

Biotechnology

IMMP - NASDAQ

July 2, 2018

Closing Price 06/29/2018	\$2.38
Rating:	Buy
12-Month Target Price:	\$7.00
52-Week Range:	\$1.25 - \$3.06
Market Cap (M):	72
Shares O/S (M):	30.3
Float:	100.0%
Avg. Daily Volume (000):	80
Debt (M):	\$6.2
Dividend:	\$0.00
Dividend Yield:	0.00%
Risk Profile:	Speculative
Fiscal Year End:	June

Total Expenses ('000)

	2017A	2018E	2019E
H1	3,716	7,440A	6,864
H2	6,917	6,877	7,436
FY	10,633	14,317	14,300



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Immutep Limited

Buy

First IND Filed in US for IMP321 (eftilagimod), Phase 2 Study with Keytruda 2H18

Summary

- Immutep announced that the company has submitted its first investigational new drug (IND) application in the US for eftilagimod (IMP321, efiti), a soluble fusion protein of the checkpoint LAG-3. The P2 study will evaluate efiti + Keytruda (collaboration with Merck, {MRK - NR}) in both lung and head & neck (H&N) cancers. The study should initiate in 2H18, initial data readout 2019.
- The P2 study (TACTI-002) will enroll up to N=120 in 15 centers across the US, EU and Australia. Patients will receive the combination therapy of efiti at the 30mg dose + Keytruda.
- The combination of efiti + Keytruda is also being evaluated in the ongoing P1 study (TACTI-mel) in patients with unresectable or metastatic melanoma that have had poor responses or disease progression on Keytruda monotherapy. In that study so far the overall response rate is 61% (11/18), including two complete responses. The data are suggestive that efiti, as an immune activator, is enhancing the immune response to otherwise "cold tumors". The expectation, in our view, given the utility of checkpoints in lung and H&N cancer, is that efiti will likewise induce increased immune activity that should be synergistic with Keytruda.
- Conclusion.** Filing the first IND in the US is a positive for Immutep as the company continues to advance efiti in melanoma, breast cancer and now both lung and H&N cancer. Data updates are expected as we move through the second half of 2018 and into 2019 which if positive should represent catalysts for the stock.

Details

IMP321, eftilagimod - it's all about the monocytes. What makes efiti unique is that it's not blocking or depleting LAG-3 antibody; it's a soluble fragment fusion protein that stimulates the immune response, particularly important are the monocytes. It's been shown that when the level of monocytes is >19%, then survival is higher and longer. Efiti induces monocyte levels well above the 19% threshold, >30% by six months. The increase in monocytes is likely why the combination with Keytruda, so far, has demonstrated high ORR and PFS in patients that are poor/failed responders to Keytruda monotherapy. What makes this study unique is that the patients are given Keytruda for three cycles and then evaluated for any response, thus any response after efiti is added suggests a therapeutic signal. A second program, a basket study (TACTI-002 in lung cancer, H&N cancer) evaluating the combination in PD-X naïve or refractory patients is expected to start in 4Q18. The first US IND was filed July 1, 2018. The study will evaluate the combination of efiti + Keytruda for 12 months using the 30mg dose of efiti. Don't forget about breast cancer. The P2b registration study (N=226, efiti + paclitaxel, AIPAC study) is enrolling with data expected in 2019. The primary endpoint of the study is PFS.

AIPAC (Active Immunotherapy PAClitaxel): This is a randomized, double-blind, placebo-controlled Phase 2b registration study (N=226) of IMP321 (or "efiti") as an adjuvant therapy in combination with frontline paclitaxel therapy in metastatic breast cancer. Progression-free survival (PFS) is the primary endpoint. In the first phase, 15 patients (n=6 at 6mg; n=9 at 30mg) were evaluated primarily for safety. IMP321 was safe and well-tolerated at both dosage levels, where 47% overall response rate (ORR) and 87% disease control rate (DCR) seen with the combination in the run-in phase of the study. ORR is consistent with historical data for Avastin with paclitaxel (48.9%) in metastatic breast cancer. The second phase of the trial entails randomization of 226 patients. Data is expected 1H19.

DISCLOSURES

Immutep Limited Rating History as of 06/29/2018

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution		As of: 07/01/18	
		% 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.	81%	35%
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.	18%	17%
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	2%	33%

*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.

I, Caroline Palomeque, 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 managed/co-managed/acted as placement agent for an offering of the securities for Immutep Limited in the past 12 months.

Maxim Group received compensation for investment banking services from Immutep Limited in the past 12 months.

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.

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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