

### Biotechnology

**IMMP - NASDAQ** February 19, 2020

<b>Closing Price 2/18/20</b>	<b>\$3.03</b>
Rating:	Buy
12-Month Target Price:	\$4.00
52-Week Range:	\$1.27 - \$3.19
Market Cap (M):	117.5
Shares O/S (M):	38.8
Float:	NA
Avg. Daily Volume (000):	123.3
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**

**Valuation is Rising as First of 2 Key Catalysts Delivers (TACTI-002 in Lung Cancer, H&N); Breast Cancer P2b is Next (CY1Q20)**

### Summary

- Yesterday, Immutep presented/reported positive data from its all-comers PD-L1 trial, TACTI-002 (Parts A and C) at the 34<sup>th</sup> German Cancer Congress in Berlin. IMMP shares are up ~35% in February as expectations build around two key catalysts.
- As shown in the lung cancer data and H&N data (TACTI-002), the first catalyst did not disappoint. That said, at a valuation of ~\$115M now, there is still more upside to IMMP shares, on our view as the next key catalyst approaches in CY1Q20; Phase 2b data from the AIPAC breast cancer trial. This trial could potentially serve to file for registration in the EU, and as such this is a significant data event for Immutep.

### Details

#### Key Takeaways – Important to note is the significance of the lung cancer data:

- **The response rate** – Albeit in a relatively small population of N=17, ORR 47%, whereas Keytruda monotherapy ORR have only been 20-25%;
- **PD-L1 expression** – In addition, the TACTI-002 responses were regardless of PD-L1 expression; in our view, that is critical as PD-L1 lower expressors are least likely to respond to Keytruda;
- **Rising above the noise** – Checkpoint combinations are essentially everywhere; hundreds of trials. With Keytruda in 1L lung cancer and only 20-25% response rates, the TACTI-002 data rises above the noise level in the space, in our view, and it is unlocking value for investors;
- Breast cancer data next, CY1Q20. AIPAC P2b trial and breast cancer space discussed below.

**TACTI-002 Phase 2.** The collaboration with Merck (MRK - NR, supply agreement) is evaluating efiti in combination with pembro in a multicenter, open-label P2 study in two cancer types (described below) that will enroll N=109 across ~15 sites in the US, EU, and Australia.

**The primary endpoint of the TACTI-002 Phase 2 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 efiti.

• **Part A.** Initial data from Part A (**1L lung cancer**, PDX naive) was positive for the first n=17 patients enrolled (now cohort 1/stage 1), where an overall response rate (ORR) of 41.2% was achieved at the interim analysis in September, which has now increased to 47%. Of note, patients were enrolled regardless of PD-L1 status. As such, the data compares to response rates seen with Keytruda monotherapy in patients with high PDL1 expression (~40%). Typical response rates seen with low PD-L1 expressors are considerably lower at 15%-20%. Following the positive results of the first interim analysis, Part A was expanded to allow for the recruitment of an additional n=19 patients (cohort 2/stage 2) for a total of n=36 in Part A. Recruitment in cohort 2 of Part A is ongoing with 7/19 presently enrolled. The majority (10/17, 59%) of patients are still under treatment; median PFS has not yet (continued on pg 2)...

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been reached and all patients have passed the 7+ months mark thus far (see Exhibit 1).

- **Parts B. (2L lung, PD-X refractory):** Recruitment is ongoing with n=23 expected to be enrolled; 13 of 23 are presently enrolled.

- **Part C. (2L head & neck, PD-X naive):** With recruitment completed in the first stage (n=18), 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. An ORR of 33% (6/18) was reported at the interim analysis. The first patient in the second cohort (stage 2) has been enrolled.

**Exhibit 1: Overall Response Rates with Efti + Keytruda in 1L NSCLC.** While the distribution of patients in the three PD-L1 subgroups (low to high) were as expected in Stage 1, the ORR observed in all three subgroups are greater than historical Keytruda monotherapy. Low PD-L1 expressors typically demonstrate an ORR of 15%-20%, for instance. Although the subject numbers are small, these results are compelling, in our view.

Patients by PD-L1 category	No. of Responses <sup>1</sup>	ORR <sup>1</sup>	Frequency in TACT-002 N (%) <sup>2</sup>	Historical <sup>3</sup> Distribution
Low (< 1%)	1	33%	3 (23%)	35%
Medium (1-49%)	3	50%	6 (46%)	35%
High (≥ 50%)	3	75%	4 (31%)	30%
NE <sup>4</sup>	1	25%	4 (n/a)	n/a
<b>Overall</b>	<b>8</b>	<b>47%</b>	<b>17</b>	

Source: Adapted from Company Reports.

**AIPAC (Active Immunotherapy PAClitaxel)Phase 2b.** The randomized, multinational, double-blind Phase 2b potentially pivotal EU trial is assessing efti as an adjuvant therapy in combination with frontline paclitaxel therapy in metastatic breast cancer. The trial is fully enrolled with N=227 patients across 30 sites. This trial is particularly important as the primary endpoint data of progression-free survival (PFS), if positive, this would be the first successful randomized trial for an antigen presenting cell activator in solid tumors, helping validate the drug class. Furthermore, if approved, efti would be the first IO in this setting, placing it in a 'sweet spot' that could help adoption. Topline data (PFS and ORR) expected in CY1Q20.

**mBC space and data expectations.** Presently, a small proportion (10%) of patients receive 1L chemo (paclitaxel). Another (somewhat larger) fraction of patients receive endocrine therapy that is followed by chemo. However, the vast majority of patients are now treated with endocrine therapy that is reinforced with a CDK4/6 inhibitor such as Ibrance, which may be followed by a PI3K inhibitor and subsequently chemotherapy. Importantly, AIPAC covers most of this modern mBC treatment landscape, where the patients have been exposed to all three types of patient populations. Historically, response rates with paclitaxel alone have been 20%-25%, which could be lower now given the shift towards treatment with CDK4/6. Correspondingly, PFS with paclitaxel alone was historically in the range of 6-8 months, which may also be lower (3-4 months) with the addition of CDK4/6 in the treatment paradigm. So, what would be viewed as a positive readout? An addition of 2-3 months in PFS and/or response rates greater than 25%, in our view, which all things considered could be viewed as a relatively low-bar, we'll see in CY1Q20.

DISCLOSURES

Immutep Limited Rating History as of 02/14/2020

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Maxim Group LLC Ratings Distribution		As of: 02/18/20	
		% 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%	47%
<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%	34%
<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.	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.

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.

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**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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