

### Biotechnology

**IMMP - NASDAQ**

June 4, 2018

<b>Intraday Price 06/4/2018</b>	<b>\$2.71</b>
Rating:	Buy
12-Month Target Price:	\$7.00
52-Week Range:	\$1.25 - \$3.06
Market Cap (M):	82
Shares O/S (M):	30.3
Float:	100.0%
Avg. Daily Volume (000):	68
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**

### Partner Novartis Presents Early Efficacy Signal Data for LAG525 + PD1

#### Summary

- At ASCO, Immutep's partner Novartis (NVS - NR) presented the first data set for Immutep's LAG525 monotherapy and in combination with Novartis' PD1 checkpoint Spartalizumab ("Sparta"). Overall safety is positive and there are early signals of efficacy in very difficult to treat patients with advanced or metastatic cancers, including triple negative breast cancer (TNBC) and mesothelioma (meso). The Novartis Poster is summarized on pages 4-10.
- Observations from this study:
  - Patient populations (Exhibit 11), N>200, heavily pretreated late stage patients, multiple cancer types and progressive disease despite SOC, intolerant to SOC or no available options. 56% failed 3+ lines of chemo.
  - Dose Escalation (Exhibit 10) - Varying doses for LAG525 and LAG525 + Sparta.
  - Safety is positive - MTD not reached, well-tolerated across a range of doses and cohorts.
  - Efficacy - A signal was observed in TNBC and mesothelioma patients with 2/5 and 3/8 demonstrating durable responses (some over 500 days) (Exhibits 14 & 15) Also see the image of TNBC patient, resolution of metastases (Exhibit 16).
  - Next step - Positive data, Novartis is advancing the combination in P2 targeting multiple tumor types (figure 2).
- Key Takeaways: This is a dose escalation, exploratory study, in heavily pretreated patients with progressing disease. As such prognosis is poor. The important takeaway for us is the combo was well-tolerated and there are signals of efficacy, particularly in TNBC and meso. Novartis is moving the program to the next stages of development (P2 design presented at ASCO too), a positive in our view for Immutep as we are now seeing the partnered LAG-3 begin to emerge as Immutep advances its own in-house pipeline with IMP321.

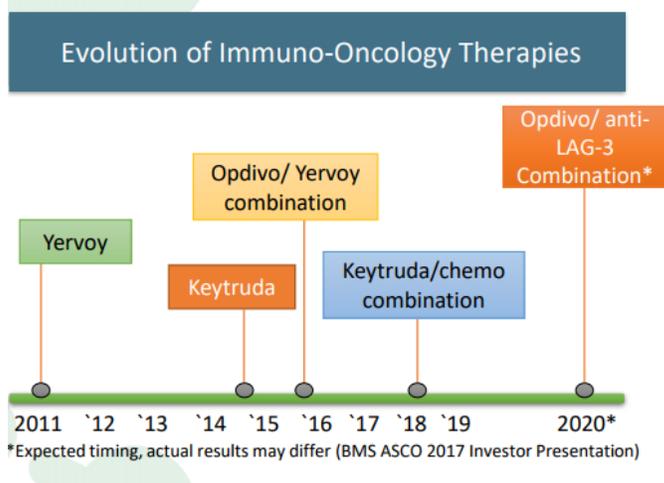
#### Details

**IMP321, efitagimod - 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. Efti induces monocyte levels well above the 19% threshold, >30% by 6 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 3 cycles and then evaluated for any response, thus any response after efiti is added suggests a therapeutic signal. A second program, a basket study (TACT-002 in lung cancer, H&N cancer) evaluating the combination in PD-X naïve or refractory patients is expected to start in 4Q18. 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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**LAG-3, the next checkpoint.** Immunotherapy continues to become widely adopted across multiple cancer types from checkpoints like PD-1, PD-L1 and CTLA4 to CAR-T therapies. The immune oncology space is expected to generate over \$34B by 2024, with checkpoints accounting for the majority of sales. Targeting checkpoints to “take the brakes off” of anti-cancer immune cells and mitigate immunosuppressive properties of the tumor microenvironment is a fundamental focus of the immune oncology space and novel combinations of immune therapeutic agents are likely to continue to integrate into the treatment paradigm. While much of the focus, particularly for checkpoints has been PD1, PD-L1 and CTLA-4, the question is what checkpoint comes next and what is the effect of targeting multiple checkpoints at once (see Nature paper review of checkpoints by Drew Pardoll – [LINK](#)) In our view, LAG-3 or Lymphocyte-activation gene-3, could be the next checkpoint to emerge. Leading that effort is Bristol-Myers Squibb with a LAG-3 checkpoint (relatlimab) in 9 trials across multiple cancer types, including combination therapy with the company’s PD1 checkpoint Opdivo. Bristol, as outlined in the company’s presentation in January 2018 (see exhibit 4) has prioritized rilatlimab (LAG-3) for full development. However, Immutep, which has a portfolio of LAG-3 products, has partnerships with Novartis (oncology) and GSK (autoimmune diseases). Immutep is a LAG-3 pure play company with four LAG-3 candidates, three of which are in six ongoing clinical trials and more data is expected to emerge over 2018 and 2019, including from trials with partners Novartis and GSK. As was the case for the PD1 and PD-L1s, there is likely to be room for multiple players in the LAG-3 space.

