

Biotechnology

IMMP - NASDAQ

June 4, 2021

Intraday Price 6/4/21	\$5.21
Rating:	Buy
12-Month Target Price:	\$8.00
52-Week Range:	\$1.03 - \$7.95
Market Cap (M):	362.7
Shares O/S (M):	69.6
Float:	NA
Avg. Daily Volume (000):	2,730.5
Debt (M):	\$6.2
Dividend:	\$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	June

Total Expenses ('000)

	2020A	2021E	2022E
H1	9,572	9,707A	9,650
H2	7,715	9,439	10,454
FY	17,287	19,146	20,104



EVENT INFORMATION

2021 American Society of Clinical Oncology (ASCO) Annual Meeting

June 4-8

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Immutep Limited

Buy

ASCO Updates, LAG-3 is Emerging – Shares Remain Undervalued

Summary

- Immutep announced updated data from the ongoing TACTI-002 and INSIGHT-004 trials of eftilagimod (efti, soluble LAG-3 protein) at the 2021 ASCO (American Society of Clinical Oncology, June 4-8).
- The key focus for us is the evolving data that continues to come out of TACTI-002 in both 1L NSCLC and 2L HNSCC. Key takeaway is that in both programs, the safety is not an issue and with each update, we are seeing building durability of response. This is most notable in 2L HNSCC where the combo of efti + pembro is maintaining ~30% objective response rate (ORR) which is around 2X what pembro has been shown historically.
- Recall both programs have been expanded with Merck; 1L NSCLC adding 74 more patients and 2L HNSCC data prompted expansion to a new trial in 1L HNSCC. Note, both were based on prior data, the ASCO 2021 data just continues to add onto the positive aspects of efti.

Details

Valuation. IMMP shares are up sharply in 2021 (65%+), but most notably in May as the LAG-3 space continues to gain traction with Bristol-Myers (BMY - NR) demonstrating positive late stage data for its LAG-3 (relatlimab) + Opdivo (nivolumab) combination. The data in our view is signaling the potential replacement of Yervoy (ipilimumab) as a combination with a PD1 with a LAG-3, perhaps ushering in the next blockbuster checkpoint in immuno-oncology (IO). As such, this bodes well for Immutep, which already has multiple collaborations/partnerships for its LAG-3 pipeline. While IMMP has risen in market cap to ~\$350M (USD), it is the only LAG-3 pure play in the IO space; combined with the data and collaborations/partnerships, we still view the shares as undervalued.

ASCO 2021 update – TACTI-002 Posters

TACTI-002 background: The Phase 2 TACTI-002 study is evaluating efti and pembro in three different indications: 1L NSCLC, 2L NSCLC, and 2L HNSCC. During the first eight, three-week cycles, patients are administered 30mg of efti every two weeks; starting at cycle 9, patients receive efti every three weeks. In addition, patients receive 200mg of pembrolizumab every three weeks. Objective response rate (ORR), Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressive Disease (PD) and Disease Control Rate (DCR) data are presented for 1L NSCLC and 2L HNSCC at ASCO 2021.

Overall, the ASCO updates are a net positive with data demonstrating durable responses in 1L lung and with additional patients in the 2L HNSCC arm an ORR that is ~2X what has been observed with pembro alone; ~15% for pembro and ~30% for the efti + pembro combo. The latter is slightly lower than the prior updates which was ~36% ORR in 2L HNSCC in October 2020 and ~31% in January. Given the poor prognosis and expected outcomes based on pembo monotherapy historically, having ~2X improvement on the ORR maintained thus far and for this long is quite significant and an important takeaway. Recall that the positive data coming out of TACTI-002 in prior updates is what led to the expanded collaboration with Merck (MRK - NR) into a program in 1L HNSCC (TACTI-003) and expansion of the 1L NSCLC arm to add 74 more patients.

