Biotechnology

IMMP - NASDAQ November 19, 2020

Closing Price 11/18/20	**$2.02**
Rating:	Buy
12-Month Target Price:	$4.00
52-Week Range:	$0.53 - $3.10
Market Cap (M):	99.6
Shares O/S (M):	49.3
Float:	NA
Avg. Daily Volume (000):	298.3
Debt (M):	$6.2
Dividend:	$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	June

Total Expenses ('000)

	2020A	2021E	2022E
H1	9,572	8,713	9,148
H2	7,715	9,439	9,911
FY	17,287	18,151	19,059

The company is domiciled in Australia and reports in A$. All financial data is converted into USD, unless noted.

Jason McCarthy, Ph.D.
(212) 895-3556
jmccarthy@maximgrp.com

Immutep Limited

Buy

Collaboration with Merck Expands in 1L Lung Cancer, Expanding to 1L Head & Neck, Equity Financing Complete

Summary

- **After a busy SITC (Society for Immunotherapy of Cancer) last week for Immutep, the company is continuing to build momentum behind its eftilagimod ("efti", soluble LAG3) platform. The company announced that with its collaborator Merck (MRK - NR), the TACTI-002 trial arm targeting 1L non-small cell lung cancer (NSCLC) is expanding to 74 more patients. Important in our view to note is that this program has KEYNOTE designation, "KEYNOTE-798", which in part separates it in the crowded oncology race to find the next combination with a checkpoint.**
- **In addition, the company is also building upon its success thus far with efti + Keytruda in 2L head & neck cancer (TACTI-002/KEYNOTE-798 arm C) with the announcement of plans to start a separate phase 2 trial in 1L disease. Keytruda already has an approval (on 6/11/19) for 1L as monotherapy in PD-L1 high expressors and in combo with chemotherapy regardless of PD-L1 status (metastatic or unresectable).**
- **We discuss both the 1L lung expansion and the rationale behind going for 1L in head & neck cancer.**
- **Another important takeaway, in our view, is that as data continues to emerge and trials expand for LAG3, this checkpoint continues to be out in front as the next potential blockbuster after the PD1/PD-L1s. Immutep is second to only Bristol (BMY - NR) in terms of number of LAG3 trials (internal and partnered), now with 10 active trials, with more coming. Bristol has 30+. Immutep also has key partners in the IO space including Merck, Merck KGaA (MKKGY - NR), Pfizer (PFE - NR), Novaritis (NVS - NR) and GalxoSmithKline (GSK - NR).**

Details

Financing update. Immutep completed an equity financing (announced concurrently on 11/18 with the efti news) issuing 123.2M shares for A$0.24 per share, an 11.2% discount to the VWAP over the prior 30 days. Immutep raised gross proceeds of A$29.6M, or $21.6M USD. Combined with existing cash, the company should now have ~$38M USD in cash on the balance sheet, providing sufficient runway well into CY22.

The expansion of the efti + Keytruda activity is based on what's been happening in the TACTI-002 trial, which is also designated KEYNOTE-798 (Trial NCT03625323, LINK). TACTI-002 is evaluating the combination in three parts; Part A in 1L NSCLC, Part B in 2L NSCLC and Part C in HNSCC. Let's look at Part A first:

Lung cancer, Efti + Keytruda. The 1L NSCLC data presented at SITC, which continued to build up prior updates in 2020, demonstrated an overall response rate (ORR) of 39.4% and disease control rate (DCR) of 66.7%. This was based on 36 evaluable patients for that update. In addition to the ITT (intent-to-treat) population data, the data in two subgroups further highlights the synergies between efti and Keytruda. In 25 patients with >1% PD-L1, the ORR is 44% vs. 27% that was shown for Keytruda monotherapy previously. In 16 patients with <50% PD-L1 (% cells expressing PD-L1) the ORR was 31.6% for the combo vs. <20% for Keytruda monotherapy. The comparisons are based on observations in KEYNOTE-042 and KEYNOTE-024.

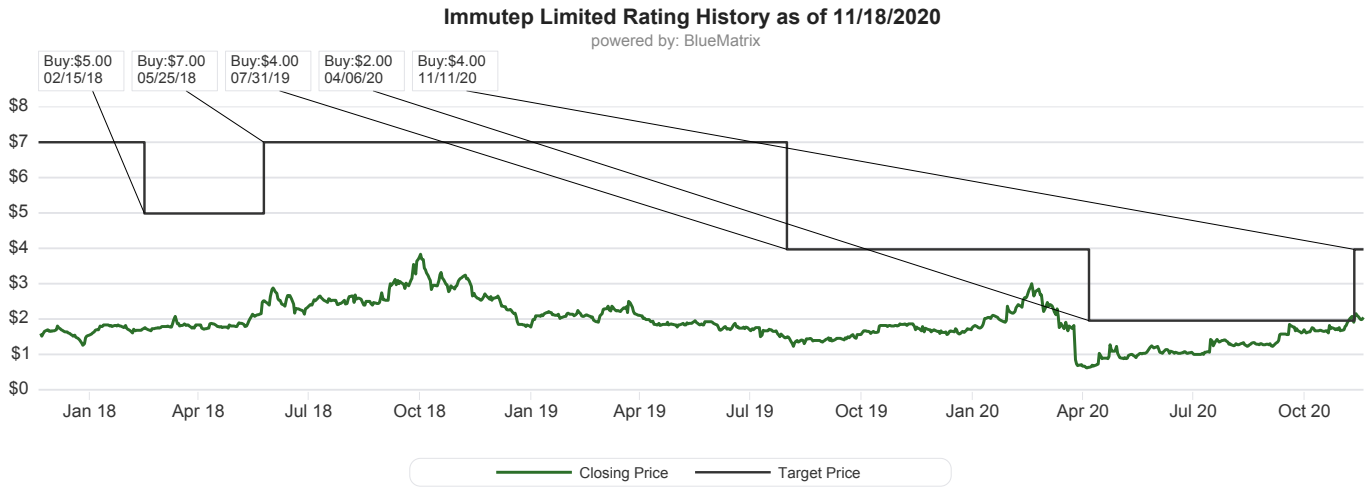
What does this mean? It suggests that the efti + Keytruda combination seems to have a therapeutic signal in low PD-L1 disease where checkpoint therapy has been less efficacious. The N-values are relatively small but encouraging, so much so that Merck and Immutep are expanding the 1L NSCLC Part A to bring in an additional 74 patients (announced 11/18). We would also point out as we have in a prior note for the SITC update, that the miss in breast cancer for efti + chemo has masked

