

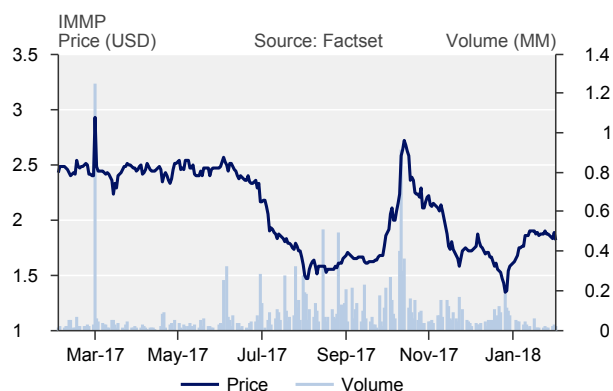
Biotechnology

IMMP - NASDAQ February 1, 2018

Intraday Price 02/1/2018	\$1.79
Rating:	Buy
12-Month Target Price:	\$7.00
52-Week Range:	\$1.25 - \$3.24
Market Cap (M):	43
Shares O/S (M):	24.0
Float:	0.0%
Avg. Daily Volume (000):	55
Debt (M):	\$0.0
Dividend:	\$0.00
Dividend Yield:	0.00%
Risk Profile:	Speculative
Fiscal Year End:	June

Total Expenses ('000)

	2017A	2018E	2019E
H1	3,716	6,437	6,759
H2	6,917	6,974	7,322
FY	10,633	13,411	14,081



Immutep Limited

Buy

LAG-3; The Next Emerging Checkpoint in Immune Oncology

Summary

- Immutep announced it received a \$1M milestone payment from China partner EOC Pharma (private) for IMP321 (eftilagimod alpha), Immutep's soluble LAG-3 candidate. An IND was filed in China in December 2017. We estimate Immutep currently has \$12M on the balance sheet (including the EOC payment) and with a quarterly burn rate of \$3M-\$3.5M, has runway into 2H18.
- Time to focus on LAG-3 - Immune oncology continues to migrate towards combination approaches, particularly for checkpoints. The question is which checkpoint will emerge to be combined with the PD1s and PD-L1s. In our view, the likely candidate could be LAG-3 as companies like Bristol-Myers Squibb, which has a deep pipeline of checkpoints has prioritized their LAG-3 (rilatlimab) for full development (9 ongoing clinical programs).
- Immutep may be right behind Bristol and has four LAG-3 assets, one of which (IMP701) has been licensed by Novartis (undisclosed milestones and royalties, we assume single digits given the early stage at the time of the license in 2015) and is being developed in combination with Novartis's PD1, PDR001. Immutep also has an in-house LAG-3 program (IMP321) in clinical development for metastatic breast cancer (P2b, combination with chemotherapy) and metastatic melanoma (P1 combination with Keytruda). More data for IMP321 is expected in 2018 and we expect data to emerge from Novartis over 2018 and 2019 (see attachment below).
- Conclusion: How big is the LAG-3 space? Like the PD1 and PD-L1 space, there is room for multiple players, in our view. With a great big Pharma partner in Novartis, we see Immutep ideally positioned to capture value in what we see as the next evolution of checkpoint inhibitors.

Details

Large indications and the right partners. Novartis (NVS - NR) has licensed IMP701 for development as a combination therapy with PD1 inhibitors in solid tumors. The ongoing clinical study in multiple cancer types has (as of January 2018) expanded to enroll another 99 patients, now N=515. Novartis will also initiate another N=160 program in hematological and solid cancer in combination with its PD1 inhibitor PDR001. GlaxoSmithKline (GSK - NR) is evaluating IMP731 in a phase I study in psoriasis with that trial expected to complete in March 2018. Immutep will receive single-digit royalties from each partnership. The lead in-house program, IMP321, an antigen-presenting cell (APC) activator that ramps up T-cell production following chemotherapy, already demonstrated POC in breast cancer and is currently in a phase IIb registration study. IMP321 could launch in 2020. A phase I study of an IMP321 combination with Keytruda in melanoma patients is also positive so far and demonstrated tumor reductions in 58% of patients (7/12). (more data: 2018).

