Immutep Limited

Immutep Presents “efti” (LAG-3) Data at SITC

Summary

- Immutep presented data from its P1 TACTI-mel study at this year’s Society for Immunotherapy of Cancer (SITC) conference, highlighting the combination of eftilagimod (soluble LAG-3) with Merck’s (MRK - NR) anti-PD1, Keytruda in metastatic melanoma.

- Consistent showing. The SITC data from the dose-escalation portion of the study (N=18) demonstrates an overall response rate (ORR) with the combo treatment consistent with prior disclosures at 33%, and a disease control rate (DCR) of 66%. Importantly, one patient (6%) achieved an immune-related complete response (irCR).

- Of note, Merck also presented data from its own in-house anti-LAG-3 (MK-4280), as monotherapy, and in combination with Keytruda, for the first time at SITC ...in a different patient population (solid tumors), but worth a closer look at the combo arm: N=15, 27% ORR, 40% DCR and 27% PR, 40% SD, no CRs.

- Conclusion. Taken together, Merck's data, while early, suggests signals of anti-tumor activity, validating Immutep's approach to treating cancers, in our view. Remember, the TACTI-mel study is also in collaboration with Merck. Still, Immutep may potentially have the edge for now with efti, slightly ahead with a Phase 2 trial and Phase 1 data suggestive of potentially deep responses with its -LAG-3 based therapy.

Details

Eftilagimod (IMP321), TACTI-mel study: Phase 1 (N=24) combining efti + Keytruda in patients with unresectable or metastatic melanoma. Part A, which is the dose-escalation part of the study, consists of a single injection of 1mg (cohort 1), 6mg (cohort 2) or 30mg (cohort 3) of efti administered every two weeks in addition to Keytruda (i.v. every three weeks). In Part B, all patients will receive a single injection of 30mg of efti every two weeks in addition to Keytruda, starting at cycle 1 of Keytruda. TACTI-mel is now fully enrolled with the final patient in Part B recruited and dosed with treatment. The study has already demonstrated positive data (from Part A).

Updated results from Part A. Overall response rates of 33% and disease control rate of 66% remained consistent with previous disclosures for Part A (n=18). Of significance, one patient (6%) achieved an immune-related complete response. In addition, 5 (28%) partial responses (irPR), 6 (33%) stabilized disease (iRSD) and 6 (33%) progressive disease (irPD) were seen with the combination treatment. Tumor shrinkage was observed in 10 (56%) of patients, including two that had complete disappearance of all lesions. Four patients still remain on treatment after 12 months. No new safety signals were observed.

Rationale for efti + anti-PD1. Together, the updated results provide a new rationale for combining an anti-PD-1 with an anti-LAG3 therapy. It now appears to be more than simply helping “release the brakes on the T-cell” to augment anti-tumor function. With efti treatment, there is a sustained increase in circulating antigen presenting cells (APCs) such as monocytes and dendritic cells. The data suggests that low monocyte numbers at baseline are associated with poor efficacy to anti-PD1 treatment in melanoma patients. Efti increases monocyte numbers in patients, thereby boosting immunity, critical for a response to anti-PD1 therapy.
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<th>% of Coverage Universe with Rating</th>
<th>% of Rating for which Firm Provided Banking Services in the Last 12 months</th>
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<td>Buy</td>
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<td>2%</td>
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*See valuation section for company specific relevant indices

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Maxim Group makes a market in Immutep Limited

Maxim Group expects to receive or intends to seek compensation for investment banking services from Immutep Limited in the next 3 months.

**IMMP**: For Immutep, we use the BTK (Biotechnology Index) as the relevant index.

**Valuation Methods**

**IMMP**: Our therapeutic model assumes a royalty structure for each LAG-3 product, initially with IMP701 and IMP731 in 2020 and followed by IMP321 in 2023 (breast cancer). Our models assume risk adjustments for each product based on the stage(s) of development. Our therapeutic
models assume a risk adjustment. We then apply a 30% discount to our free-cash-flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a price target.

**Price Target and Investment Risks**

**IMMP:** Aside from general market and other economic risks, risks particular to our price target and rating for Immutep include: (1) Development—To date, LAG-3 checkpoint modulators have not been approved; (2) Regulatory—The company's ongoing and future studies may not be sufficient to gain approval; (3) Commercial—The company lacks commercial infrastructure to support a launch if approved; (4) Financial—The company is not yet profitable and may need to raise additional capital to fund operations; (5) Collaborative—The company has ongoing collaborations with large pharmaceutical companies who could back out of the partnerships, setting back development on product lines and increasing costs; (6) High volatility of the company's stock price.

**RISK RATINGS**

Risk ratings take into account both fundamental criteria and price volatility.

**Speculative** – **Fundamental Criteria:** This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. **Price Volatility:** Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

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