1L NSCLC (lung), Poster Title: Results from a phase II study of eftilagimod alpha (soluble LAG-3 protein) and pembrolizumab in patients with PD-L1 unselected metastatic non-small cell lung carcinoma

Patients in the 1L NSCLC arm were immunotherapy-naive and unselected for PD-L1 expression. As part of the ASCO 2021 update, note the N value of the trial at N=36 is the same as prior updates in late 2020 and the important takeaway is that efti +

pembro is continuing to demonstrate positive safety and durable responses. Data cutoff was 4/16/21 and a total of 37 patients were included. ORR was 41.7%, CR 5.6%, PR 36.1%, SD 27.8%, PD 16.7% and 13.9% were not evaluable. DCR was 69.4%. In a prior update, also N=36 the ORR was 36.1% and DCR was 66.7%. We would also point out that when only evaluable patients are considered, the ORR is 48.4% in the ASCO 2021 update and 39.4% in the prior update. Data in our view are demonstrating durability in response, as well as some deepening of response. We are looking towards the expansion patient data (additional 74 patients, enrollment ongoing); timing for data updates is not yet disclosed.

2L HNSCC (Head & Neck), Poster Title: *Results from a phase II study of eftilagimod alpha (soluble LAG-3 protein) and pembrolizumab in patients with PD-L1 unselected metastatic second-line squamous head and neck carcinoma*

The HNSCC cohort comprised 37 patients unselected for PD-L1 expression who had progressed while on or after receiving 1L platinum-based therapy. Thirty-five patients were evaluated as of the January 2021 data cut-off. An ORR of 31.4% was observed, as was a DCR of 40%. Median PFS was 2.1 months, with 35% of patients assessed remaining progression-free after six months. CR, PR, and SD of 11%, 20%, and 9% were noted, respectively. A median OS of 12.6 months was observed. No adverse events resulting in treatment cessation were observed. As part of the ASCO 2021 update ORR, CR, PR, SD and PD were 29.7%, 13.5%, 8.1%, and 45.9%, respectively. DCR was 37.8% and in only evaluable patients, the ORR was 35.5%. Similar to the lung cancer data noted above, the key takeaway for us is the continued safety and emerging durability of responses for the combo efti + pembro. Recall that the prior data had already signaled enough activity to trigger a collaboration expansion with Merck in 1L HNSCC. We look forward to updates from that program as well as continued updates from TACTI-002.

Data from INSIGHT-004 trial speaks to the safety and therapeutic potential of efti and avelumab in advanced solid tumors.

Poster Title: *Phase I INSIGHT platform trial: Advanced safety and efficacy data from stratum D evaluating feasibility and safety of eftilagimod alpha (soluble LAG-3 protein) combined with avelumab in advanced solid tumors*

Stratum D of the INSIGHT trial platform is evaluating efti in combination with avelumab in advanced solid tumors. Strata A and B assess the intratumoral or intraperitoneal administration of efti, respectively. Stratum C evaluates efti in combination with SOC. Patients in Stratum D were treated with 800mg of avelumab in combination with efti administered once every two weeks. Patients in cohort 1 (n=6) were given 6mg of efti, while those in cohort 2 (n=6) were administered 30mg. The primary endpoint of the trial is safety. Of the 12 patients evaluated, the ORR was 41.7%, suggesting early activity of the combination in a very difficult to treat population. All responses were PRs (5/12, 41.7%) with one SD and six PDs; DCR was 50%. Overall, safety is positive and the data are early but already demonstrating a positive signal. More mature data and more patients are needed to better understand the potential of this combination and which specific tumor type or types may be the most responsive to this treatment. More to come.

DISCLOSURES

Immutep Limited Rating History as of 06/03/2021

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution		As of: 06/03/21	
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	85%	56%
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months.	15%	48%
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	0%	0%

**See valuation section for company specific relevant indices*

I, Jason McCarthy, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

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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 IMP701 and IMP731 with commercialization in 2025, eftilagomod (efti) (royalty-free) in 2024 for 1L and 2L NSCLC, as well as 2L HNSCC, and metastatic breast cancer (1L + chemo) in 2025. 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) Foreign exchange fluctuations as the company is domiciled in Australia; (7) 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.

High – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. **Price Volatility:** The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

Medium – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

Low – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST



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