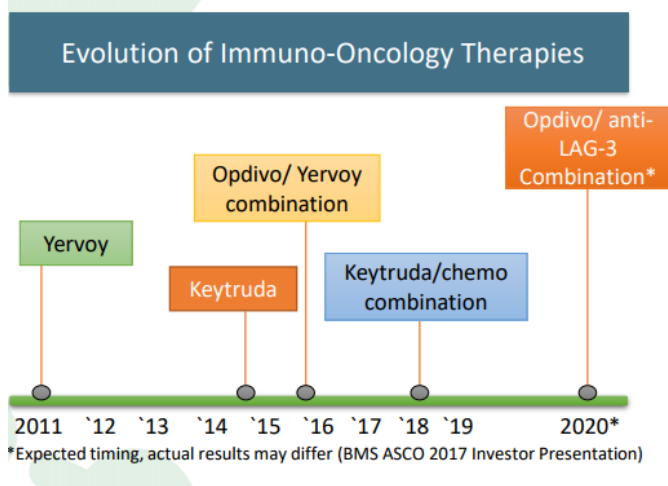
IMP321 is Immutep's lead LAG-3 candidate, and it's in development as an immune adjuvant or immune stimulator. IMP321 is a soluble dimeric recombinant form of LAG-3Ig, a fusion protein used to increase the immune response to tumors by stimulating dendritic cells through high affinity binding to MHC class 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). What's important to note is that both LAG-3 and CD40 can do this without inflammation. IMP321 was developed by Dr. Frédéric Triebel in the late 1990s as a dendritic-cell activator. When used at low doses, it can be used as a T-cell adjuvant for cancer vaccines. At higher doses, IMP321 can be combined with cancer chemotherapy to ramp up the immune response by driving dendritic cells and monocytes to increase tumor antigen presentation.

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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 (Exhibit 5) and GSK (Exhibit 6). 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 ⁽¹⁾		●	●	●	●	244
LAG525	Novartis ^{(1), (2)}			●	●		675
Relatlimab	BMS		●	●	●	●	3,139
GSK2831781	GSK ⁽²⁾		●				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 ⁽³⁾		●				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.

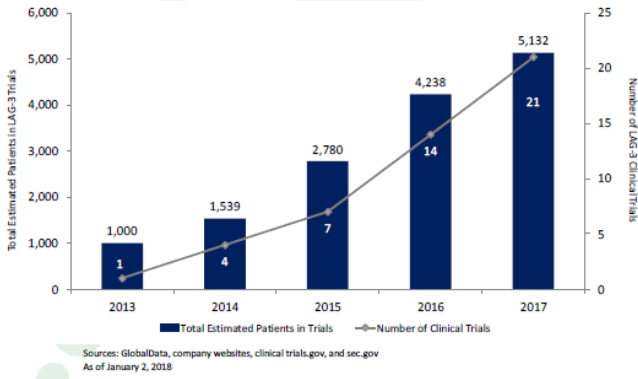
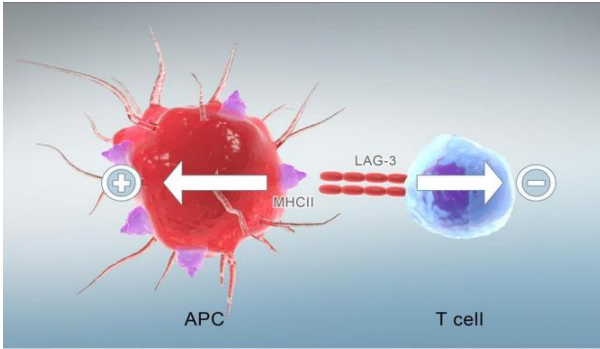
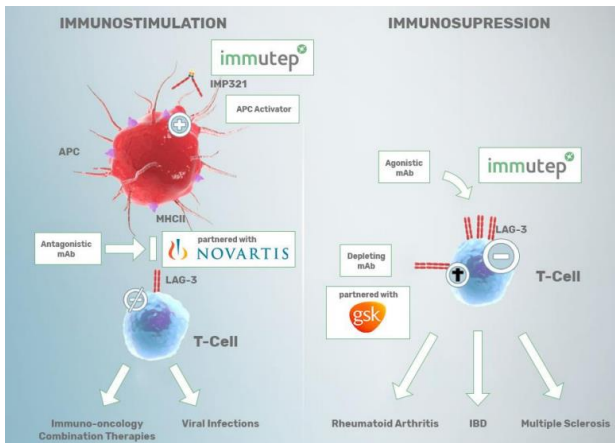


