

### Biotechnology

**IMMP** - NASDAQ

March 25, 2021

Intraday Price 3/25/21	\$3.30
Rating:	Buy
12-Month Target Price:	\$8.00
52-Week Range:	\$0.53 - \$7.95
Market Cap (M):	162.6
Shares O/S (M):	49.3
Float:	NA
Avg. Daily Volume (000):	857.8
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	9,707A	9,650
H2	7,715	9,439	10,454
FY	17,287	19,146	20,104



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

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## Immutep Limited

Buy

### Bristol Brings LAG-3 to the Forefront in Checkpoints with First Positive P3 Trial; Bodes Well for Efti and LAG-3 Pipeline

#### Summary

- We note that this morning Bristol (BMY - NR) announced positive P3 data from the ongoing study of anti-LAG-3 candidate relatlimab + Opdivo vs. Opdivo alone in unresectable or untreated metastatic melanoma. This is the first P3 dataset in the LAG-3 space, which bodes well for Immutep and the LAG-3 space, in our view, which is developing a pipeline of LAG-3 focused assets. IMMP shares are up ~25% on the news.
- The primary endpoint in the P3 RELATIVITY-047 for progression-free survival (PFS) was met, though no specific data numbers were given. Overall survival (OS) and longer-term followup are ongoing. In prior studies, shown below, the combination has shown added benefit on PFS and OS in this setting. Important to note, in our view, is also the safety profile, which is better than the nivo + ipi combo previously.
- For Immutep, this is further validation that leveraging the LAG-3 axis could emerge as the next step in the immune checkpoint space as it continues to look beyond CTLA4 and PD1/PDL1, as well as how to leverage combinations to enhance or resensitize patients to these therapies. We have recently seen ipi have an impact on ipi-naive but PD1-failed late stage melanoma, basically ending the case of TLR9s, but widening the door for other approaches like IL-12 (OncoSec, ONCS - Buy) and TIL cell therapy (Iovance, IOVA - NR). LAG-3, for which Bristol has over 30 trials, and Immutep being partnered with Novartis (NVS - NR), GlaxoSmithKline (GSK - NR) and Merck (MRK - NR), with today's LAG-3 phase 3 data, must move into the mainstream conversation of what comes next in immune oncology.

#### Details

**LAG-3 in immune oncology space.** LAG-3 continues to emerge as the next potential checkpoint modulator along side the PD1/PDL1s and CTLA4. With the majority of patients in general, including melanoma, having poor responses or eventually failing PD1/PDL1 response, combinations will be key to drive the space forward. LAG-3 increased expression of LAG-3, like PD1, may lead to inadequate immune responses. It has also been shown that LAG-3 expressing is increased in patients that have been previously exposed to anti-PD1 therapy. As such, targeting LAG-3 in the setting with and/or without a PD1 may expand the patient population that is responsive to the checkpoint therapy. As such, Bristol has 'quietly' emerged as the LAG-3 leader from a number of trials perspective, with over 30 LAG-3 focused trials, of course including the RELATIVITY-047 P3 trial announced on 3/25. This is the first P3 to have a positive readout of a LAG-3.

**Prior relatlimab data.** This study, which is described below, initiated in 2018 following positive data in the P1/2 study presented at ASCO 2017. These data were in immune-oncology experienced melanoma patients, more specifically as an expansion cohort that required patients to have progressed on 1-3 prior therapies, one of which having to be a PD1 or PD-L1. Other immune therapy's exposure was excluded. Fifty five patients were enrolled; in their prior exposure to PD1 or PD-L1 the response rates were complete response (CR) of 22% (12/55), partial response (PR) of 29% (16/55), and stable disease (SD) of 40% (22/55). Of the 55, 48 were evaluable for relatlimab + opdivo; LAG-3 + PD1. In these patients 13% PRs (6/48) and 42% SDs (20/48) were observed. These data were further stratified by LAG-3 expression; >1% LAG3, N=25; there was 20% PRs and 64% disease control rate (DCR); in <1% LAG-3, N=14, the PR was only 7% and DCR was only 36%. PD-L1 expression levels did not appear to have a role. Bottom line is the response rate or stable disease, or overall disease control rate, improved beyond PD1 or PD-L1 use,

setting the stage for the P2/3 RELATIVITY-047 trial for relatlimab + opdivo, shown next.

