goetzpartners SECURITIES

FLASH NOTE

Immutep Limited (IMM-AU)

Targeting first-line head and neck with Merck & Co

OUTPERFORM

Target Price AUD0.900
Current Price AUD0.370

KEY TAKEAWAY

Immutep announced they are extending their partnership with Merck & Co ("MSD") to develop an eftilagimod alpha ("efti") pembrolizumab ("pembro") combination as a first line therapy for HNSCC (head and neck cancer). The planned randomized controlled trial TACTI-003 trial involving 160 patients builds on impressive Phase 2 TACTI-002 data (also with MSD), which showed a doubling of overall response rate with efti-pembro in normally unresponsive PD-1 / PD-L1 second line HNSCC patients, including 3 complete responses, as well as encouraging data in first- and second-line NSCLC (non-small cell lung cancer). Efti also yielded substantial overall survival benefits in combination with chemo in the AIPAC Phase IIb in metastatic breast cancer ("mBC"). Generally well-tolerated, efti looks well-placed to become a major component of the oncology armoury. With the prospect of further data from TACTI-002, final AIPAC survival data and potentially positive read through from BMS's Phase III / registrational trial over the course of 2021E, we reiterate our OUTPERFORM recommendation and AUD$ 0.9 target price.

Urgent need for better HNSCC therapies - Complex and difficult to treat there is an urgent need for new treatments for HNSCC, which currently affects around 900k and kills 450k patients worldwide.

Vast improvement in 2nd line compared to standard of care – The ORR in 2nd line HNSCC was twice that seen in KEYNOTE-12, a study using pembrolizumab alone in a similar population (ORR 36% vs. 18%). We are optimistic on PFS and OS with all responding patients, including 3 complete responders bar one still under therapy. In a difficult to treat 2nd line NSCLC population, 50% were alive at 12 months, in comparison to 6 months seen with chemotherapy standard of care. The Data Monitoring Committee has recommended entry into the 2nd expansion stage.

Important benefit for low PD-L1 expressing patients – Whilst immune checkpoint inhibition therapy has dramatically improved prognosis for many cancers, those who express low levels of PD-L1 mostly fail to see clinical benefit with monotherapy. In a first line NSCLC population after efti-pembrolizumab combination, one patient with <1% PD-L1 expression saw a complete response, whilst 4 / 11 subjects with 1% - 49% PD-L1 expression saw partial responses, repeated in 3 / 5 patients with the same expression levels in the 2nd line HNSCC group. This provides evidence that efti could deliver meaningful benefit to patients that currently face poor outcomes due to ICI unresponsiveness.

Impressive overall survival ("OS") data in mBC Immutep's Phase IIb AIPAC study in metastatic breast cancer ("mBC") shows efti-chemo benefits subgroups representing >60% of patients. In patients <65 years or with low starting monocyte count, efti plus paclitaxel increased OS by +7.1 months and +9.4 months respectively, in comparison to paclitaxel plus placebo ($p<0.05$). CD8 T cell analysis saw a sustained elevation in the efti group correlated with prolonged OS. Given other clinical benefits evident across the whole patient population and efti safety, these data are under discussion with US and European regulators with regards the route to approval.

Positive read through from BMS LAG-3 - BMS has indicated that its anti-LAG-3 relatlimab Phase III registrational trial in melanoma is expected to readout shortly. A positive result would clearly have a positive read through for Immutep.

Further upside - Our risk adjusted sum-of-the-parts valuation of efti and other pipeline assets, indicates that there is substantial upside from current levels. With the prospect of more data from both TACTI-002 and AIPAC as well as the readout from BMS imminent, we see at least 2 - fold upside 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 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: Increasing data supports use of efti in oncology combos. 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.

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- (BRISTOL MEYERS SQUIBB)
- (BIOTECHNOLOGY)
- (BIOTECH)
- (MERCK & CO)
- Immutep Limited (IMM-AU)

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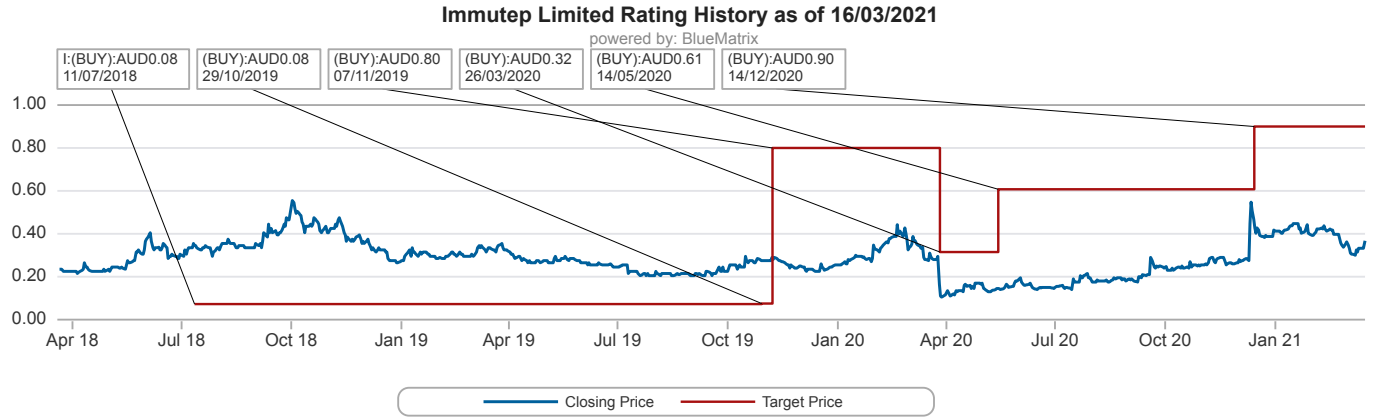

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