Exhibit 4. LAG-3 as a Therapeutic Target. LAG-3 is widely expressed on tumor infiltrating T cells (TILs) and cytotoxic T cells. As such it's an ideal target for checkpoint blockade. Functionally, LAG-3 is similar to CTLA-4 (target of Yervoy) and PD-1 (Keytruda, Opdivo). Shown below: 1- Positive regulation 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. Targeting LAG-3- In-house (IMP321) and partnered programs to Novartis and GSK. Targeting LAG-3 has potential in multiple oncology (Novartis partnership) and autoimmune indications (GSK partnership), as well as an antigen presenting cell activator (Immutep, in-house).



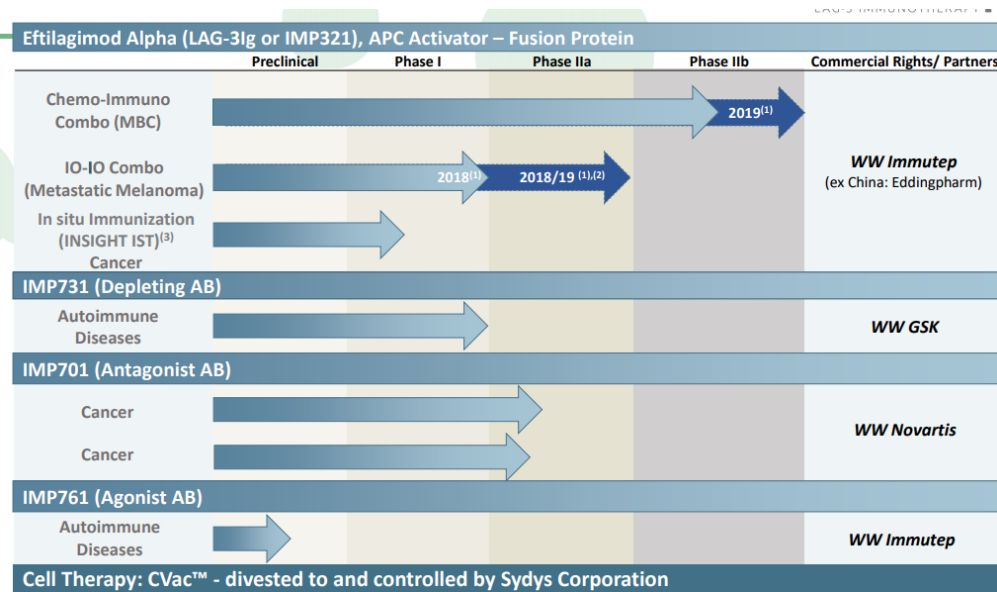
Source: Immutep Presentation

Exhibit 6. Bristol-Myers Squibb has Prioritized LAG-3 Development. Behind Opdivo and Yervoy, Bristol continues to develop anti-LAG 3 and has prioritized this as a lead immune oncology asset from its portfolio of molecules (Shown Below). Bristol is conducting 9 clinical programs, including combinations with Opdivo, which could lead to registration in the coming years. Immutep, by comparison has three LAG-3 assets in various stages of development and partnerships to both Novartis and GSK.



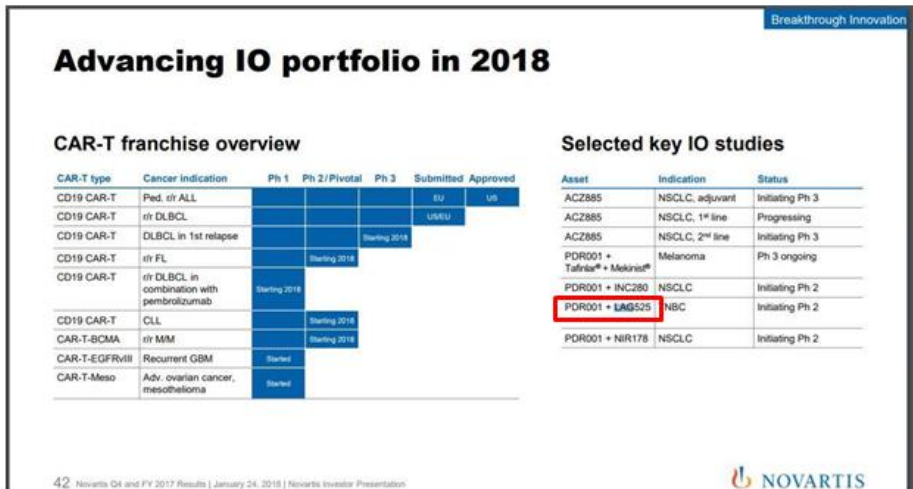
Source: Modified (red arrow) from Bristol-Myers Squibb presentation at JP Morgan Conference 2018.

