

### Biotechnology

**IMMP** - NASDAQ

January 10, 2020

<b>Closing Price 1/9/20</b>	<b>\$1.89</b>
Rating:	Buy
12-Month Target Price:	\$4.00
52-Week Range:	\$1.27 - \$3.19
Market Cap (M):	73.3
Shares O/S (M):	38.8
Float:	NA
Avg. Daily Volume (000):	44.2
Debt (M):	\$6.2
Dividend:	\$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	June

#### Total Expenses ('000)

	2018A	2019A	2020E
H1	7,058	8,364	8,512
H2	7,032	8,525	9,221
FY	14,090	16,889	17,733



## Immutep Limited

**Buy**

### TACTI-002 Head & Neck Cancer Study is Expanding, Data Updates Over 2020 – Reiterate Buy

#### Summary

- Immutep announced that it is expanding Part C of the ongoing Phase 2 TACTI-002 study due to positive data, following the Data Monitoring Committee's (DMC) decision after the predefined number of partial responses observed had been met. Another n=19 patients will now be enrolled in Part C of the study.
- The study. Recall that TACTI-002 is a collaboration with Merck (MRK - NR), evaluating Immutep's eftilagimod (LAG3) in combination with Keytruda, regardless of PD-L1 status. The trial consists of three parts: A) 1L lung cancer (NSCLC); B) 2L NSCLC; and C) 2L head and neck (HNSCC).
- Significance of expansion? Since patient recruitment initiated in 1Q19, two of the three parts have been expanded owing to the positive interim outcomes. Taken together, the data is encouraging, reflective of potential synergistic activity, and should bolster further confidence in the program, in our view.
- Also, watching for an update on AIPAC in 1Q20, which we expect to be the next inflection point.

#### Details

**TACTI-002 Phase 2.** The collaboration with Merck (supply agreement) is evaluating efti in combination with pembrolizumab in multicenter, open-label P2 study that will enroll (N=109) across ~15 sites in the US, EU, and Australia. The primary endpoint of the study is an objective response rate (ORR) in accordance with iRECIST. Key secondary endpoints include: safety and tolerability of the combo; response rate according to iRECIST 1.1; disease control rate (DCR); progression free survival (PFS); overall survival (OS); and pharmacokinetic and immunogenicity profile of efti.

- **Part A.** Initial data from Part A (1L lung cancer, PDX naive) was positive for the first n=17 patients enrolled (now cohort 1), where a partial response (PR) rate of 41.2% and a stable disease (SD) rate of 35.3% were achieved, for a disease control rate (DCR) of 76.5 at the interim analysis in September 2019. Of significance, patients were enrolled regardless of PD-L1 status. As such, the data compares to response rates seen with Keytruda monotherapy in patients with high PD-L1 expression (~40%). Typical response rates seen with low PD-L1 expressors are considerably lower at 15%-20%. Following the positive results of the interim analysis, Part A was expanded to allow for the recruitment of an additional n=19 patients (cohort 2) for a total of n=36 in Part A. Recruitment in cohort 2 of Part A is ongoing with more mature data expected in 1Q20.
- **Parts B.** (2L lung, PD-X refractory): Recruitment is ongoing with n=36 expected.
- **Part C.** (2L head & neck, HNSCC): With recruitment completed in the first stage, and following the DMC's decision to expand Part C (having met the number of predefined partial responses), a second cohort will enroll n=19.

**Keytruda in 2L HNSCC.** Keytruda received accelerated approval in 2L HNSCC, regardless of PD-L1 status, based on the results of KEYNOTE-012, with an overall response rate (ORR) of 16% (deepening to 18% thereafter), lasting for ≥6 months for 82% of patients, which included a complete response (CR) rate of 5%. Chemo options (cetuximab, methotrexate, and a taxane) in 2L are worse (10%-13%) and without any clear demonstration of improvement in overall survival (OS).

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**AIPAC Phase 2b.** The randomized, multinational, double-blind Phase 2b potentially pivotal EU trial is assessing efi as an adjuvant therapy in combination with frontline paclitaxel therapy in metastatic breast cancer (mBC). The trial is fully enrolled with N=227 patients across 30 sites and PFS. This trial is particularly important as the primary endpoint data, if positive, would be the first successful randomized trial for an antigen presenting cell activator in solid tumors, helping validate the drug class. Furthermore, if approved, efi would be the first IO in this setting, placing it in a "sweet spot" that could help adoption. Primary endpoint data expected in 1Q20.

DISCLOSURES

Immutep Limited Rating History as of 01/08/2020

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution		As of: 01/09/20	
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
<b>Buy</b>	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	84%	46%
<b>Hold</b>	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.	16%	32%
<b>Sell</b>	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	1%	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.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

**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.

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## RISK RATINGS

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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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