Biotechnology

IMMP - NASDAQ September 20, 2021

Intraday Price 9/20/21	**$3.65**
Rating:	Buy
12-Month Target Price:	$8.00
52-Week Range:	$1.53 - $7.95
Market Cap (M):	278.1
Shares O/S (M):	76.2
Float:	NA
Avg. Daily Volume (000):	341.5
Debt (M):	$6.2
Dividend:	$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	June

Total Expenses ('000)

	2021A	2022E	2023E
H1	9,707	9,399	9,948A
H2	7,462	9,799	10,777
FY	17,169	19,198	20,726

Immutep is listed on the ASX (IMM) and with ADR's traded on NASDAQ (IMMP). 1 ADR= 10 shares of common stock.

Naureen Quibria, Ph.D.
(212) 895-3620
nquibria@maximgrp.com

Immutep Limited

Buy

The Case for LAG-3 is Building

Summary

- **Could a LAG-3 be the next approved checkpoint? This morning, Bristol-Myers Squibb (BMY - NR) announced that the FDA had accepted Bristol's Biologics License Application (BLA) for LAG-3 (relatlimab) / PD-1 (nivolumab) combination as treatment for patients with metastatic melanoma for Priority Review. PDUFA is March 19, 2022.**
- **This follows shortly after an update on the Phase 2/3 RELATIVITY-047 study at this year's ESMO Congress (being held from Sept. 16-21), where prolonged benefit was reported with relatlimab/nivo combination vs. nivo monotherapy (see details below).**
- **Recall, LAG-3 as a checkpoint has generated significant interest since Bristol's initial RELATIVITY data release on March 25, 2021.**
- **What about Immutep's eftilagimod ('efti')? Immutep currently has the most LAG-3 products (four in total) and is the only company exploring the utility of LAG-3, both in immune-oncology and in autoimmune disease. The lead asset, efti, has a differentiated mechanism of action, as a soluble LAG-3 fusion protein that acts as an antigen-presenting cell (APC) activator (vs. a direct inhibitor). To date, efti has demonstrated activity and a good safety profile in multiple trials (such as TACTI-002 currently underway in combination with Merck's {MRK - NR} Keytruda).**
- **Conclusion. Bristol's LAG-3 is set for regulatory review, ahead of the checkpoint TIGIT, which may come as a surprise to some. While Bristol's relatlimab may be the first-to-market, there is room for multiple LAG-3 players (just like PD-1/PD-L1s), in our view.**

