



# FLASH NOTE

## Immutep Limited (IMM-AU)

### TACTI-mel final data confirm efficacy signals

#### KEY TAKEAWAY

Immutep reported final results for the Phase I TACTI-mel trial testing lead asset eftilagimod alpha ("efti", soluble LAG-3 protein that stimulates dendritic cells) plus anti-PD-1 pembrolizumab (Keytruda) in 24 patients with unresectable / metastatic melanoma. The data, which is in line with previous interim analyses, shows encouraging efficacy signals and a benign safety profile. Albeit in a small sample size, the results compare favourably to clinical data for Keytruda monotherapy in similar patients. We believe the data supports the continued development of efti in combination with established agents to further increase response rates, a strategy that Immutep is implementing across multiple tumour types and combinations. The key inflection point for Immutep is data from the Phase IIb AIPAC trial testing efti plus chemo in metastatic breast cancer ("mBC"). Positive results would increase our target price by 43% to A\$0.112. We reiterate our OUTPERFORM recommendation.

#### Majority of patients responded to treatment, some experienced deep responses

The TACTI-mel trial included 18 patients in Part A and 6 patients in Part B, all of which received efti (subcutaneously) every 2 weeks: (1) Part A - 18 patients, split into 3 groups of 6 patients that received efti 1mg, 6mg or 30mg for 6 months starting at cycle 5 of pembro (IV) 2mg/kg every 3 weeks; (2) Part B - 6 patients that received efti 30mg for 12 months starting at cycle 1 of pembro. The overall response rates ("ORR") were 33% (A) and 50% (B), tumour shrinkage was experienced by 56% (A) and 66% (B) of patients, and the disease control rate ("DCR") was 66% in both groups. Importantly, 6 patients (25%) across both groups experienced a complete disappearance of all target tumour lesions - a remarkable result given the poor prognosis of most patients, most of which had metastatic disease (50% liver mets, 67% lung mets, 75% metastatic stage M1c).

#### Data compares favourably to clinical results for pembro monotherapy

Overall, the TACTI-mel data compares favourably to the official results from the KEYNOTE-002 and KEYNOTE-006 studies testing pembrolizumab as monotherapy in advanced melanoma, where the ORR ranged from 21% in patients refractory to anti-CTLA-4 ipilimumab (KEYNOTE-002) to 34% in ipilimumab-naïve patients (KEYNOTE-006). Larger trials would obviously be required to confirm the signals seen in TACTI-mel.

#### Phase IIb AIPAC data in Q1/2020E the key inflection point

We do not currently include efti in melanoma in our forecasts or valuation, as management has yet to decide whether or not to continue development in this crowded indication. The key inflection point for Immutep is first progression-free survival ("PFS") data from the Phase IIb AIPAC trial testing efti in combination with paclitaxel in mBC. The indication currently accounts for c.70% of our sum-of-the-parts ("SoTP") valuation. Positive data would add A\$0.034 per share, based on increasing the probability of success to 65% (from 40%).

## OUTPERFORM

Target Price AUD0.078

Current Price AUD0.030

# 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 efitlagimod 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

Eftilagimod alpha completes the Phase IIb AIPAC trial in mBC in 2020E, Immutep signs a \$1bn licensing deal with a large pharma partner, and efti receives conditional approval in 2020E in Europe. US launch follows one year later. Immutep has sufficient cash to fund operations until YE2020E. Revenue from the expected efti licensing deal means that Immutep does not need to raise further funds.

### Bluesky Scenario

Immutep signs a more lucrative licensing deal for efti than the \$1bn reflected in our forecasts, including a substantially larger upfront payment (we model \$50m).

### Downside risk

Efti fails to show a benefit in the Phase IIb AIPAC trial. Conditional approval is not granted based on Phase IIb data. Immutep is unable to sign a licensing deal for efti by YE2020E.

## 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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### Companies Mentioned in this report

- Biotechnology (BIO)
- Immutep Limited (IMM-AU)

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### IMM-AU

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