Biotechnology

IMMP - NASDAQ January 29, 2020

Intraday Price 1/29/20	**$2.27**
Rating:	Buy
12-Month Target Price:	$4.00
52-Week Range:	$1.27 - $3.19
Market Cap (M):	88.0
Shares O/S (M):	38.8
Float:	NA
Avg. Daily Volume (000):	50.1
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

Inflection Points Approaching- Lung Cancer Data (February), Breast Cancer Data (March)

Summary

- **Immutep provided a quarter update yesterday (1/28/20), reporting ~$14M in cash and cash equivalents at the end of December, providing sufficient runway through key catalysts (AIPAC, etc.), in our view.**
- **AIPAC. Positive data in this P2b study of eftilagimod (efti) plus standard of care in metastatic breast cancer (mBC) with soc, paclitaxel, may support registration of efti in mBC. Data from the study are expected in 1Q20 (March).**
- **Significance of AIPAC? If efti (LAG3) is approved based on AIPAC, efti would represent a new class of immune oncology (IO) drug. Why? Checkpoints such as PD-1/PD-Ls directly target cytotoxic T-cells. Efti is an antigen presenting cell activator, which targets dendritic cells (DCs) that, in turn, promote T-cell expansion and proliferation to elicit an immune response.**
- **We are also watching TACT-002 (Part A). Another key inflection point for Immutep is the mature data readout of Part A from TACT I-002, which is evaluating efti in combination with Keytruda in 1L lung cancer. Key to remember here is that this is an all-comers PD-L1 trial. Keytruda, as a monotherapy is only approved in lung cancer patients that express high levels of PD-L1 (>50%). Why? In all-comers (includes low PD-L1 expressors), only 20%-25% response rates are achieved with Keytruda as a single agent. At the interim analysis, efti + Keytruda showed an ORR of 41.2%. We expect to see more mature data from the study at this year's 34th German Cancer Congress in February. Positive results in the clinic could offer an alternative to the more toxic Keytruda + chemo option, in our view.**

Details

AIPAC (**A**ctive **I**mmunotherapy **PAC**litaxel)**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 1Q20.

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.

TACTI-002 Phase 2. The collaboration with Merck (MRK - NR, supply agreement) is evaluating efti 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.

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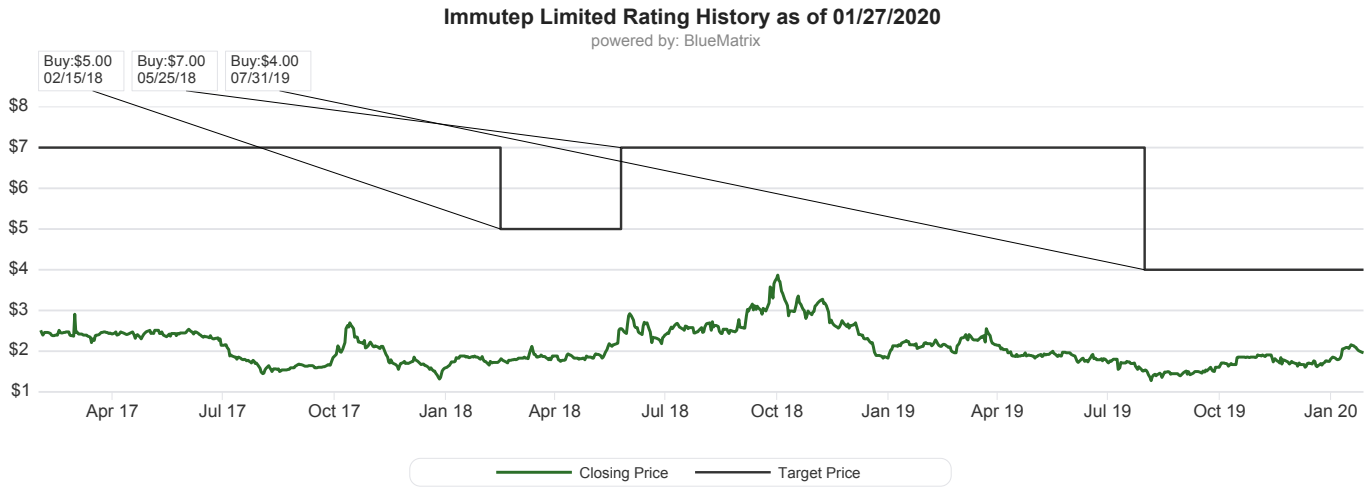
The primary endpoint of the TACTI-002 Phase 2 study is an objective response rate (ORR) in accordance with iRECIST. Key secondary endpoints include: safety and tolerability of the combo; response rate according to iRECIST 1.1; disease control rate (DCR); progression free survival (PFS); overall survival (OS); and pharmacokinetic and immunogenicity profile of 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% was achieved at the interim analysis in September. 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 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 at the 34th German Cancer Congress.

• **Parts B.** (2L lung, PD-X refractory): Recruitment is ongoing with n=36 expected.

• **Part C.** (2L head & neck, PD-X naive): 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.

DISCLOSURES



Maxim Group LLC Ratings Distribution		As of: 01/28/20	
		% 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.	**84%**	**47%**
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.	**16%**	**35%**
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.

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.

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.

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