**Exhibit 1. Immune Oncology Landscape:** CTLA-4, PD1 and PD-L1 are approved for multiple indications and PD-1 blockade has become a therapeutic backbone. However, only 15-40% of patients respond (depending on cancer type and other underlying factors) to monotherapy, and combinations of Opdivo and Yervoy have demonstrated toxicities. As such new combinations with efficacy and a better safety profile like with LAG-3 are in development from Bristol as well as Immutep’s partner Novartis. Immutep is also developing a soluble LAG-3, IMP321 in combination with chemotherapy or PD1 checkpoints.



Source: Immutep Presentation

**Exhibit 2. LAG-3 Therapeutic Landscape.**

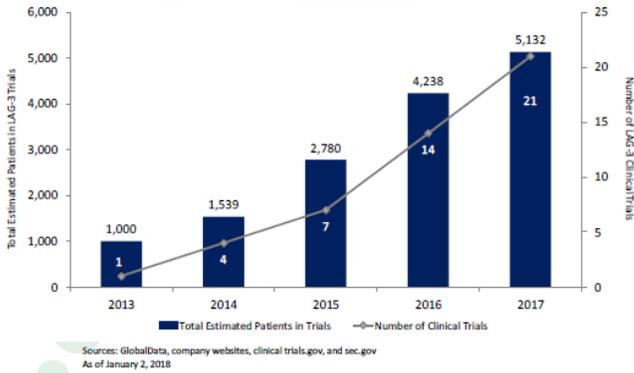
*Immutep is the leader in developing LAG-3 modulating therapeutics*

Program	Company	Preclinical	Phase I	Phase I/ II	Phase II	Phase IIb	Total Estimated Patients
Eftilagimod Alpha	Immutep <sup>(1)</sup>		●	●	●	●	244
LAG525	Novartis <sup>(1), (2)</sup>			●	●		675
Relatlimab	BMS		●	●	●	●	3,139
GSK2831781	GSK <sup>(2)</sup>		●				67
BI 754111	B.I.		●				75
MGD013	Macrogenics		●				131
MK4280	Merck & Co. Inc.		●				240
REGN3767	Regeneron/ Sanofi		●				283
TSR-033	Tesaro		●				260
Eftilagimod Alpha	RKF <sup>(3)</sup>		●				18
IMP761	Immutep	●					N/A
N/A	Agenus/ Incyte	●					N/A
N/A	F-star Bio/ Merck	●					N/A
N/A	Peregrine Pharma.	●					N/A
N/A	RXI Pharmaceuticals	●					N/A

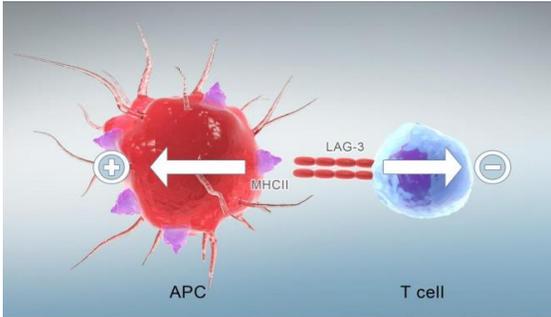
Notes:  
 (1) Includes AIPAC and TACTI-mel clinical trials  
 (2) Immutep partnered program  
 (3) As of January 2, 2018 one clinical trial had not opened enrollment  
 (4) INSIGHT investigator sponsored clinical trial  
 ● Indicates product candidate developed by Immutep research & development  
 Sources: GlobalData, company websites, clinical trials.gov, and sec.gov  
 As of January 2, 2018

Source: Immutep Presentation

**Exhibit 3. Increasing Number of Clinical Trials Targeting LAG-3.** Since 2013, the number of clinical trials targeting LAG-3 has grown from 1 to 21 in 2017. Immutep’s three assets, IMP321, IMP701 and IMP731 are in a combined six ongoing clinical trials.

