goetzpartners SECURITIES

FLASH NOTE

Immutep Limited (IMM-AU)

Pipeline on track at operational update

OUTPERFORM
Price target AUD0.078
Price AUD0.042

KEY TAKEAWAY

At its Q1 update, Immutep confirmed that all clinical development projects for lead asset eftilagimod alpha ("efti") are on track. This includes the Phase IIb AIPAC trial for efti in combination with chemotherapy (paclitaxel) in metastatic breast cancer ("mBC"), for which data is expected in H2/2019E. Efti accounts for >90% of our sum-of-the-parts derived target price ("TP") of A$0.078 per share and the mBC indication alone for nearly 70%. Positive Phase IIb would increase our TP by 43% to A$0.111, based on increasing the probability of success to 65% (from 40%). We expect 2019 to be a decisive year for Immutep and rich in news flow across all pipeline assets. We reiterate our OUTPERFORM recommendation.

Efti Phase IIb AIPAC trial on track for PFS read-out in H2/2019E
Efti is a lymphocyte activation gene-3 ("LAG-3") Ig fusion protein that kick-starts the immune response by driving the maturation and activation of dendritic cells. It is currently being tested in multiple advanced solid tumours. The most advanced programme is the Phase IIb AIPAC trial in HR-positive, HER2-negative mBC that started in December 2015. Despite a slow-down in recruitment as reported in June this year related to the incorporation of CDK4/6 inhibitors into the treatment paradigm for mBC, Immutep now confirms that the trial remains on track to report progression-free survival ("PFS") data in H2/2019E. 155 patients (68% of the total number of 226) have already been recruited and the PFS read-out will be based on 152 events. A positive outcome could form the basis of a conditional approval and an attractive licensing deal with a large pharma partner. We forecast launch in 2020E and peak sales of c.$820m in mBC alone.

Efti Phase II TACTi-002 trial may start recruiting in early 2019E
The TACTI-002 trial will test efti in combination with pembrolizumab, Merck's leading PD-1 inhibitor Keytruda, in up to 110 patients with advanced lung (1st and 2nd line) or head & neck cancer (2nd line). Today Immutep announced that the site selection process has been completed, which could allow for the first patient to be recruited in early 2019E. In addition, Immutep will present a poster addressing the trial design at the Society for Immunotherapy of Cancer ("SITC") Annual Meeting (7-11 November) in Washington. Together these indications account for c.20% of our TP for Immutep, based on launch in 2025E and combined peak sales of $2.1bn.

Final data for efti TACTI-mel Phase I trial expected in 2019E
The importance of the Phase I TACTI-mel trial testing efti in combination with pembrolizumab in 24 patients with unresectable / metastatic melanoma is that it is the first trial to provide proof-of-concept for the combination with Keytruda. First data presented in May 2018 showed a highly promising overall response rate of 61%. In August Immutep reported that the trial was fully recruited (24 patients). Final data remains on track for 2019E and Immutep will present interim data at SITC, including at an oral presentation focused on safety and efficacy data in 18 patients. We note that we do not include melanoma in our valuation for Immutep, but this may change should management decide to move this indication forward.

Investigator-led Phase I INSIGHT trial has recruited 10 patients
Additional updates provided for efti include: (1) Patient recruitment for the investigator-led INSIGHT trial exploring intra-tumoral and intra-peritoneal administration of efti is ongoing, with 10 patients already recruited; (2) the necessary regulatory submissions to start recruiting patients for the Phase I trial testing efti plus Merck KGaA's / Pfizer's anti-PD-L1 avelumab (under a clinical trial collaboration and supply agreement) have started. The study, which will be executed as an amendment to the INSIGHT trial, is expected to enrol 12 patients with different solid tumours to evaluate safety and tolerability, and identify the recommended Phase II dose for efti when combined with avelumab. We look forward to first human data prior to including this combo into our Immutep valuation.

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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

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 shows 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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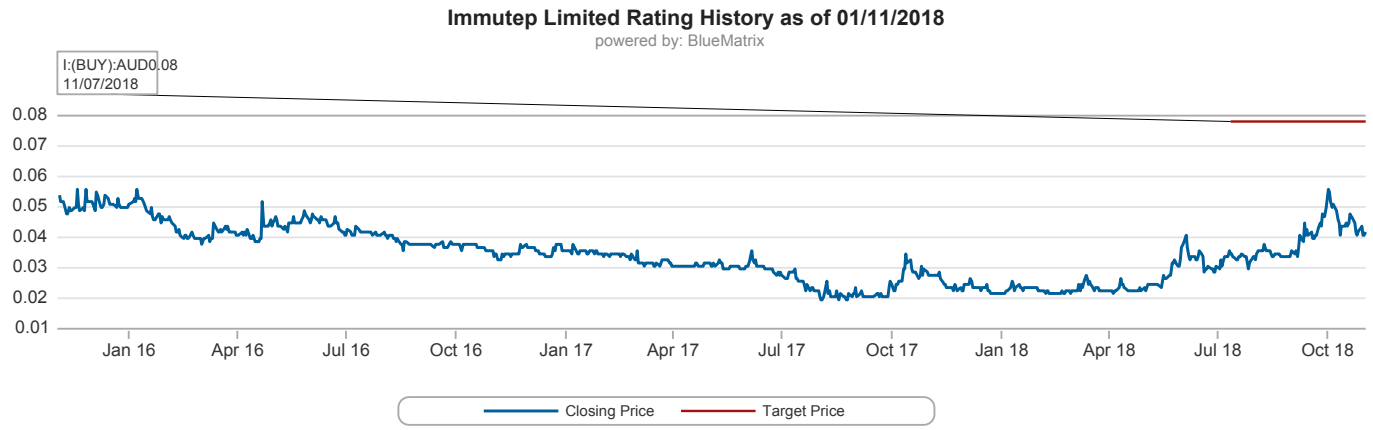

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