Details

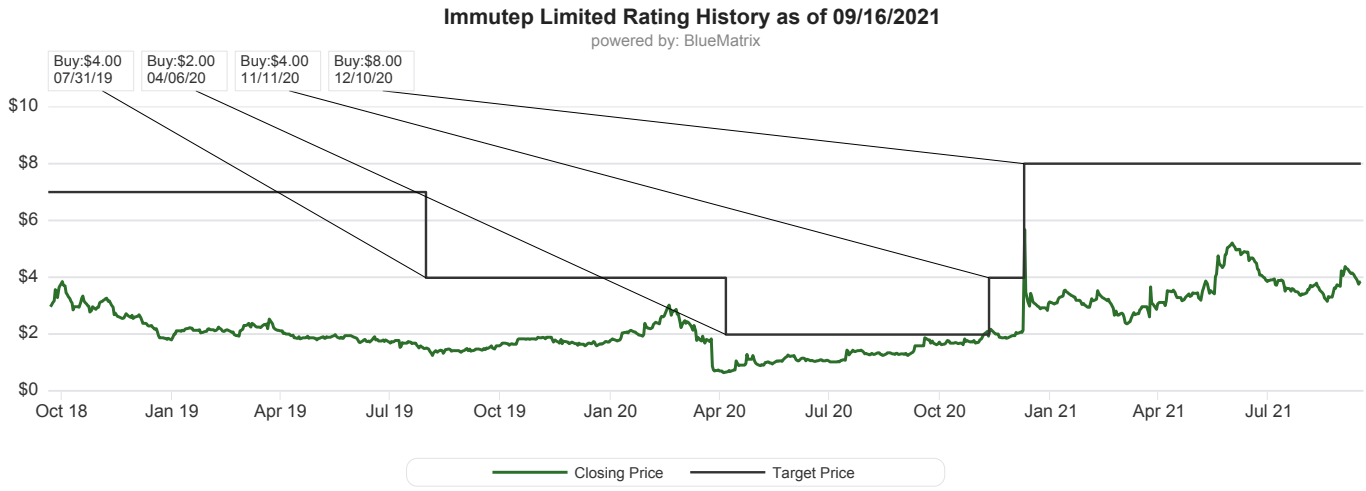
RELATIVY-047 study is a positive readthrough for efti. The Phase 2/3 RELATIVITY study (N=714) is evaluating fixed dose relatlimab (anti-lag 3) in combination with anti-PD-1 antibody, nivolumab (nivo), in 1L metastatic or unresectable melanoma patients. The trial design is also stratified by both PD-L1 and LAG-3 expression. Data from the RELATIVITY study reported at the 2021 ASCO Annual Meeting reported significant PFS (progression-free benefit) benefit seen with the combination of relatlimab + nivo (n=355) over nivo monotherapy (n=359): 10.12 months vs. 4.63 months. (HR=0.75). There were also no significant safety signals (SAEs Grade 3/4 of 18.9% observed with combo vs. 9.7% with monotherapy). On efficacy, 1-year PFS of relatlimab/nivo (47.7%) was numerically lower to cross trial to CheckMate-067 comparison of nivo/ipi (50%). On safety, the combo demonstrated a significantly better safety profile cross trial (18.9% vs. 59%, respectively). At this year's ESMO Congress (Sept. 16-21), Bristol reported additional efficacy results. Prolonged benefit was observed with combination treatment vs. single agent nivo. The combination led to a longer treatment-free interval (TFI), as well as a reduction in risk of progression or death following the next line of therapy. Specifically, patients that received the doublet and discontinued the treatment (n = 167) experienced a longer TFI vs. single-agent nivolumab (n = 151): median TFI of 3.22 (range, 0.1-30.4) vs. 1.41 (range, 0.1-25.6), respectively. Relatlimab plus nivolumab also reduced the risk of progression following the next line of systemic therapy (PFS2). The median PFS2 in the doublet arm had not yet been reached while the single therapy arm was 20.04 months. While we await overall survival (OS) data, we believe the positive combination broadly validates LAG-3 as a checkpoint target and continues to build the case for LAG-3 and for Immutep's eftilagimod. With a PDUFA data of March 19, 2022, LAG-3 appears to be on the road to becoming the third approved checkpoint.

Near-term catalysts for Immutep. While multiple operational updates are expected (such as trial initiations and recruitment updates), we are watching for data readouts on:

1. AIPAC final overall survival (OS) data – multicenter, placebo-controlled, randomized trial (N=227) of efti in combination with chemotherapy in HER2-/HR+ metastatic breast cancer patients; final OS data is expected in 2H21.
2. TACTI-002 (KEYNOTE-798) – the ongoing Phase 2 study is evaluating efti with pembrolizumab in 1L non-small cell lung cancer (NSCLC), 2L in NSCLC in PDX-refractory patients, and 2L head and neck squamous cell carcinoma (HNSCC); potential update in 2H21.

Company overview: *Immutep is a clinical-stage biotechnology company that is focused on developing LAG-3 both as an immune stimulator and an immune suppressor, for cancer and for autoimmune diseases, respectively. The company's lead product candidate is eftilagimod alpha (efti), a soluble LAG-3 fusion protein, that is being evaluated in combination with chemotherapy or immune therapy for multiple advanced cancers. The company also has licensing deals with large pharma for additional LAG-3 products: GSK'781 with GlaxoSmithKline (GSK - NR) and LAG525 with Novartis (NVS - NR).*

DISCLOSURES



Maxim Group LLC Ratings Distribution			As of: 09/19/21
		% 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.	**87%**	**53%**
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.	**13%**	**44%**
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*		

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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: We forecast sales for efti in metastatic breast cancer in 2025 (EU, US) and in 2027 (China), in non-small-cell lung cancer in 2025 (EU, US), and in head and neck in 2024 (EU, US). We assume royalty revenues for LAG525 in 2025 (EU, US) and for GSK'781 in 2027 (EU, US). We use a 30% discount rate and attribute equal weighting to our FCF, discounted EPS and SOTP to derive our 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 is domiciled in Australia; (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

New York City
300 Park Ave., 16th Floor
New York, NY 10022
Tel: 212-895-3500

Miami Beach
555 Washington Ave., Suite 320
Miami Beach, FL 33139
Tel: 786-864-0880

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

100 Crossways Park Drive West
Suite 207
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: 561-465-2605

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