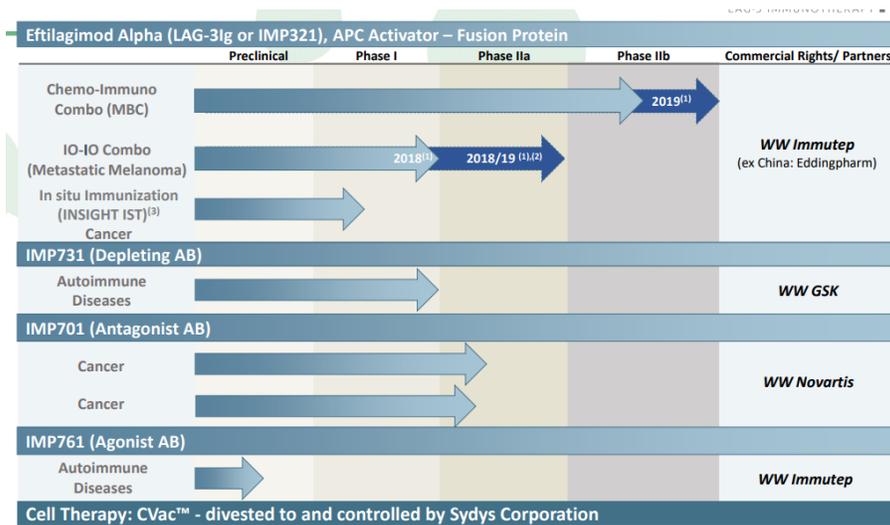


**Exhibit 4. LAG-3 as a Therapeutic Target.** LAG-3 is widely expressed on tumor infiltrating T cells (TILs) and cytotoxic T cells. As such it’s an ideal target for checkpoint blockade. Functionally, LAG-3 is similar to CTLA-4 (target of Yervoy) and PD-1 (Keytruda, Opdivo). Shown below: 1- Positive regulation of antigen presenting cells (APC) increases antigen presentation to cytotoxic CD8 T cells (tumor killing) and 2- Negative regulation by the tumor leads to a decrease in T cells.



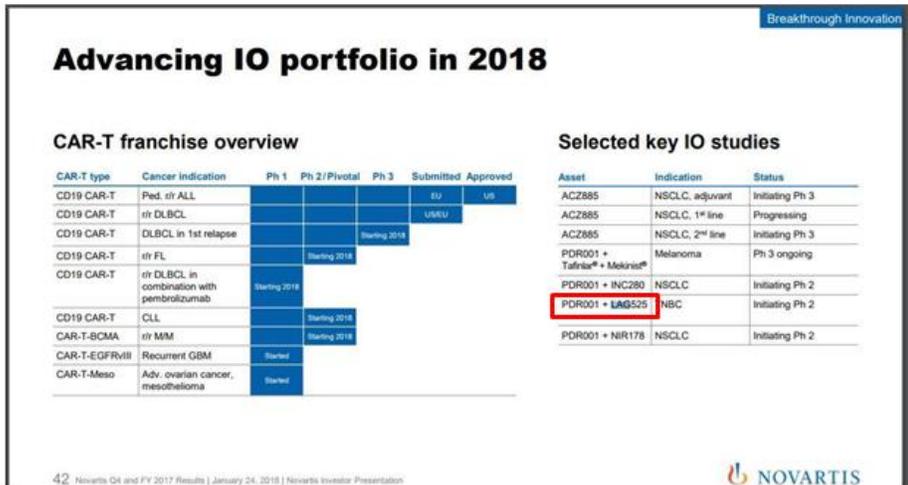
Source: Immutep Presentation

**Exhibit 5. Immutep Pipeline of LAG-3 Assets.**



Source: Immutep presentation

**Exhibit 6. Novartis (Immutep’s Partner) Continues to Advance Immutep’s LAG-3, IMP701.** Novartis is conducting a study in patients with advanced malignancies, evaluating Immutep’s LAG-3 checkpoint IMP701 (LAG525) alone or in combination with Novartis’ PD1 checkpoint PDR001 (data presented at ASCO 2018, see below). The trial, which started in 2015, recently expanded to add another 99 patients, now N=515. The study completion date is April 2019 ([TRIAL LINK](#)). Novartis initiated a new trial combining PDR001 with LAG525 in patients (N=160) with advanced hematological malignancies and solid tumors ([TRIAL LINK](#)).



Source: Modified (red box) from Novartis YE-2017 Presentation, January 24, 2018.

**ASCO 2018**

The following is from a presentation from partner Novartis’ (NVS - NR) combination trial with Immuteps LAG-3, “Phase I/II Study of LAG525 ± Spartalizumab (PDR001) in Patients With Advanced Malignancies.”<sup>1</sup>

**Exhibit 7. Scientific Rationale for LAG525 and Spartalizumab.**

**Scientific rationale**

LAG525 is a humanized immunoglobulin G4 (IgG4) monoclonal antibody (mAb) that binds LAG-3 with subnanomolar affinity in *in vitro* assays, inhibiting the LAG-3 interaction with MHC class II molecules.<sup>4</sup>

The humanized IgG4 anti-PD-1 mAb, spartalizumab (PDR001), binds PD-1 with subnanomolar affinity, blocking the interactions between the receptor and its ligands programmed death-ligand 1 (PD-L1) and programmed death-ligand 2 (PD-L2).<sup>5</sup>

In preclinical models, LAG-3/PD-1 co-blockade synergizes to enhance an antitumor response.<sup>6</sup>

