



FLASH NOTE

Immutep Limited (IMM-AU)

Efti-pembro combo: A new option in NSCLC?

OUTPERFORM

Target Price AUD0.800

Current Price AUD0.450

KEY TAKEAWAY

Immutep released more encouraging data from the TACTI-002 trial testing lead asset eftilagimod alpha ("efti") plus Merck & Co.'s anti-PD-1 pembrolizumab (Keytruda) in 1L & 2L non-small cell lung cancer ("NSCLC") and 2L head and neck squamous cell carcinoma ("HNSCC") ahead of a presentation today at 34th German Cancer Congress. The data demonstrates tumour responses at all levels of PDL-1 expression from >50% to <1%. At more than 7 months the trial has also yet to reach median progression-free survival ("PFS"). These data highlight the potential of efti-anti-PDL-1 combos. PFS data from the potentially registrational Phase IIb AIPAC trial with efti plus chemo in metastatic breast cancer ("mBC") are expected in Q1/2020E. Positive data would lift our valuation by c.36% and open the door to a substantial big pharma licensing deal. We reiterate our OUTPERFORM recommendation.

Combination extends ICI benefits - Benefits of ICI pembrolizumab monotherapy are largely confined to the 30% of patients with >50% of tumour cells expressing the PDL-1 marker. Patients with expression levels >50% do not enjoy much benefit. Although a small early trial, the results showing an almost 50% ORR across all patients at any level of PDL-1 expression are obviously extremely encouraging. While yet to achieve median PFS, at more than 7 months the trend is also positive. With ORR on a par with the pembro-chemo combo, this potentially opens the door to a new effective first line option for this patient group.

An alternative to pembro-chemo - Combination of pembro with chemotherapy has already been shown to extend response into patients with <50% PDL-1 and currently the preferred option in these patients. Given the obvious downsides of chemotherapy with respect to tolerability, TACTI-002 efficacy and good tolerability data indicates the possibility that efti-pembro combo could become the preferred first option with chemo only applied later.

Positive signals in Head and Neck and moving into second stage - Although as with NSCLC, relatively low pembro responses can be boosted by combo with chemo, the 33% response with the efti-pembro combo on the first 6 patients also comparable to the chemo combo. With both part A (First Line NSCLC) and Part C (second line head and neck) now recruiting for the second expansion stage and Part B (second line NSCLC) starting, we can anticipate further news flow over the next 12 months.

Potential as PDL-1 combo or stand-alone - With the AIPAC Phase IIb which trials efti in combination with chemo in metastatic breast cancer due to report, it is possible that the drug may not only have an impact on PD-L1 responses, but also as a powerful standalone product.

Substantial upside - Our sum-of-the-parts valuation based on risk-adjusted net present values ("rNPVs") for efti and other pipeline assets, indicates that a positive result for AIPAC would increase our A\$0.80 TP by c.36% to A\$1.086. This could form the basis of a conditional (EU) / accelerated (US) marketing approval and launch in 2021E in Europe / the US generating peak sales of >\$800m in mBC alone. With AIPAC data, we anticipate Immutep will sign a large pharma partner in H2/2020E.

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 2021E in Europe and the US. 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 than the \$50m we currently model.

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.

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Companies Mentioned in this report

- (MERCK & CO INC (MRK US))
- Biotechnology (BIO)
- Immutep Limited (IMM-AU)

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Immutep Limited Rating History as of 19/02/2020

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IMM-AU

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