple therapy to expand responsive patient population: Efti-pembro-chemo combination has shown to be safe and well tolerated in first line NSCLC INSIGHT-003. Having previously shown signs of synergy with chemo in the AIPAC phase 2 in metastatic breast cancer ("mBC"), the interim data from the phase 1 triple therapy has shown promising early response rates of 72.7% in a majority patient population with PD-L1 TPS <50%.

NSCLC opportunity in excess of $6bn: The bulk of Merck's $17.2bn 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, with Fast Track designation hoping to expedite this launch.

Approaching PD-X patent expiry feed pharma appetite: Key patents are due to expire on PD-X products including pembrolizumab. Under threat from biosimilars, large pharma will be hungry for new products to protect and extend their proprietary markets; few other PD-X combos have delivered, and the chemo combo is not sufficient to extend patents.

Further opportunities in solid cancers: While NSCLC will be the focus for Phase 3 expected to start in H2/2023E, IMM will continue to explore opportunities in head and neck cancer ("HNSCC") and metastatic breast cancer ("mBC"). The ongoing TACTI-002 and -003 trials will continue to generate efti-PD-X combo data in HNSCC, where, with the right data, FDA Fast Track status could open the door to accelerated approval. Given the encouraging overall survival data, IMM will continue to talk to regulators and potential partners about the development of efti in breast cancer; the efti mBC programme in China should hopefully in any case move forwards.

EQUITY RESEARCH

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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-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 $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

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

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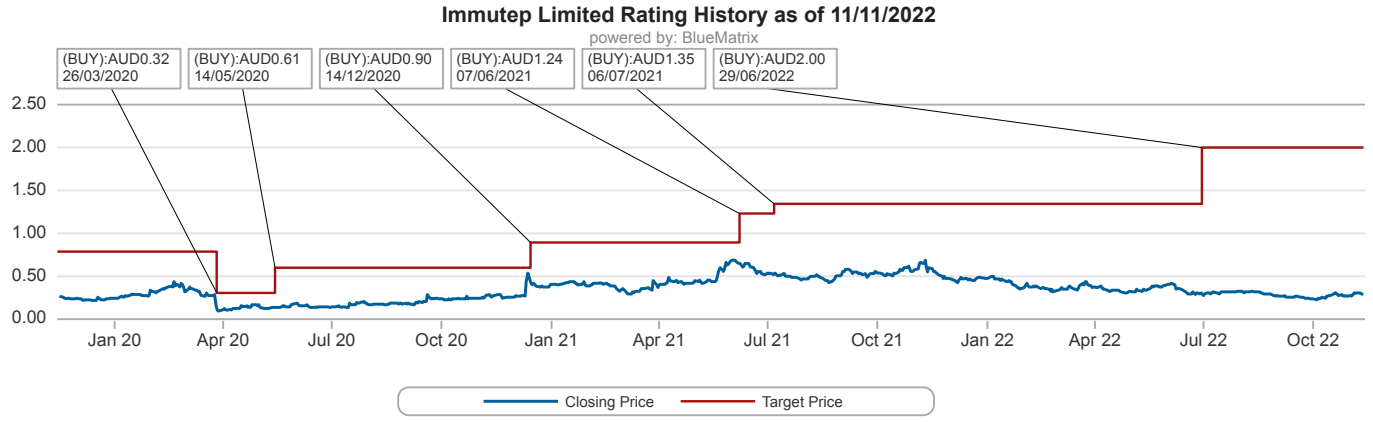

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GPSL has received compensation from Immutep Limited for the provision of research and advisory services within the previous twelve months.

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