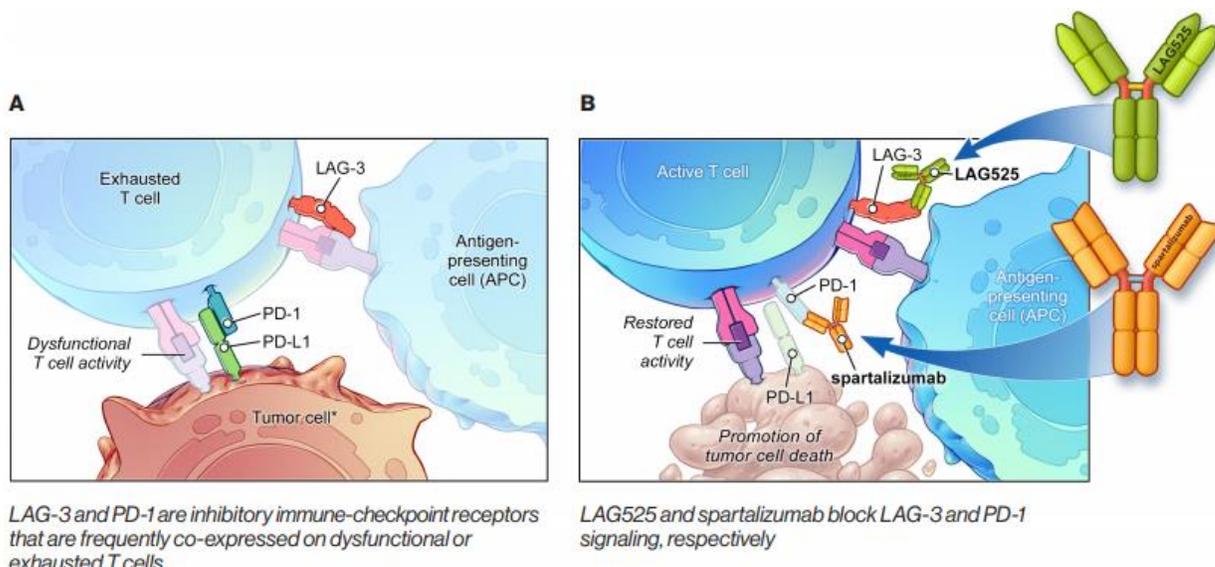
Blockade of LAG-3 and PD-1 may restore antitumor effector T-cell signaling, function, and proliferation.<sup>17</sup>

The clinical program for LAG525 explores whether LAG-3 blockade restores activity of antitumor effector cells with LAG525 monotherapy, and also enhances antitumor activity of PD-1 inhibition when administered in combination with spartalizumab.

Source: Novartis ASCO 2018 Presentation

**Exhibit 8. Mechanism of Action for LAG525 and Spartalizumab. (A)** LAG-3 is an immunoreceptor which is expressed on activated and regulatory T-cells, NK cells, and dendritic cells. It’s frequently co-expressed with programmed cell death protein 1 (PD-1) on Dysfunctional T-cells. LAG-3 downregulates T-cell signaling and function in effector T-cells while supporting the suppressive phenotype of regulatory T-cells. **(B)** Blockade of LAG-3 restores effector T-cell activity and diminishes the suppressive activity of regulatory T cells, this effect enhances the anti-tumor activity of PD-1 inhibition.

<sup>1</sup> Hong, David, et al. “Phase I/II Study of LAG525 ± Spartalizumab (PDR001) in Patients With Advanced Malignancies.” *Novartis, ASCO 2018*. 4 June 2018.



LAG-3, lymphocyte activation gene-3; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1.  
\*Or antigen-presenting cell.

Source: Novartis ASCO 2018 Presentation

**Exhibit 9. Phase I/II Trial Design.** The LAG525X2101C trial is an open-label phase I/II study of LAG525 monotherapy and in combination with spartalizumab (n=255). The Phase 1 portion of the study is a dose escalation trial with the primary endpoint of finding the recommended phase 2 dose of LAG525 and the combination of LAG525 and spartalizumab. The trial has secondary endpoints of safety/tolerability, preliminary antitumor activity (ORR, progression-free survival, duration of response, and disease control rate), and to assess the pharmacodynamics, emergence of anti-drug antibodies, and potential predictors of activity for the drug. The trial will enroll patients with advanced/metastatic solid tumors who have progressed despite standard therapy or are intolerant to standard therapy.



MTD, maximum tolerated dose; NSCLC, non-small cell lung cancer; RCC, renal cell carcinoma; RP2D, recommended Phase II dose; TNBC, triple-negative breast cancer.  
\*Dose expansion will no longer be conducted for single-agent LAG525.

Source: Novartis ASCO 2018 Presentation

**Exhibit 10. Dosing Schedule by Study Arm.** The following table shows the number of patients for each given dose of spartalizumab and LAG525. The therapies were administered via intravenous injection.

Study arm/schedule	Patients (n)	LAG525	Spartalizumab
LAG525 Q2W	17	1 mg/kg	-
	12	3 mg/kg	
	6	5 mg/kg	
	6	10 mg/kg	
	6	15 mg/kg	
	30	240 mg	
	30	400 mg	
LAG525 + spartalizumab Q2W	6	0.3 mg/kg	1 mg/kg
	6	1 mg/kg	80 mg
	6	80 mg	240 mg
	5	80 mg	240 mg
LAG525 + spartalizumab Q3W	20	240 mg	300 mg
	6	400 mg	
	12	600 mg	
LAG525 Q4W	5	3 mg/kg	-
	6	5 mg/kg	
	11	10 mg/kg	
	5	400 mg	
LAG525 + spartalizumab Q4W	7	80 mg	240 mg
	6	400 mg	400 mg
	12	800 mg	
	6	1000 mg	
LAG525 Q2W + spartalizumab Q4W	11	80 mg	400 mg
	6	240 mg	
	6	300 mg	

Q2W, every 2 weeks; Q3W, every 3 weeks; Q4W, every 4 weeks.