the positive news flowing out of the TACTI-002 trial (the breast cancer miss was in March). Note that this is essentially a checkpoint combination study; efti (LAG3 soluble) + Keytruda (PD1). Bristol (BMY - NR) gained an approval in 1L NSCLC for its Opdivo (PD1) + Yervoy (CTLA4) checkpoint combo in the US (EU prior to that) in May 2020 (based on the CheckMate-227 trial, PD-L1 1% or greater). In terms of the comparison to Immutep/Merck data for ORR, the Opdivo/Yervoy combo ORR was 36%.

As such, thus far, efti/Keytruda is at 44% ORR. More time, more data is the next step, which is why 74 patients are being added to extend the trial for efti + Keytruda. Bristol is also the most active group in LAG3 with 30+ trials, as LAG3 is viewed as the next potential blockbuster checkpoint, which in our view is why Merck is working with Immutep. Immutep's pipeline is based on its LAG3 candidates.

Head & Neck cancer, 2L data paves the way to 1L. Let's start by looking again at the TACTI-002 (KEYNOTE-798) data in 2L presented at SITC. In PART C of the study, patients with 2L HNSCC are being enrolled with the SITC update including a total of N=28 with 23 evaluable. Overall, the ORR was 35.7% and in the evaluable patients was 43.5%. The latter compares favorably to Keytruda in this setting at ~15% ORR based on observations in KEYNOTE-012 and KEYNOTE-040. While we await the next steps and updates for the 2L work, the combination of efti + Keytruda is moving into a new, separate phase 2 study in 1L HNSCC. Details for the new trial, to our knowledge, have not yet been disclosed, and we await updates. In the 1L setting, Keytruda was approved in June 2019 for both monotherapy in PD-L1 expressing disease and in combination with chemotherapy in metastatic or unresectable 1L disease regardless of PD-L1 status. Keytruda was the first checkpoint into the HNSCC space and subsequently moved into 1L. The Bristol Opdivo/Yervoy combo in HNSCC was not as successful over Opdivo alone in 2L, where Opdivo already has an approval. Overall though, Keytruda has emerged as the dominant checkpoint in HNSCC and with efti, could be looking to expand its footprint. Phase 2 for Immutep in 1L HNSCC is next, likely starting in 2021.

DISCLOSURES



Maxim Group LLC Ratings Distribution			As of: 11/18/20
		% 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.	**81%**	**52%**
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.	**19%**	**50%**
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.

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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 IMP701 and IMP731 with commercialization in 2025, as well as IMP321 (royalty-free) in 2025 for 1L and 2L NSCLC, as well as 2L HNSCC. 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) foreign exchange fluctuations as the company reports in A$; (7) 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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ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

Corporate Headquarters

The Chrysler Building
405 Lexington Ave., 2nd FL
New York, NY 10174
Tel: 212-895-3500

Capital Markets/Syndicate: 212-895-3695
Corporate Finance: 212-895-3811
Corporate Services: 212-895-3631
Equity/Options Trading: 212-895-3790
Equity Research: 212-895-3736
Fixed Income Trading: 212-895-3875
Global Equity Trading: 212-895-3623
Institutional Sales: 212-895-3873
Institutional Sales Trading: 212-895-3873
Portfolio/Transition Trading: 212-895-3567
Prime Brokerage: 212-895-3723
Wealth Management: 212-895-3624

Woodbury, Long Island

20 Crossways Park Drive North
Suite 304
Woodbury, NY 11797
Tel: 516-393-8300

Red Bank, New Jersey

246 Maple Avenue
Red Bank, NJ 07701
Tel: 732-784-1900

West Palm Beach, Florida

105 South Narcissus Avenue
Suite 222
West Palm Beach, FL 33401
Tel: 561-508-4433

San Rafael, California

4040 Civic Center Drive
Suite 200
San Rafael, CA 94903
Tel: 212-895-3670

Aventura, Florida

20801 Biscayne Blvd
Suite 432 / 433
Aventura, FL 33180
Tel: 516-396-3120

Stamford, Connecticut

700 Canal Street
Stamford, CT 06902