FLASH NOTE

Immutep Limited (IMM-AU)

BMS shows LAG-3 - PD-1 combo boosts PFS in melanoma

KEY TAKEAWAY

Bristol Myers Squibb just announced that RELATIVITY-047 evaluating combination of its anti-LAG-3 Relatlimab with Opdivo had a significant benefit on progression-free survival. The Phase 2 / 3 trial in patients with untreated or unresectable melanoma showed a PFS of 10.12 months with the relatlimab combo compared to 4.63 months with Opdivo alone. This is the first time a treatment regimen has shown benefit over PD-1 alone in melanoma. These data to be presented at ASCO (American Society for Clinical Oncology) meeting (June 2021) are clearly positive for Immutep’s partnered anti-LAG-3 LAG525 currently in Phase II with Novartis. With Immutep’s Effilagimod alpha (“efi”) also showing positive benefits in combination with PD-1 in HNSCC (head and neck cancer) and non-small cell lung cancer (“NSCLC”), these new data highlight the potential of Immutep’s in-house and partnered programme. Additional new data from the TACTI-002 Phase 2 in HNSCC and NSCLC and TACTI-004 in solid tumours will be released during ASCO on 4th June. With final AIPAC survival data also expected over the course of 2021E, we reiterate our OUTPERFORM recommendation and AUD$ 0.900 target price.

LAG525 anti-LAG-3 in multiple trials with Novartis Out-licensed as IMP701 to CoStim Pharmaceuticals Inc. now owned by Novartis (“NVS”) LAG525 is in 5 clinical trials encompassing both solid tumours, including mBC and melanoma, and blood cancers. These studies involve the use of a variety of drugs in combination with LAG525, including chemotherapy, immune-oncology biologics, and small molecules.

More efi-pembro data on HNSCC and NSCLC at ASCO - Immutep recently announced an extension of its randomised controlled trial TACTI-003 trial involving 160 patients builds on impressive Phase 2 TACTI-002 data (also with MSD), which showed a doubling of overall response rate with efi-pembro in normally unresponsive PD-1-PD-L1 second line HNSCC patients, including 3 complete responses. Immutep has also seen encouraging data in first- and second-line NSCLC (non-small cell lung cancer). Recruitment is ongoing for patients with 2nd line NSCLC (part B) which was previously expanded. 27 patients of 36 have received treatment. In the 2nd line HNSCC part C recruitment of patients is complete. Further data not yet published on this and the Phase 2 TACTI-004 trial in solid tumours will be published at ASCO in June 2021.

Further upside - Our risk adjusted SoTP valuation of efi and other pipeline assets, indicates that there is substantial upside from current levels. With the prospect of more data from both TACTI-002 and AIPAC we see more than 50% upside from current levels. Hence, we maintain and reiterate our OUTPERFORM recommendation and AUD$ 0.900 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 eflagimod 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

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<tr>
<th>Base Case - GP Investment Case</th>
<th>Bluesky Scenario</th>
<th>Downside risk</th>
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<tr>
<td>Immutep generates further clinical data on efti and secures an outlicensing deal over the next 12 - 18 months.</td>
<td>N/A</td>
<td>Company is unable to generate further positive data on efti and fails to achieve licensing deal.</td>
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Peer Group Analysis

SWOT

Strengths: Increasing data supports use of efti in oncology combos. 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 (eflagimod 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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