



FLASH NOTE

Immutep Limited (IMM-AU)

£4m from GSK extend cash runway to YE2020E

OUTPERFORM

Target Price AUD0.078

Current Price AUD0.025

KEY TAKEAWAY

Immutep received a £4m milestone from partner GSK related to dosing of the first patient in the Phase II trial for GSK2831781 (IMP731) in ulcerative colitis ("UC"). The asset was partnered in 2010 in a deal worth £64m plus royalties on sales. To our knowledge, GSK2831781 is the only LAG-3 targeting agent in clinical development for UC, a market with limited available therapeutic options. We believe that the drug could generate sales in excess of \$2bn if successful. This is not yet adequately reflected in our valuation, which is largely based on Immutep's lead asset eftilagimod alpha ("efti"), in development for multiple advanced cancers. The key inflection point for Immutep is Phase IIb data for efti from the AIPAC trial in metastatic breast cancer ("mBC"), expected in Q1/2020E. A positive result would increase our valuation by c.43% to A \$0.112 per share. We reiterate our OUTPERFORM recommendation.

First patient dosed in GSK2831781 Phase II in UC. Market opportunity of >\$2bn

GSK2831781 is a highly potent, humanised mAb developed by GSK based on Immutep's IMP731 that was engineered to have enhanced antibody-dependent cell cytotoxicity ("ADCC"). It depletes recently activated T cells that accumulate at the diseased organ site by binding to LAG-3 on their cell surface. GSK2831781 addresses the root cause of UC and therefore acts upstream of available agents. GSK previously completed (1) a Phase I / Ib trial in healthy volunteers and patients with plaque psoriasis that showed a clean safety profile and encouraging clinical improvements, and (2) compelling *in vitro* studies using colonic biopsy samples from UC patients, which together paved the way for development in UC. The Phase II trial started in May 2019 and proof-of-concept data is expected in H2/2020E. We estimate the potential market opportunity for GSK2831781 in UC at c.\$2.4bn, of which Immutep would be entitled to tiered single-digit royalties.

Phase IIb (AIPAC) data for efti in metastatic breast cancer the key event

AIPAC is a Phase IIb trial testing efti / paclitaxel vs. paclitaxel alone in HER2-negative, HR positive mBC. The recruitment of 227 patients was completed in June 2019, with top-line data expected in Q1/2020E. Positive data for the primary endpoint progression-free survival ("PFS") could serve as the basis for regulatory filings in Europe and the US. We forecast launch in Europe / the US in 2020E / 2021E and peak sales of c.\$820m in mBC alone. Our model assumes that Immutep signs an attractive licensing deal with a large pharma partner that includes a \$50m upfront payment, up to \$1bn in total milestones payments, and 15% - 21% royalties on sales. A safety run-in in 15 patients and presented at ASCO 2017 showed a partial response rate ("PR") of 47% and a disease control rate ("DCR") of 87%. This is consistent with data from the 30-patient Phase I / II trial, where the ORR was 50% and the DCR 90%.

Multiple catalysts in the coming 12 months

Following the recent capital increase of A\$10m and the receipt of the £4m milestone, Immutep should have sufficient cash to fund operations to YE2020E and hence beyond the AIPAC read-out. Other key data points for efti in the coming 12 months include: (1) final data from the Phase I TACTI-mel trial in metastatic melanoma (combo with anti-PD-1 Keytruda), (2) first data from the Phase II TACTI-002 trial in 2L head & neck cancer, and 1L / 2L lung cancer (Keytruda combo), (3) first data from the Phase I IKF INSIGHT study (one arm tests combo with anti-PD-L1 Bavencio).

Valuation largely based on eftilagimod alpha

Efti accounts for >90% of our sum-of-the-parts ("SoTP") valuation, mainly because it is the most advanced asset with the largest body of data and owned by Immutep (excl. Chinese rights). Efti in mBC alone accounts for c.70% of the valuation. Net cash and revenue from GSK2831781 and IMP701 (partnered with Novartis) account for the remaining value.

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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- (NOVARTIS AG (NOVN SW))
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- Immutep Limited (IMM-AU)

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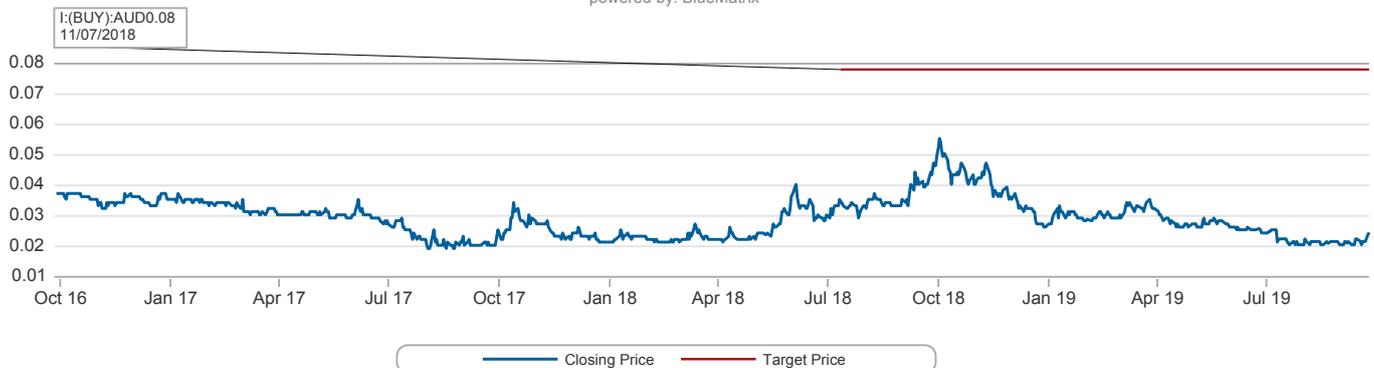
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