goetzpartners SECURITIES

FLASH NOTE

Immutep Limited (IMM-AU)

ASCO data underscores efti-PD-1 / L1 synergy

OUTPERFORM

Target Price AUD0.610
Current Price AUD0.180

KEY TAKEAWAY

Further data from TACTI-002 and first initial data INSIGHT-004 trials released at ASCO provide further evidence of synergy between eftilagimod alpha ("efti") and PD-1 / PD-L1 immune checkpoint inhibitors. Previously released TACTI-002 data had indicated that efti plus Merck & Co's pembrolizumab generated responses in first line NSCLC patients with even with low PD-L1 levels. The new data confirms this and indicates progression-free survival ("PFS") >9 months. It also confirms potential benefit in 2nd line head and neck squamous cell carcinoma ("HNSCC") with the efti - pembro combination outperforming pembro monotherapy on overall response rate ("ORR") compared to historic data (38% vs. 18%) including one patient with a complete response. The initial INSIGHT-004 Phase 1 data investigating a combination of efti with Merck KGaA / Pfizers's avelumab in a range of normally ICI solid cancers indicates that the combination is safe and well tolerated. With 3 patients still to go, an encouraging 4 out of the 9 patients so far evaluated showed a response in what are normally non-ICI-responsive cancers. With the AIPAC trial date indicating additional benefits of efti in combination with chemotherapy in subgroups accounting for ≈ 50% of metastatic breast cancer patients, efti has potential to play a major role in cancer therapy. We reiterate our OUTPERFORM recommendation and AUD$ 0.610 target price.

Potential to extend benefits of PD-1 / PD-L1 ICIs in many cancers - Dramatic benefits of ICI treatments are mostly confined to a minority of patients in certain cancers. With efti opening the throttle and ICIs releasing the immune brake, data from TACTi-002 Phase II trial suggest that efti is well tolerated and could extend the impact of PD-1 / L1 ICIs in NSCLC and HNSCC into unresponsive low PD-1 / L1 tumours. The unusual occurrence of late-responders in the efti-combo reinforces the drugs potential efficacy. While INSIGHT-004 is essentially focussed on safety, the response seen in these mostly ICI unresponsive most gastrointestinal tumours is encouraging, indicating the wide potential benefits of efti combination in solid tumours with limited alternative treatment options.

Evidence of synergy with chemo - Data analysis in the AIPAC trial suggested an increased benefit from efti when patients were actively receiving chemo, which disappeared when chemo was stopped. This suggests not only that efti anti-tumour effects might improve from exploring different chemo regimens, but also combination with other inflammatory / immune stimulating interventions such as radiotherapy. Synergy with chemo combined witth efti's good safely and tolerability could open the door to triple efti, PD-1 / L1 therapy. With pembro chemo increasingly the standard of care in NSCLC such a triple therapy could provide a valuable option in otherwise unresponsive patients.

AIPAC supports efti development in mBC patient subgroups - Although the positive trend in overall PFS over paclitaxel did not achieve significance, positive responses in patient sub-groups indicate benefits for >50% of mBC patients. Stratifying patients by weakened immunity or more aggressive disease could provide the basis for mBC Phase III design. Overall survival data for mBC is expected YE 2020E.

Substantial upside - Our risk adjusted sum-of-the-parts valuation of efti and other pipeline assets, indicates that, despite some recovery, the market still undervalues efti following the AIPAC trial 'disappointment'. With an increasing body of positive data and more expected over next 12 months, we see upside 3 - fold from current levels.

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 outliciensing 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: Leader in the understanding of LAG-3; broadest LAG-3 focused pipeline; validation from large pharma partners (Novartis, GSK, Merck & Co.); funded for >12 months.

Weaknesses: One single asset (eftilagimod alpha) accounts for the lion share of value; efti has not demonstrated convincing efficacy in monotherapy settings; efti is protected mainly by use and formulation patents, as the composition of matter patent has already expired.

Opportunities: LAG-3 could become the third pillar in immune checkpoint therapy and efti is the most advanced LAG-3 focused asset; efti could be the first immuno-oncology drug to be approved for metastatic breast cancer; oncology drugs addressing high unmet needs often enjoy shorter development and approval timelines than therapeutics in other disease areas; significant M&A activity in the immuno-oncology space.

Threats: EMA and FDA raise the hurdles for immunotherapy drugs.

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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- (MERCK & CO INC (MRK US))
- (PFIZER INC (PFE US))
- Biotechnology (BIO)
- Immutep Limited (IMM-AU)

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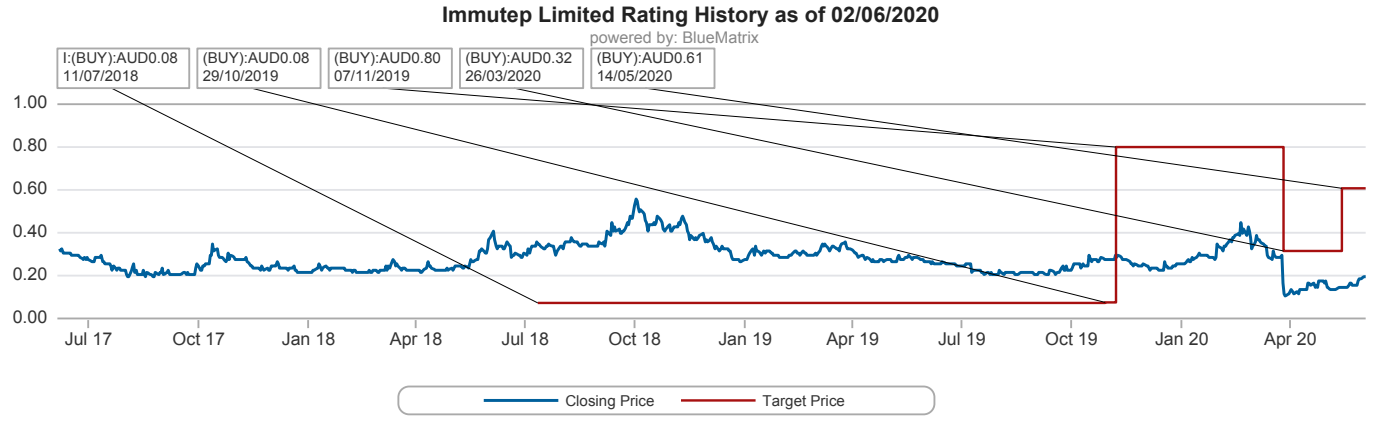

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