IMMUTEP LIMITED

Biotechnology

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goetzpartners SECURITIES

FLASH NOTE

Immutep Limited (IMM-AU)

Boosting checkpoint utility in lung and other solid cancers

OUTPERFORM

Target Price AUD2.000
Current Price AUD0.280

KEY TAKEAWAY

A development update from Immutep highlights the potential for eftilagimod alpha ("efti") to substantially boost the impact of immune checkpoint inhibitors in the treatment of metastatic non-small cell lung carcinoma ("NSCLC") and other major solid cancers. Data from the TACTI-002 study indicated efti-PD-1 / L1 (PD-X) combinations could provide a safer and better tolerated alternative to chemotherapy in first line NSCLC, and substantially expand treatment responsive populations. With INSIGHT-003 testing the additional first line impact of efti-PD-X-chemo triple therapy in NSCLC due to report first data Q4/2022, the planned Phase 3 NSCLC trial could position efti combos as a mainstay of NSCLC therapy. While the potential $6bn opportunity in NSCLC remains IMM's immediate focus, efti combos could clearly have a substantial impact in other solid cancers. Data from the AIPAC metastatic breast ("mBC") Phase 2b trial provided statistically improvements in overall survival ("OS") and potential efti-chemo synergy. Head and neck cancer ("HNSCC") cancers, we anticipate efti total peak sales of at least $8bn; valuing the company at c.AUD 1.7bn (AUD 2.03 / share). Although the share price has been hit by market turbulence and flight from risk, efti looks an attractive asset as PD-X patents expire. Financed to 2024E and with more data in the pipeline, IMM looks well-placed to explore licensing or other opportunities to crystalise its value. 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 standard of care ("SoC") for 70% of late-stage NSCLC patients. Pembro-efti combinations delivered a 42% overall response rate ("ORR") and 9.3-month median progression free survival ("mPFS") compared to 50% and 7.2 month with pembro-chemo SoC respectively. Avoiding the severe acute and long-term side effects, efti could provide an alternative to chemo for the majority of NSCLC patients.

Potential to expand responsive patient population: Safe and well tolerated, efti has already shown signs of synergy with chemo in the AIPAC Phase 2 in metastatic breast cancer ("mBC"). First data on a triple pembro-chemo-efti combination in the INSIGHT-003 study should report Q4/2022E.

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.

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.

Further opportunities in breast as well as head and neck cancers: While NSCLC will be the focus for Phase 3, IMM will continue to explore opportunities in HNSCC and 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 2022E; 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)
- (MERCK)
- Immutep Limited (IMM-AU)

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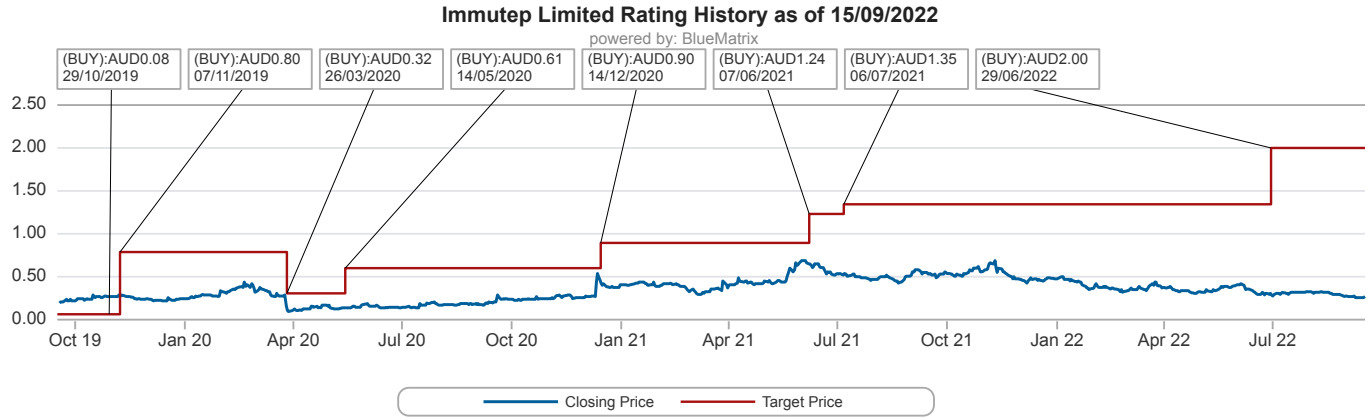

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IMM-AU
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