goetzpartners SECURITIES

# FLASH NOTE

## Immutep Limited (IMM-AU)

### Efti combos move towards centre stage at ASCO

**OUTPERFORM**

Target Price AUD1.240
(from AUD0.900)
Current Price AUD0.665

**KEY TAKEAWAY**

**Data presented at the ASCO further supports the use of eftilagimod alpha ("efti") in PD-1 / PD-L1 immune checkpoint inhibitor ("ICI") combinations. These include data in 1st line NSCLC (non-small cell lung cancer) and 2nd line HNSCC (head and neck cancer). The new Phase 2 TACTI-002 interim results show that 7 patients have now seen complete responses to the efti-pembrolizumab ("pembro") combo (2 in 1st line NSCLC and 5 in 2nd line HNSCC). Treatment was well tolerated in the total 127 patients. With 48.4% of evaluable patients responding, the 1st line NSCLC efti-pembro data compares well to anti-PD-L1-chemo; but more sustained and without the toxicity. Striking data in normally PD-1 / PD-L1 unresponsive 2nd line HNSCC revealed double the ORR expected from ICI alone, including 5 complete responses. With the efficacy and safety of LAG-3 targeted mAbs highlighted in BMS's Relativity047 trial, the Immutep pipeline looks increasingly positioned at the centre of cancer immune-therapy. We reiterate our OUTPERFORM recommendation and increase our target price to AUD$ 1.24 (from AUD $ 0.90).**

**Strong basis for HNSCC Phase 2b –** The ORR in 2nd line HNSCC was 30% in intention-to-treat and 36% in evaluable patients; twice that in KEYNOTE-12 using pembro alone (ORR 36% vs. 18%). All responses were durable with no responders progressing within 6 months; five were complete responders. This is a firm basis to move to the TACTi-003 Phase 2b.

**Efficacy of chemo-PD-L1 combo in NSCLC without the toxicity –** The PFS in 1st line NSCLC for efti-pembro patients was 8.2 compared to 11.2 months in high PD-L1 expressors and 4.1 in low. Two patients had a complete response with no responders progressing within 6 months. These responses compare favourably with the currently most potent NSCLC therapy PD-L1-chemo; but without the toxicity.

**Early promise in other non-responsive solid cancers -** Data from the Phase 1 TACTI-004, released at ASCO, suggests that efti can also have benefit with other solid tumours such as cervical or gastroesophageal that are normally not responsive to anti-PD-L1. This suggests that efti could bring benefits to patients where treatment options remain limited.

**Efti potential in multiple combinations -** We believe growing evidence of safety and sustained efficacy will put LAG-3 targeted therapies and particularly efti increasingly at the centre of cancer therapy. Shown effective in combination with anti-PD-L1, efti also looks to have benefit in combination with chemotherapy. Data from the AIPAC breast cancer study published the end of 2020 indicated efti-chemo combination has benefits in large patient subgroups. These benefits could be extended by simple modifications to the treatment protocol. Efti may also have benefits when combined with novel therapies, The Phase 1 / 2a Insight-005 aims to test in combination with Merck KGaA's bintrafusp alfa (M7824) in the treatment of solid tumours.

**Further upside from increasingly de-risked pipeline** - 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. We believe Immutep's in-house and out-licensed pipeline have been substantially de-risked. Efti as a result of TACTI-002 and LAG525 out-licensed to Novartis as a result of BMS's positive anti-LAG-3 Relativity047 trial. Increasing success probability suggest significant 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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- (BIOTECH)
- (BIOTECHNOLOGY)
- Immutep Limited (IMM-AU)

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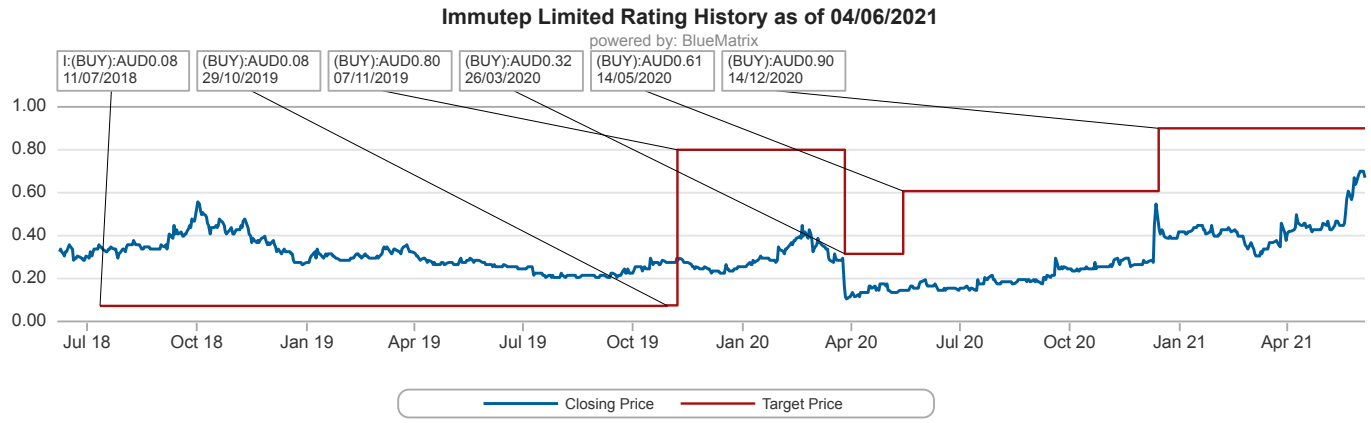


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