Source: Novartis ASCO 2018 Presentation

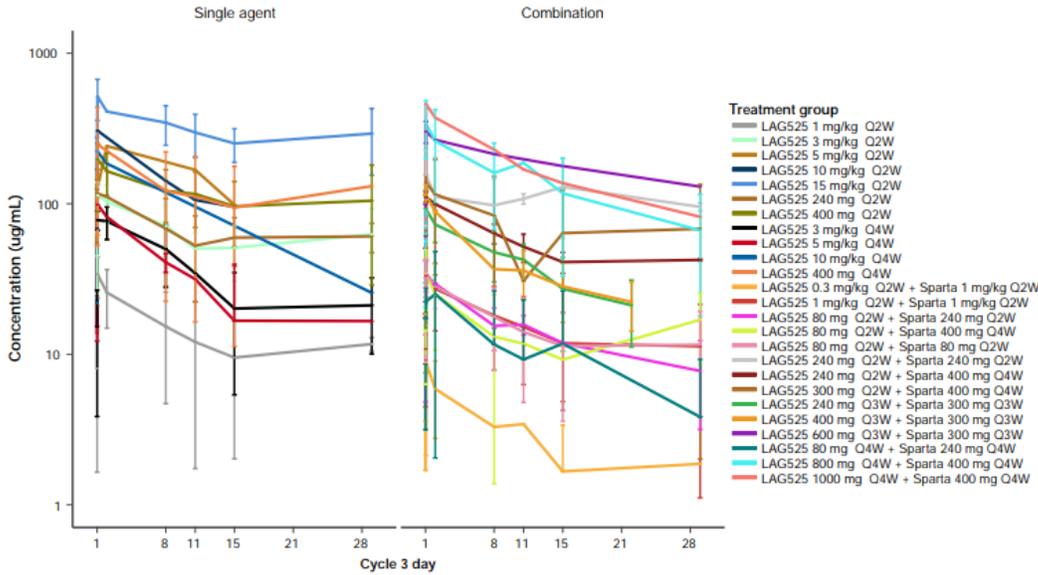
**Exhibit 11. Demographics of Patient Population.** The majority (56%) of patients in the trial had received 3 or more prior antineoplastic therapies.

	LAG525 (n=134)	LAG525 + spartalizumab (n=121)	All patients (n=255)
Median age, years (range)	59 (26–81)	58 (19–77)	58 (19–81)
<b>WHO/ECOG performance status, n (%)</b>			
0	51 (38.1)	45 (37.2)	96 (37.6)
1	78 (58.2)	72 (59.5)	150 (58.8)
Missing	5 (3.7)	4 (3.3)	9 (3.5)
<b>Prior antineoplastic medications, n (%)</b>			
Yes	132 (98.5)	116 (95.9)	248 (97.3)
No	1 (0.7)	5 (4.1)	6 (2.4)
Missing	1 (0.7)	0	1 (0.4)
<b>Number of regimens</b>			
1	17 (12.7)	17 (14.0)	34 (13.3)
2	34 (25.4)	36 (29.8)	70 (27.5)
≥3	81 (60.4)	63 (52.1)	144 (56.5)
<b>Type of advanced tumor at diagnosis</b>			
Hepatocellular carcinoma	7 (5.2)	0	7 (2.7)
Endometrial cancer	6 (4.5)	4 (3.3)	10 (3.9)
Renal cell carcinoma	7 (5.2)	3 (2.5)	10 (3.9)
Non-small cell lung cancer	19 (14.2)	8 (6.6)	27 (10.6)
Head and neck cancer	2 (1.5)	6 (5.0)	8 (3.1)
Breast cancer (HER2+ or ER/PR+)	5 (3.7)	3 (2.5)	8 (3.1)
Cutaneous melanoma	13 (9.7)	5 (4.1)	18 (7.1)
Colorectal cancer	12 (9.0)	7 (5.8)	19 (7.5)
Prostate cancer	5 (3.7)	1 (0.8)	6 (2.4)
TNBC	0	5 (4.1)	5 (2.0)
Mesothelioma	2 (1.5)	8 (6.6)	10 (3.9)
Other*	56 (41.8)	71 (58.7)	127 (49.8)

ECOG, Eastern Cooperative Oncology Group; ER, estrogen receptor; HER2+, human epidermal growth factor receptor 2-positive; PR+, progesterone receptor-positive; TNBC, triple-negative breast cancer; WHO, World Health Organization.  
\*Other includes: basal cell carcinoma, cervical cancer, cholangiocarcinoma, esophageal cancer, gastric cancer, gastrointestinal stromal tumor, liposarcoma, malignant neoplasm of thymus, nasopharyngeal cancer, non-cutaneous melanoma, sarcoma, small cell lung cancer, and uveal melanoma.

