IMMUTEP LIMITED

Biotechnology

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goetzpartners SECURITIES

FLASH NOTE

Immutep Limited (IMM-AU)

Positive interim analysis for TACTI-002

OUTPERFORM

Target Price AUD0.078
Current Price AUD0.025

KEY TAKEAWAY

Immutep reported a positive interim analysis for the Phase II TACTI-002 trial testing lead asset eftilagimod alpha ("efti"), a soluble LAG-3 protein, in combination with anti-PD-1 Keytruda (pembrolizumab) in advanced 1L and 2L lung cancer (NSCLC) and 2L head & neck cancer (HNSCC). This allows the trial to be expanded with additional patients. Overall, this provides additional support for the combination of efti with pembrolizumab following encouraging data from the Phase I TACTI-mel trial in advanced melanoma. Efti in NSCLC currently accounts for c.20% of our sum-of-the-parts ("SoTP") derived target price of A$0.078 per share. 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.

Tacti-002 is a Phase II trial testing efti / pembro in 1L & 2L NSCLC, and 2L HNSCC

The TACTI-002 trial, conducted under a clinical trial and supply agreement with Merck & Co., consists of three parts and has a total recruitment target of 109 patients regardless of PD-L1 status: (1) Part A in 1L NSCLC (up to 36 patients, (2) Part B in PD-1 refractory 2L NSCLC, and (3) Part C in 2L HNSCC. Part A had initially enrolled cohort 1 consisting of 17 patients, and the positive outcome of the interim analysis allows for the recruitment of cohort 2 consisting of 19 patients. Recruitment is ongoing for Part B and Part C.

Predefined safety and efficacy thresholds met

At the planned interim analysis, the results for the first 17 patients were as follows: 41.2% of patients had a partial response ("PR") according to RECIST 1.1, and 35.3% had stable disease ("SD"), taking the total disease control rate to 76.5%. Even if more responses could be expected later on, this already compares favourably with Keytruda monotherapy, which leads to a response rate of c.40% in patients with ≥50% PD-L1 expression on the tumour but only 15% - 20% in those with 1% - 49% PD-L1 expression.

Upside to valuation following positive interim analysis

Our valuation is largely based on efti in multiple indications. mBC accounts for nearly 70% of our valuation, NSCLC for 20% and HNSCC for 3%, with income from partnered assets and net cash accounting for the remainder. We see upside to our valuation following the encouraging interim analysis for the TACTI-002 trial and await more mature data at the 34th Annual Meeting of the Society for Immunotherapy of Cancer ("SITC") from 6 - 10 November 2019.

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

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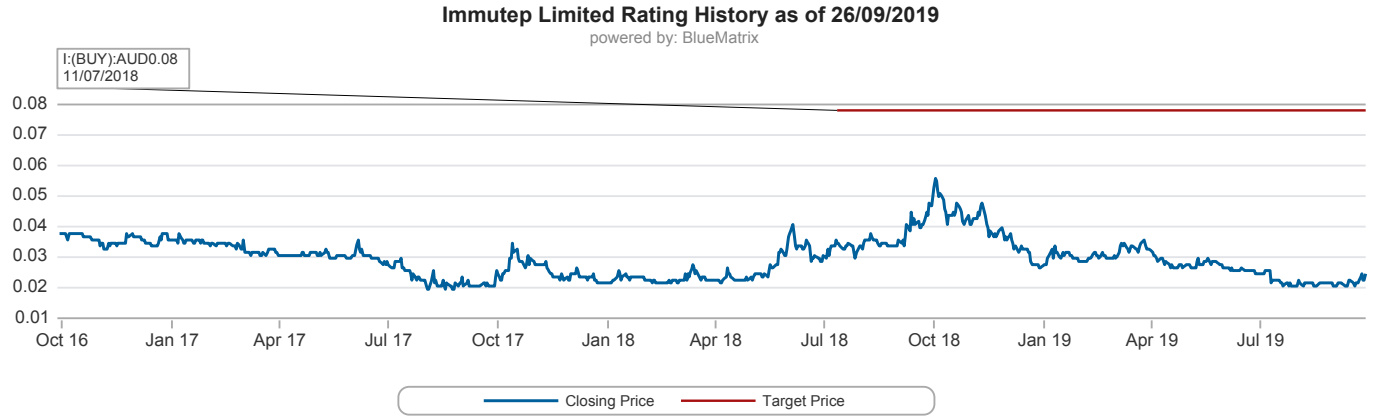

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GPSL has received compensation from Immutep Limited for the provision of research and advisory services within the previous twelve months.

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