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FLASH NOTE

Immutep Limited (IMM-AU)

Striking support for efti - checkpoint inhibitor combos

OUTPERFORM

Target Price AUD0.610
Current Price AUD0.270

KEY TAKEAWAY

Data presented at the SITC further support the use of eftilagimod alpha ("efti") in PD-1 / PD-L1 immune checkpoint inhibitor ("ICI") combinations. These include very encouraging data in normally unresponsive 2nd line HNSCC (head and neck cancer) and 2nd line NSCLC (non-small cell lung cancer) and, as well as further indications of improved responses in the second 1st line NSCLC expansion cohort. The new Phase 2 TACTI-002 interim results show that 5 patients have now seen complete responses to the efti-pembrolizumab combo (2 in 1st line NSCLC and 3 in 2nd line HNSCC), whilst treatment was well tolerated in the total 91 patients. Striking data in normally PD-1 / PD-L1 unresponsive 2nd line HNSCC revealed double the ORR expected from ICI alone, including 3 complete responses. Promising responses were seen in predominantly low PD-L1 expressing 2nd line NSCLC compared to the chemo standard of care triggering entry into the second expansion phase. These increasingly positive data further highlight the potential of efti-ICI combos. With the prospect of a potentially positive read through from BMS's Phase III / registrational trial reporting late 2020E / early 2021E, we reiterate our OUTPERFORM recommendation and AUD $ 0.610 target price.

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.

Further positive signals in 1st line NSCLC – Both stages of the 1st line NSCLC arm of TACTI-002 are now complete. At first glance, there appears to be a noticeable drop in ORR compared to that in the first stage (39.4% vs. 53.0%). Close inspection reveals a lower (21.1%) ORR in Stage 2, but a similar proportion of combined responders and stabilised patients. It is possible that second stage patients may just be slower to respond due to their higher median age (74 vs. 65), proportion of less robust ECOG 1 ECOG 0 (16 / 19 vs. 5 / 17) and perhaps a greater proportion of non-squamous cases (14 / 19 vs. 7 / 17).

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. Excitingly, in the 1st 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.

Positive read through from BMS LAG-3 - BMS has indicated that its anti-LAG-3 relatimab Phase III registrational trial in melanoma will readout end of 2020E or beginning of 2021E. 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, despite significant recent increases, there is still substantial upside. With the prospect of more data and the readout from BMS around YE2020, 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: 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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I, Dr. Chris Redhead, hereby certify that the views regarding the companies and their securities expressed in this research report are accurate and are truly held. I have not received and will not receive direct or indirect compensation in exchange for expressing specific recommendations or views in this research report.

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Companies Mentioned in this report

- (BRISTOL MEYERS SQUIBB)
- Immutep Limited (IMM-AU)

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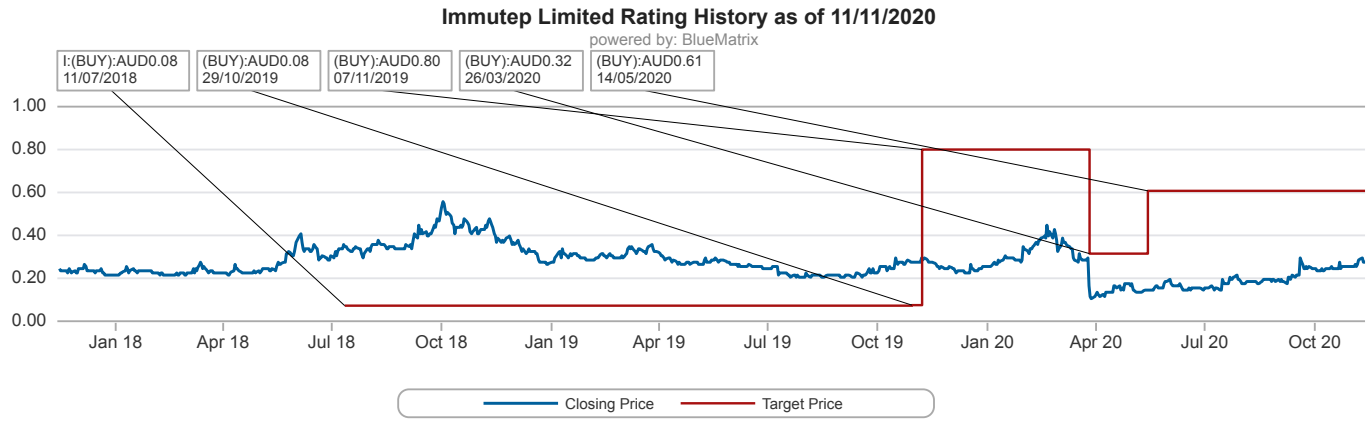

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GPSL has received compensation from Immutep Limited for the provision of research and advisory services within the previous twelve months.

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