Source: Novartis ASCO 2018 Presentation

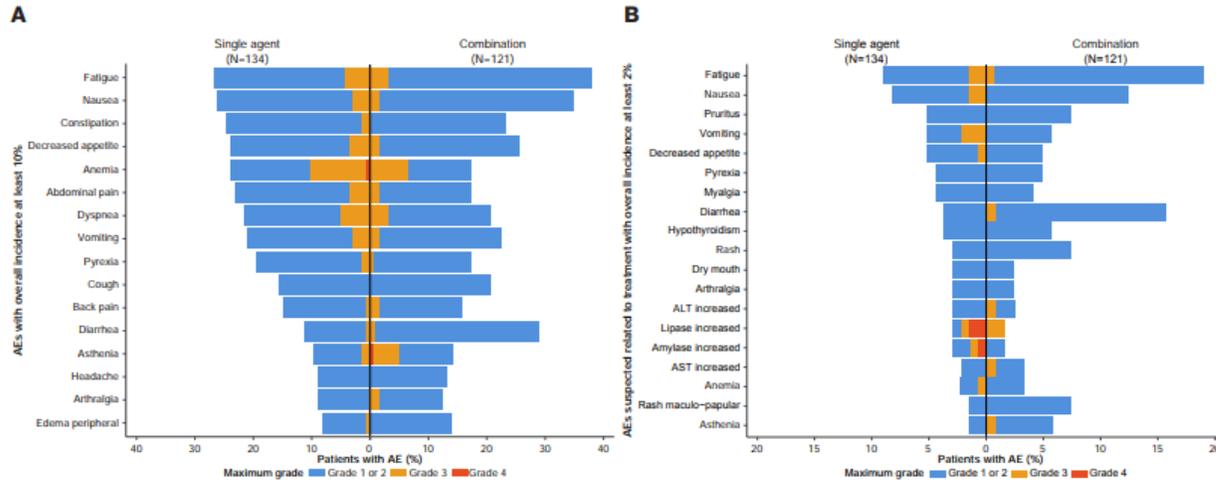
**Exhibit 12. Pharmacokinetic Properties of LAG525 and LAG525+spartalizumab.** The PK study found that the concentration levels achieved for LAG525 combination were similar to that for an equivalent dose of combination therapy. The estimated median half-life for the typical patient was 17 days.



Q2W, every 2 weeks; Q3W, every 3 weeks; Q4W, every 4 weeks; Sparta, spartalizumab. Negative lower limits of the error bar are set to mean.

Source: Novartis ASCO 2018 Presentation

**Exhibit 13. Safety and Tolerability as Measured By Adverse Events.** The Most common AEs suspected to be treatment related were fatigue (9%) and nausea (8%) for LAG525 alone and Fatigue (19%), diarrhea (16%), and nausea (12%) for the combination. Serious AEs occurred in 7 patients on LAG525 and 7 patients in the combination arm. MTD not reached, overall well tolerated.



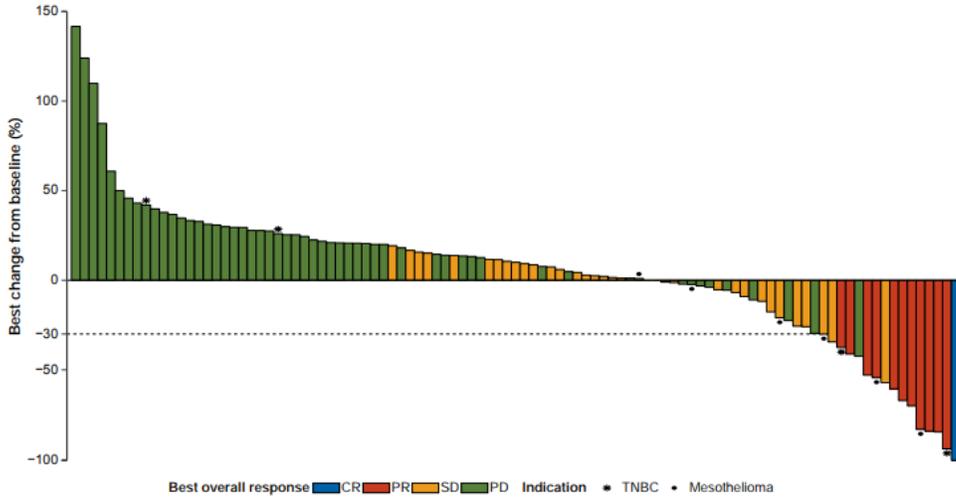
*AEs regardless of causality (overall incidence ≥10%)*

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase.

