



FLASH NOTE

Immutep Limited (IMM-AU)

Key takeaways from investor meetings in London

KEY TAKEAWAY

In this flash note we summarise key areas of focus at investor meetings we hosted in London and further take the opportunity to flag the clinical trial collaboration and supply agreement Immutep signed with Merck KGaA / Pfizer focused on evaluating anti-PD-L1 Bavencio (avelumab) with Immutep's lead asset eftilagimod alpha ("efti"). 2019 will be a decisive year rich in pipeline events and we see room for significant upside from our conservative AUD0.078 target price. The company is burning c.AUD10m / year and is fully funded until YE2019E in the absence of income from a potential licensing deal. We maintain and reiterate our **OUTPERFORM** recommendation.

Broadest LAG-3 targeted pipeline including four distinct mechanisms of action

Since its discovery by IMM CMO / CSO Frédéric Triebel in the early 1990's, LAG-3 has been gaining increasing attention from industry due to its potential to become the 3rd pillar in the immune checkpoint arsenal, with >10,000 patients now enrolled in clinical trials involving a LAG-3 targeted therapy. IMM's pipeline includes two oncology-focused assets, (1) efti (Ph IIb solid cancers), a LAG-3 Ig fusion protein that binds to MHC class II on antigen-presenting cells ("APCs") and (2) IMP701 (Ph II solid tumours), an anti-LAG-3 mAb that blocks the negative signalling on T cells thus releasing the breaks on the immune system (similar to anti-PD-1 / L1 and anti-CTLA-4 mAbs); and two assets for auto-immune disease, (3) IMP731 (Ph II ulcerative colitis), an anti-LAG-3 depleting mAb that kills auto-reactive T cells, and (4) IMP761 (preclinical), a LAG-3 stimulating mAb that down-modulates auto-reactive T cells.

Efti is the only LAG-3 targeted therapy that acts via APC stimulation

The vast majority of the LAG-3 targeted therapies in clinical development are LAG-3 blocking mAbs, such as BMS's relatlimab and IMM's own IMP701. Efti is the only molecule in this field that acts on the ligand, i.e. MHC class II on dendritic cells ("DC") rather than the receptor, i.e. LAG-3 on T cells, leading to DC maturation and activation into professional APCs. This in turn leads to T cell activation via normal physiological processes and is therefore a process that can and has been shown to complement the immuno-modulatory functions of chemotherapy and blockade of other immune checkpoints. A key benefit of being used to stimulate APCs rather than to block LAG-3 on T cells means that only 2% - 3% receptor occupancy is necessary to achieve the desired effect, which has translated into a low dose of up to 30mg / patient and hence excellent safety (only transient erythema at the injection site has been observed in treated patients so far), as potentially a low cost of goods.

New clinical trial collaboration & supply agreement adds pharma partners

On 24 Sep IMM announced that it would work with Merck KGaA / Pfizer to test efti plus avelumab in advanced solid malignancies. This collaboration is similar to the one IMM already has with Merck & Co for efti, consisting in the pharma partner(s) supplying clinical trial material for a Phase I trial, which in this case will be an amendment of the ongoing investigator-led INSIGHT trial and focus on safety. Importantly, IMM retains all rights to efti and hence the ability to sign a potential licensing deal with any bidding company following Phase IIb data (AIPAC trial) for efti in HR +ve / HER2 -ve metastatic breast cancer ("mBC") in 2019E. We remind investors that IMM already has *bona fide* licensing deals with Novartis (IMP701), GSK (IMP731) and EOC (efti, China only).

2019 is a decisive year rich in news flow across all pipeline assets

The most important catalyst for IMM shares is Phase IIb data from the AIPAC trial testing efti in combination with chemo (paclitaxel), which could form the basis of a conditional approval and an attractive licensing deal. The combination already led to encouraging overall response rates ("ORR") of 47% in the 15-patient safety run-in and 50% in the 30-patient Phase I/II trial. Other pipeline events in 2019E include: (1) final data from the TACTI-mel Phase I trial in melanoma (combo with anti-PD-1 Keytruda), (2) first data from the TACTI-002 Phase II trial in lung and head & neck cancer (combo with Keytruda),

OUTPERFORM

Price target AUD0.078

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and (3) first data from the Phase I INSIGHT trial. We maintain and reiterate both our OUTPERFORM recommendation and AUD0.078 target price.

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 2019, Immutep signs a \$1bn licensing deal with a large pharma partner in H2/2019E, and efti receives conditional approval in 2020E in Europe. US launch follows one year later. Immutep has sufficient cash to fund operations until Q4/2019E. 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 Q4/2019E.

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 \$10.5bn in 2017 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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- (PFIZER INC (PFE US))
- Biotechnology (BIO)
- Immutep Limited (IMM-AU)

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