IMMUTEP LIMITED

Biotechnology

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goetzpartners SECURITIES

FLASH NOTE

Immutep Limited (IMM-AU)

Efti breast trial: Down certainly not out

OUTPERFORM

Target Price AUD0.320
(from AUD0.800)
Current Price AUD0.120

KEY TAKEAWAY

Given high expectations and market backdrop, disappointing AIPAC Phase IIb metastatic breast cancer data has hit the stock hard. While the lack of a statistically significant improvement in overall progression free survival ("PFS") compared to chemotherapy alone is a substantial set back, the stock decline would suggest that Eftilagimod alpha ("efti") is dead; not so in our view. Although the current data will not support the hoped for regulatory approval in mBC, patient subgroup responses and other signals should encourage continued development in mBC and mould pivotal Phase 3 design. The data also does not have negative read-over into other programmes such as ICI combinations. Recent encouraging data from the TACTI-002 study in non-small cell lung cancer ("NSCLC") and first positive signals in head and neck suggest the drug may extend the benefits of immune checkpoint inhibitors ("ICI"). While the company will need to refinance either through partnering or the capital markets, we see significant unrecognised residual value in the stock, including the licensed programs with GSK and Novartis. We recommend the stock OUTPERFORM at a reduced TP of AUD0.32 (from AUD0.80).

Data supports efti development in mBC patient subgroups - Although the positive trend towards improved overall PFS over paclitaxel was not statistically significant, analysis revealed potentially more pronounced effects in significant (up to 50%) patient sub-groups. These included patients with a weakened immune system with lower pre-trial monocyte count as well as patients with potentially more aggressive disease or who had a poorer status at the beginning of the trial. This could drive patient stratification and mould design in a future Phase III in mBC.

Synergy with chemo; potential for further combinations - While the overall effect on PFS was not statistically significant, there were signs of synergy with the paclitaxel chemotherapy. Data suggested that there was a noticeably larger impact of efti compared to the control in the first seven months of treatment when patients were receiving chemo, but disappeared thereafter when chemo removed. This implies that the efti effect may be enhanced by the presence of a sustained 'co-inflammatory' stimulus. This observation should not only mould future mBC trials, but may have implications in extending the benefits of efti in other indications such as NSCLC where an efti / chemo combo seems an obvious next step. This could also drive the exploration of other inflammatory / immune stimulating combinations such as radiotherapy.

Potential to extend benefits of ICIs - The potentially dramatic benefits of ICI treatments are normally confined to a minority of patients in certain cancer indications. Recent data from TACTi-002 trial suggests that efti has the potential to extend the impact of the ICI pembrolizumab in NSCLC and perhaps head and neck cancer. Encouraging results from this small trial suggests that the benefits could be on a par with pembro-chemo combos in NSCLC, opening the door to new less toxic first line option in NSCLC. Following encouraging results from the first few head and neck patients, the expansion phase in both first line NSCLC and second line head and neck has been initiated resulting in addition clinical news flow over the next twelve months.

Need for finance - While the company appears well funded at least until YE2020, it will clearly need to seek finance to sustain development. Given the positive signals from the efti data and the strength of the rest of the pipeline, we are optimistic that this can be achieved through development partnering or the capital markets.

Substantial upside - Our sum-of-the-parts valuation based on risk-adjusted net present values ("rNPVs") for efti and other pipeline assets, indicates that the market no longer ascribes any value to efti. While of little surprise given the expectations and current capital markets, this is an over-reaction in our view. While there is clearly now some financing risk, data indicates that efti may still have substantial potential in combination with ICIs and perhaps as a monotherapy in stratified patient populations or with modified treatment regimens. Ascribing just a 10% - 20% probability to these programmes yields a valuation of two to three times the current valuation.

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 successfully completes on going clinical trials and is able to refinance based on resulting and current data.

Bluesky Scenario
N/A

Downside risk
Company is unable to secure finance based on current and on-going trial data.

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.

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- (GLAXOSMITHKLINE PLC (GSK LN))
- (NOVARTIS AG (NOVN SW))
- Biotechnology (BIO)
- Immutep Limited (IMM-AU)

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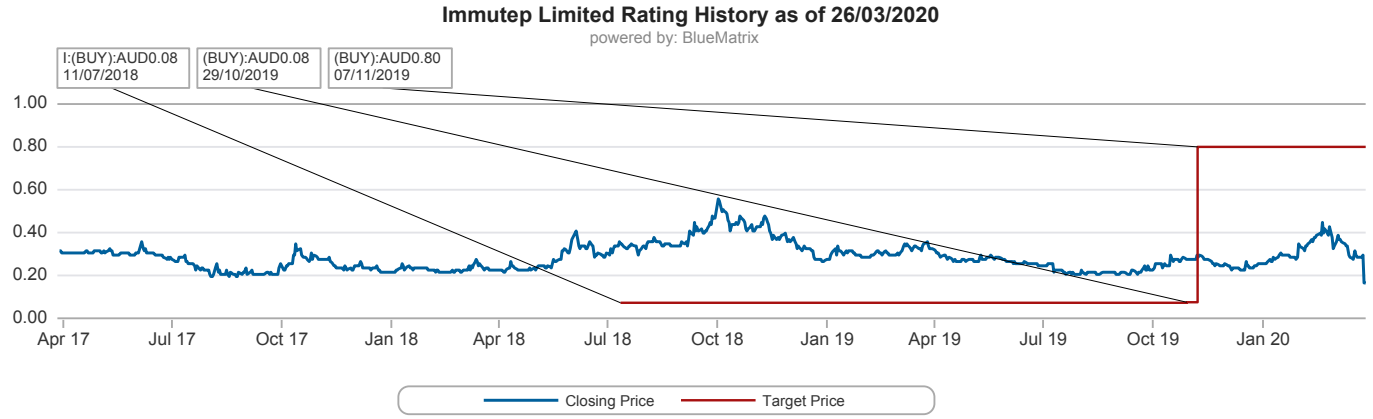

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GPSL has received compensation from Immutep Limited for the provision of research and advisory services within the previous twelve months.

IMM-AU
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