*Treatment-related AEs (overall incidence ≥2%)*

Source: Novartis ASCO 2018 Presentation

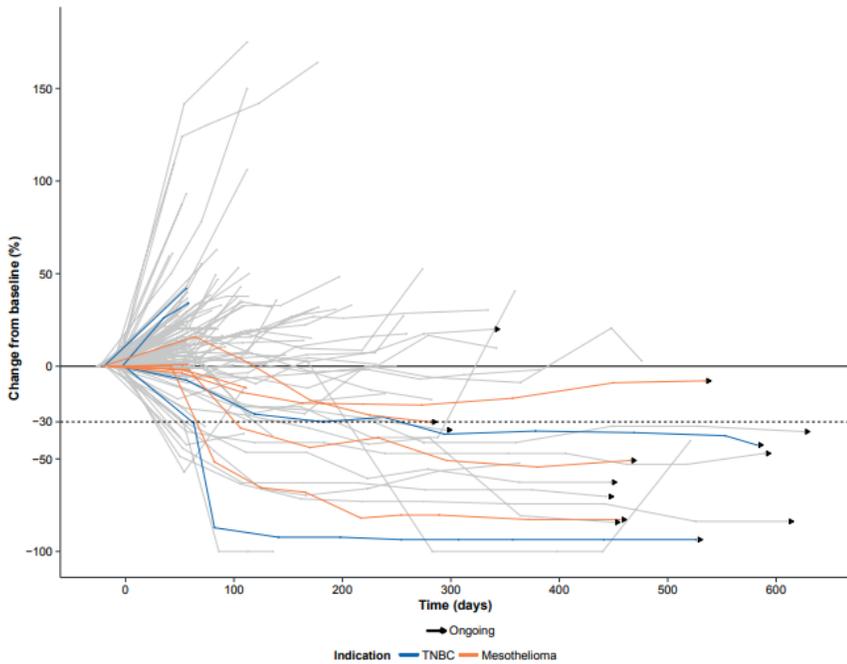
**Exhibit 14. Response to Therapy for Combination of LAG525 and Spartalizumab.** At the Jan 15 data cutoff, complete or partial response was measured in 12/121 evaluable patients (1 CR, 11PR). The CR was in a patient with Thymoma receiving LAG525 240 mg + spartalizumab 300 mg Q3W. PRs occurred in Mesothelioma (n=2), triple-negative breast cancer (n=2), nasopharyngeal carcinoma, adrenocortical carcinoma, cervical cancer, urothelial carcinoma, gastric cancer, prostate cancer, and unknown primary. Note that an additional PR was reported in mesothelioma after the cutoff date.



CR, complete response; PD, progressive disease; PR, partial response; SD, stable disease; TNBC, triple-negative breast cancer.  
 The additional PR reported in a patient with mesothelioma after the data cut-off is color coded as SD in this figure. N=101 evaluable; 20 patients (including 2 with mesothelioma and 1 with TNBC) were not evaluable due to postbaseline assessment not yet performed, discontinuation prior to first postbaseline assessment, or missing tumor measurements.

Source: Novartis ASCO 2018 Presentation

**Exhibit 15. Durability of Response for Combination Therapy, >500 Days in Several Patients.** The following chart reports the durability of response by measuring the size of tumors over the course of treatment. Durable responses were measured in 3/8 patients with mesothelioma and 2/5 patients with TNBC.



TNBC, triple-negative breast cancer.

Source: Novartis ASCO 2018 Presentation

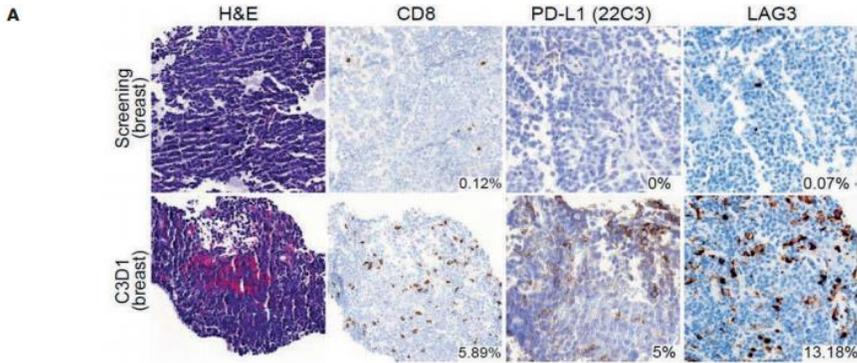
**Exhibit 16. Case Example: Resolution of TNBC Skin Metastases After Combination Therapy.** The following image is from a patient with TNBC skin metastases who had progressed following multiple chemotherapies. After receiving 8 cycles of treatment with LAG525 240mg + spartalizumab 300mg (Q3W dosing), the patient experienced substantial resolution of metastases.



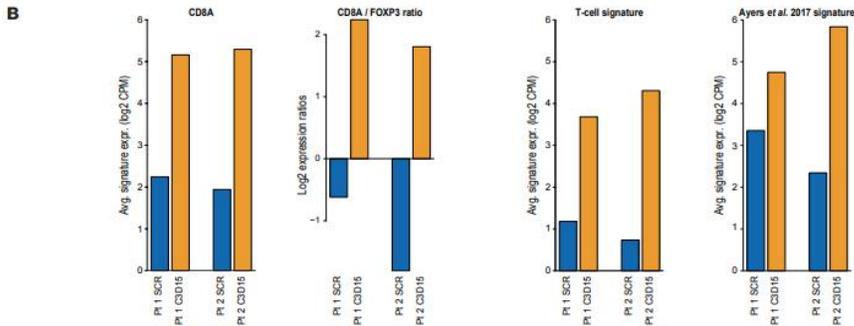
Images courtesy of Dr. Silvia Damin, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan. Pt. patient, Q3W every 3 weeks, TNBC, triple-negative breast cancer.

