



# FLASH NOTE

## Immutep Limited (IMM-AU)

### Door re-opens to first eftilagimod alpha approval

## OUTPERFORM

Target Price AUD0.900  
(from AUD0.610)  
Current Price AUD0.430

#### KEY TAKEAWAY

**Newly released overall survival ("OS") data from Immutep's Phase IIb AIPAC study in metastatic breast cancer ("mBC") shows eftilagimod alpha ("efti") chemotherapy combination meaningfully benefits subgroups representing >60% of the patient population. 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's established safety, these data could be sufficient for regulatory approval in mBC; discussions with US and European regulators are prioritised. The data could also open the door to efti-chemo combination in other cancers such as NSCLC. On this basis, we reiterate our OUTPERFORM recommendation with an increased TP of AUD 0.90 (was AUD 0.61)**

**Basis for regulatory approval** - With a median OS of 20.2 months after efti + paclitaxel treatment vs. 17.5 months with paclitaxel alone, there was a positive trend across the study population (p=0.14). There was a statistically significant rise c.50% from 14.8 to 21.9 months with efti vs. placebo (p=0.012) in patients <65yrs. Patients recruited with diminished immune function (baseline monocytes <0.25x10<sup>9</sup> cells/L) demonstrated 74% longer survival with efti vs. placebo (22.4 months vs. 12.9 months p=0.020). Subjects with more aggressive Luminal B type disease also showed improved OS (+3.8 months, p=0.077). With 40% of events still to report the trial could close mid-2021E. The clear impact on OS in subgroups, the safety of the drug and wider benefits across the patient population described below may provide a strong basis for provisional marketing approval.

**Benefits apparent across whole patient population** - In contrast to the unchanged 7.3 month progression free survival ("PFS"), overall response rate and disease control rate were 10% higher with efti (48.3% vs. 38.4% and 85.1% vs. 75.9% respectively), although not statistically significant. Also, while quality of life scores deteriorated at week 25 with placebo, this was not the case with efti, indicating an improved patient burden. The absence of OS reduction in efti compared to placebo following CDK4/6 therapy is also of note given the therapy's increasing use. These data indicate real benefits of efti to the whole patient population. Given overall improvements in PFS observed with efti in the first seven months when patients received chemo, benefits to the whole patient population could be extended by adopting a longer chemo regimen; more in line with the normal US standard of care; likely in the planned EOC Pharma China trial.

**Potential to extend efti-chemo into other cancers** - Synergy with the paclitaxel chemotherapy implies that the efti effect may be enhanced by the presence of a sustained 'co-inflammatory' stimulus. Maintaining chemo throughout efti treatment, as might be expected in US protocols could extend OS benefits to all patients. Given its good safety and tolerability, this 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.

**Approved plans for China trial** - EOC Pharma, Immutep's partner for efti development in China, announced the NMPA has approved Phase II trial mirroring the AIPAC design for efti + paclitaxel. Fully funded by EOC Pharma, this study aims to recruit 152 patients. Successful development of efti in China could generate substantial royalties and milestones; and treatment option for c.1.6m women p.a. in China.

**Substantial additional upside** - Assuming 45% probability for approval for mBC during 2021E, our risk adjusted sum-of-the-parts valuation of efti and other pipeline assets, indicates a fair value per share of AUD 0.9 rising to AUD 1.30 on mBC approval.

## 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.

## Important Disclosures: Non-Independent Research

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### Companies Mentioned in this report

- Immutep Limited (IMM-AU)

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### IMM-AU

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