**Phase 2/3 RELATIVITY-047 trial meets primary endpoint.** The Phase 2/3 study is evaluating the efficacy of Bristol Myers Squibb's (BMY - NR) anti-LAG-3 Ab relatlimab in combination with Opdivo in patients with untreated metastatic or unresectable melanoma. Primary endpoint is PFS, with OS and objective response rate (ORR) as secondary endpoints. N=714 were randomized 1:1 to either the combination treatment arm or the single-agent treatment arm. Patients in the combo arm received 160mg of relatlimab and 480mg of Opdivo. Patients in the single-agent arm received 480mg of Opdivo alone. Patients were administered therapy every four weeks until disease recurrence, consent withdrawal, or the occurrence of toxicity. The company announced that the trial met its progression-free survival (PFS) primary endpoint though no specific data was presented. The follow-up for OS, one of the trial's secondary endpoint, is ongoing. While we await the PFS numbers and survival data, we can look at the activity of Opdivo in similar/other settings in melanoma.

**Checkmate 066:** Phase 3, 1L setting, Stage 3 or 4 melanoma., untreated, evaluating nivo + decarbazine vs. decarbazine, N=418. At one year OS 73% vs. 42%, median ORR not reached vs. 6-months, progressive disease 47% vs. 85%;

**Checkmate 037:** Phase 3, ipilimumab (ipi) refractory, open label, nivo + chemo, N=631 unresectable stage 3 or metastatic melanoma patients having progressed on ipi. OR was 31.7% vs. 10.6% CR and PR of 3% and 28% vs. 0% and 11%. Median duration of response not reached vs. 3.5 months;

**Checkmate 067:** Phase 3, N=945 with unresectable stage 3 or metastatic melanoma, evaluating nivo, nivo (maintenance) + ipi, ipi + nivo (maintenance). The groups are basically combo treatment with nivo maintenance, nivo monotherapy and ipi monotherapy. Endpoints were PFS and OS, similar to what is happening in the RELATIVITY-047 study (above). The median PFS and ORR was 11.5, 6.9 and 2.9 months, respectively, and 57.6, 43.7 and 19%, respectively. There were issues with AEs in the combo arm. Note in the LAG-3/nivo study, the safety is far better; this is critical in our view. Next we await the actual PFS number and OS data for RELATIVITY-047.

**What does this mean for LAG-3 and Immutep?** The data reported by Bristol represents the first Phase 3 data-set on an anti-LAG-3 antibody (Ab), positioning anti-LAG Abs to be added to the ICI armamentarium that currently comprises anti-PD-1/PD-L1 and anti-CTLA-4 antibodies. We view the positive data regarding relatlimab as further validation of Immutep's LAG-3 platform.

Immutep's lead asset, elftilagimod alpha (efti), focuses on stimulating CD8+ T-cells via the activation of antigen-presenting cells (APCs), as opposed to targeting LAG-3 to mitigate immune silencing (similar to anti-PD-1/PD-L1 and anti-CTLA-4 ICIs). Efti is a soluble dimeric recombinant form of LAG-3Ig, a fusion protein used to increase the immune response to tumors by stimulating dendritic cells through high affinity binding to MHC class II molecules on the dendritic cell surface. LAG-3 is one of two proteins shown to be able to properly condition dendritic cells (and monocytes) to undergo maturation and step-up the stimulation of antigen targeting T-cells (the other is CD40 ligand).

The company has other LAG-3 focused assets in its pipeline. IMP731 (Glaxo, GSK - NR) is a cytotoxic anti-LAG-3 antibody that is being developed for the treatment of autoimmune diseases (partnered). In this case, LAG-3 is treated as a marker for T-cells, which IMP731 can home-in on and destroy. IMP701 (partnered, Novartis, NVS - -NR) is an anti-LAG-3 monoclonal antibody that targets inhibitory signaling pathway instigated by LAG-3. By targeting this pathway, IMP701 may enable CD8 T-cells to launch a more effective cytotoxic response against tumor cells.

While these partnerships are important to the Immutep story, the lead internal program(s) is with soluble LAG-3 protein, elftilagimod, or IMP321. This program has demonstrated positive data in metastatic breast cancer in combination with chemotherapy, and in a multi-armed trial in combination with Keytruda as part of the company's ongoing collaboration with Merck (MRK - NR), targeting 1L lung cancer and both 1L and 2L head & neck cancer. Please refer to our prior notes for these programs, each of which has reported positive updated data over 4Q20 and 1Q21; [LINK1](#), [LINK2](#), [LINK3](#).

DISCLOSURES

Immutep Limited Rating History as of 03/23/2021

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Maxim Group LLC Ratings Distribution		As of: 03/24/21	
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
<b>Buy</b>	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	83%	54%
<b>Hold</b>	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.	17%	50%
<b>Sell</b>	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 IMP701 and IMP731 with commercialization in 2025, eftilagomod (efti) (royalty-free) in 2024 for 1L and 2L NSCLC, as well as 2L HNSCC, and metastatic breast cancer (1L + chemo) in 2025. 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 is domiciled in Australia; (7) High volatility of the company's stock price.

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## RISK RATINGS

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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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