Source: Novartis ASCO 2018 Presentation

**Exhibit 17. Biomarker results from patients with TNBC Treated with Combination Therapy.** (A) Immunohistochemistry analysis of tumor samples demonstrates increased levels of CD8, PD-L1, and LAG-3 after 3 cycles of treatment. (B) RNA sequencing analysis demonstrated increased tumor expression of CD8, CD8/FOXP3 ratio, T-cell signature, and Ayers M et al. 2017 signature genes on treatment cycle 3 day 15 compared to baseline in two TNBC patients.



IHC (percent marker area) on tumor tissue from a patient with TNBC with PR, at baseline and at C3D1 (Pt 2, LAG525 240 mg + spartalizumab 240 mg, Q2W)



Quantification of RNAseq gene expression from the 2 patients with TNBC with PR: CD8A, CD8/FOXP3 ratio, T-cell signature, Ayers M et al. 2017 signature, at baseline (SCR) and at C3D15 of LAG525 + spartalizumab treatment

Avg, average; C, cycle; CD8, cluster of differentiation 8; CPM, counts per million; D, day; expr, expression; H&E, hematoxylin and eosin; IHC, immunohistochemistry; Lag-3, lymphocyte activation gene-3; PD-L1, programmed death-ligand 1; PR, partial response; Pt, patient; Q2W, every 2 weeks; RNAseq, RNA expression; SCR, screening; TNBC, triple-negative breast cancer.

Source: Novartis ASCO 2018 Presentation

**Exhibit 18. Conclusions.**

Treatment with LAG525 alone or in combination with spartalizumab was well tolerated across a broad range of doses and schedules. The most common study drug-related AEs were fatigue and nausea for LAG525 alone, and fatigue, diarrhea, and nausea for the combination. DLTs observed with LAG525 + spartalizumab occurred without dose dependency, and included immune-mediated AEs previously reported with other immune checkpoint inhibitors.

An MTD was not reached for either single-agent LAG525 or the combination of LAG525 + spartalizumab.

Preliminary antitumor activity was observed for LAG525 + spartalizumab, including one CR and 11 PRs per RECIST v1.1.

- Most responses are durable, ongoing  $\geq 1$  year, including in patients with metastatic TNBC and mesothelioma previously treated with chemotherapy.

Biomarker data from 2/5 responding patients with TNBC showed on-treatment immune activation of baseline immune-cold tumors.

- Metastatic TNBC response to anti-PD-(L)1 therapy has previously been associated with tumor-infiltrating lymphocytes, PD-L1 positivity, and treatment in the first-line.<sup>9-13</sup>
- Shrinkage of immune-cold tumors in this small number of previously treated patients with TNBC receiving LAG525 + spartalizumab suggests that dual checkpoint inhibition may be more effective than single-agent PD-1 inhibition.

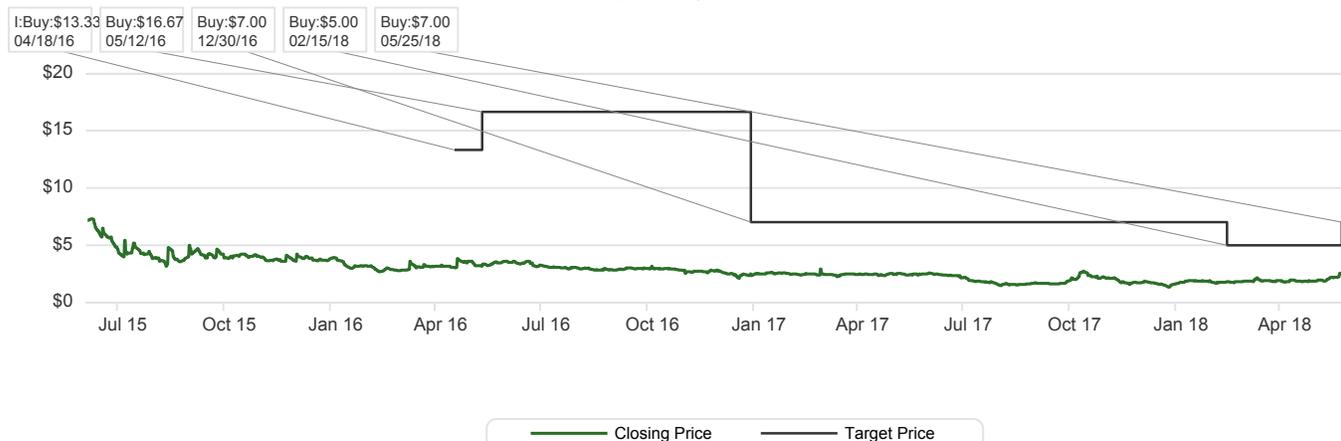
The Phase II portion of LAG525X2101C, investigating LAG525 in combination with spartalizumab, is ongoing in selected indications, including TNBC and mesothelioma.

Source: Novartis ASCO 2018 Presentation

DISCLOSURES

Immutep Limited Rating History as of 06/02/2018

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution		As of: 06/03/18	
		% 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.	79%	34%
<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.	18%	19%
<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.	2%	25%

\*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 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 Prima Biomed, 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 Prima Biomed 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.

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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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