

Biotechnology

IMMP - NASDAQ

July 31, 2018

Closing Price 07/30/2018	\$2.60
Rating:	Buy
12-Month Target Price:	\$7.00
52-Week Range:	\$1.25 - \$3.06
Market Cap (M):	79
Shares O/S (M):	30.3
Float:	100.0%
Avg. Daily Volume (000):	87
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



Immutep Limited

Buy

First US-Based Study of IMP321 Gets Green Light from FDA, Initiating 2H18

Summary

- Immutep announced that the FDA has approved its investigational new drug (IND) application in the US for efitlagimod alpha (IMP321, efiti), a soluble fusion protein of the checkpoint LAG-3. The P2 study is expected to initiate in 2H18 and evaluate the combination of efitlagimod with Keytruda in lung cancer or head & neck (H&N) cancer patients. Initial data expected in 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.
- Immutep's combinations keep coming; chemotherapy or immune therapies. What makes efitlagimod unique is the LAG3 fusion protein's ability to act as an antigen presenting cell (APC) activator. Activated APC cells drive the production and sustained response of anti-tumor T cells. As such combining an APC with chemotherapy (i.e., the P2b study in breast cancer) or with a Keytruda (i.e., the P1 melanoma study, and now lung or H&N cancer) should be synergistic.
- Conclusion. FDA approval of the IND is another positive for Immutep as it builds out its LAG-3 pipeline. More catalysts lay ahead in 2H18 and 2019 from all three in-house clinical programs for IMP321, as well as from partnered LAG3 assets to Novartis (NVS - NR) and GlaxoSmithKline (GSK - NR), which should continue to drive a higher valuation and unlock value for IMMP shareholders, in our view.

Details

The P2 study (TACTI-002) will enroll up to n=120 in 15 centers across the US, EU and Australia. It will evaluate the safety and efficacy of the combination of efiti with Merck's Keytruda (pembrolizumab) in patients with non-small cell lung carcinoma or head and neck (H&N) carcinoma. It will be a Simon two-stage, non-comparative, open-label, single-arm, multicenter clinical study. Patients will receive the combination therapy of efiti at the 30mg dose + Keytruda from day 1 of cycle 1 of Keytruda. **See prior notes for review of the P2b study in breast cancer and P1 study in melanoma.**

MP321, efitlagimod—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 patient-derived xenograft (PD-X) of naïve or refractory patients is expected to start in 2H18. 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.

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DISCLOSURES

Immutep Limited Rating History as of 07/30/2018

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution		As of: 07/30/18	
		% 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.	82%	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.	16%	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

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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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ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST



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