Exhibit 7. Immutep Pipeline of LAG-3 Assets.



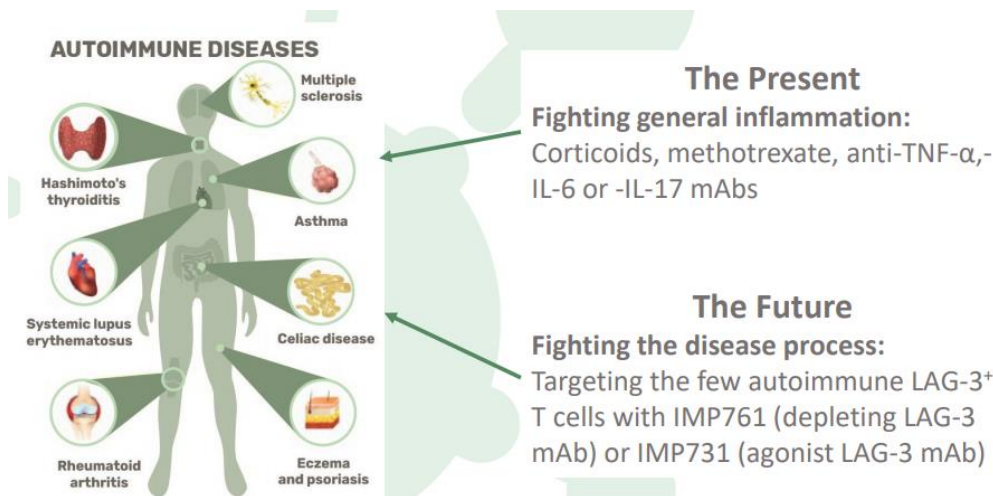
Source: Immutep presentation

Exhibit 8. 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. 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 is also initiating a new trial combining PDR001 with LAG525 in patients (N=160) with advanced hematological malignancies and solid tumors ([TRIAL LINK](#)). As per clinicaltrials.gov, the trial is expected to initiate February 8, 2018.



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

Exhibit 9. LAG-3 Potential in Autoimmune Disease, Partnership with GSK. Shown below is the potential of targeting LAG-3 in multiple autoimmune diseases. GlaxoSmithKline’s (GSK) Program for autoimmune diseases is evaluating Immutep’s IMP731 (GSK2831781) LAG-3 antibody. A phase I program evaluating IMP731 in healthy subjects vaccinated with BCG vaccine and patients with plaque psoriasis. The study will evaluate safety, PK/PD, immunogenicity and efficacy. The study is expected to complete in March 2018 ([TRIAL LINK](#)).



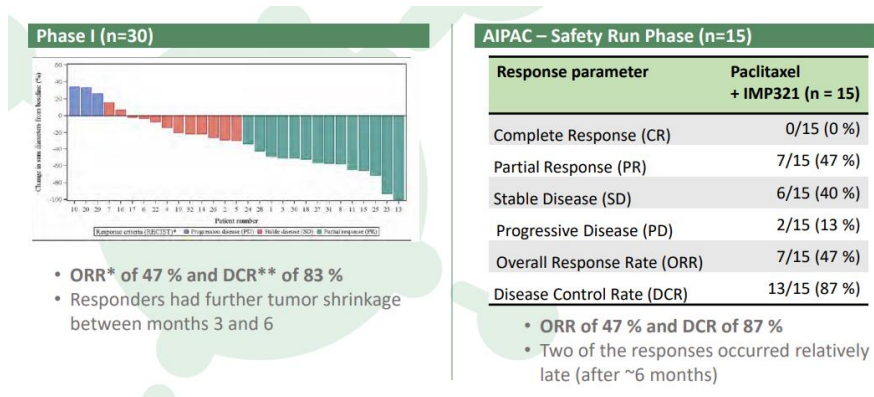
Source: Immutep presentation

IMP321 (eftilgimod alpha): IMP321 is being developed by Immutep for metastatic breast cancer (MBC) and metastatic melanoma, and an investigator-sponsored study in advanced solid tumors is ongoing. IMP321 is a LAG-3lg fusion protein, consisting of a dimer of LAG-3 that has been engineered to be soluble rather than expressed on the surface of cells. IMP321 is an antigen presenting cell activator, or APC activator. The role of an APC activator is to generate more efficacious T cell responses. IMP321 has demonstrated a positive safety profile and early efficacy in both breast cancer and melanoma. IMP321 has the potential to be used in various combinations from checkpoints to chemotherapy.

Clinical Development: A European P2b trial in metastatic breast cancer in combination with chemotherapy, the AIPAC trial (Active Immunotherapy PAClitaxel) is ongoing. The 15 patient safety run-in period was completed and the trial entered the randomized phase in early 2017. Patients are randomized to two arms, each with 113 patients to receive IMP321 + paclitaxel or placebo + paclitaxel. The primary readout of the trial is expected in 1H19. In N=30 overall response rate of 47% with a disease control rate of 83%. In metastatic melanoma, the P2 TACTI-Mel (Two ACTIVE Immunotherapeutics in Melanoma) study is ongoing evaluating IMP321 + Keytruda. The first dose escalation from 1mg to 6mg was completed and confirmed by the DSMB in 2016. The second and third cohorts are fully recruited (December 2017) and data from all three cohorts is expected in mid-2018.

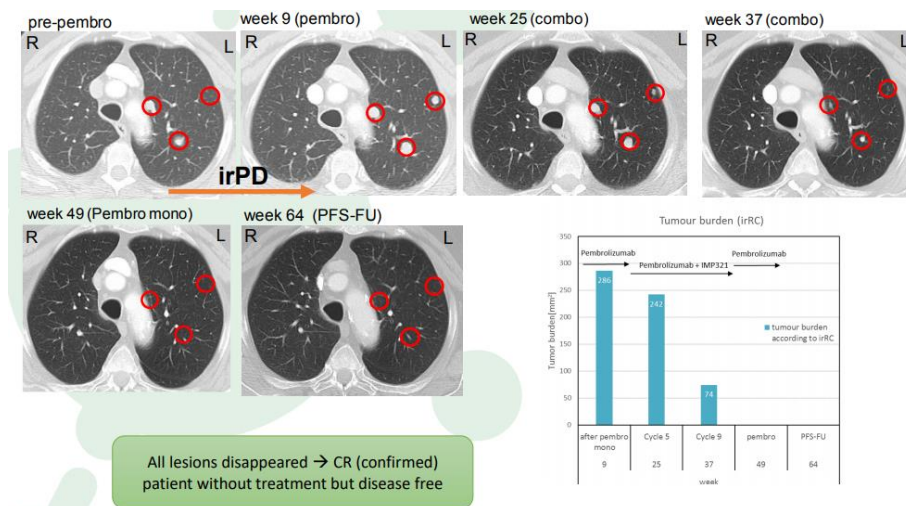
Safety Profile: As of November 2017, 221 patients have been exposed to IMP321 (80 healthy, 141 cancer) with repeated dose schedule every two weeks via subcutaneous injection. 119/141 patients received 1mg-6mg doses, with the highest at 30mg. 103/141 patients received IMP321 in combination with chemotherapy. As of the November cutoff, 53 SAEs in 38 patients were observed though not related to IMP321.

Exhibit 10. IMP321 + Chemotherapy in Metastatic Breast Cancer. In P1, N=30, the overall response rate was 47% with disease control rate of 83%.



Source: Immutep presentation

Exhibit 11. IMP321 + Keytruda in Metastatic Melanoma. Shown below are scans of a patient before Keytruda, after keytruda monotherapy and then following Keytruda + IMP321 over 64 weeks (total). All lesions disappeared and the patient had a confirmed complete response.



Source: Immutep presentation

DISCLOSURES

Immutep Limited Rating History as of 01/31/2018

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution		As of: 01/31/18	
		% 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%	34%
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither significantly 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%	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.

I, Jason Kolbert, 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 IMP321 in 2020 and followed by IMP731 in 2023. 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.

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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