

EQUITY RESEARCH COMPANY UPDATE

Biotechnology

Intraday Price 01/31/2019	\$2.24
Rating:	Buy
12-Month Target Price:	\$7.00
52-Week Range:	\$1.66 - \$4.21
Market Cap (M):	74.8
Shares O/S (M):	33.4
Float:	NA
Avg. Daily Volume (000):	47
Debt (M):	\$6.2
Dividend:	\$0.00
Dividend Yield:	0.00%
Risk Profile:	Speculative
Fiscal Year End:	June

Total Expenses ('000)							
	2017A	2018A	2019E				
H1	3,716	7,058	7,101				
H2	6,917	7,032	7,693				
FY	10.633	14.090	14.795				



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Immutep Limited

Buy

Provides Update- Catalysts Ahead in 2019 in Several Programs around LAG-3

Summary

- Immutep provided a corporate update detailing upcoming clinical milestones for 2019. We estimate the company has ~\$18M in cash, providing runway into mid-2020. This includes the \$5.2M in proceeds from a private placement in December 2018.
- Four efti programs are reporting data in 2019:
 - AIPAC Phase 2b metastatic breast cancer: efti + paclitaxel combination; Primary endpoint PFS data expected in 2H19.
 - TACTI-002 Phase 2 1/2L lung and 2L head & neck cancer: efti + Keytruda combination; commencing recruitment soon; first data expected 2H19.
 - Tacti-mel Phase 1 melanoma: efti combination with Keytruda; Part B interim data reported in 4Q18; final data expected later this year.
 - Insight-004 Phase 1 solid tumor: efti + avelumab; trial to initiate 1H19 with initial data in 2019.
- Conclusion. Investment in LAG-3 has continued to increase among pharma and biotech. Between 2017 and 2019, the number of clinical trials involving LAG-3 products has increased to 47, from 21. We view Immutep as an emerging leader in the LAG-3 space. While valuation has pulled back ~50% from a peak in October 2018, there are multiple catalysts ahead in 2019 and the company should have sufficient capital to reach them to drive higher valuation.

Details

Eftilagimod, TACTI-mel study. Phase 1 (N=24) combining efti + Keytruda in patients with unresectable or metastatic melanoma. TACTI-mel is now fully enrolled with the final patient in Part B recruited and dosed with treatment. The study has reported positive data from Part A and early positive data from Part B (See note 11/27; LINK). Final data is expected later in 2019.

Eftilagimod, TACTI-002 study. The Phase 2 collaboration with Merck in lung cancer and H&N cancer that will enroll up to N=110. Patients will receive the combination therapy of efti at the 30mg dose + Keytruda - Initiate 1H18, initial data 2H19.

Eftilagimod, AIPAC study: Phase 2b registration study (N=226) of efti as an adjuvant therapy in combination with paclitaxel therapy in metastatic breast cancer. Progression-free survival (PFS) is the primary endpoint. As of Jan 19th, 179 patients have enrolled out of the N=226 target. Data is expected in 2H19.

Eftilagimod, INSIGHT-004 Trial, collaboration with Merck KGaA (MKKGY - NR) / Pfizer (PFE - NR). The P1 INSIGHT trial of the efti + avelumab in solid tumors continues to enroll (N=13 so far). The trial expansion (INSIGHT-004) in collaboration with Merck and Pfizer should initiate in 1H19 with target enrollment of N=12, data updates expected in 2019.

Eftilagimod-based cancer vaccine, collaboration with Cytlimic (private). Cytlimic will run clinical trials evaluating efti as part of a cancer vaccine containing Cytlimic's cancer peptide vaccine, called CYT001.

IMP731 (depleting antibody), partnered to GlaxoSmithKline (GSK - NR). GSK2831781 is derived from IMP731. POC data expected in 2020 in ulcerative colitis.

IMP701 (antagonist antibody), partnered to Novartis (NVS - NR). Novartis has 4 studies ongoing with LAG525 (aka IMP701) with a fifth to commence soon in TNBC. Across the trials, N=1100 patients are expected to be evaluated.

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. Immutep, which has a portfolio of LAG-3 products, has partnerships with Novartis (oncology) and GSK (autoimmune diseases), and has emerged among the leaders in the space. Immutep is a LAG-3 pure play company with four LAG-3 candidates and more data is expected to emerge over 2019. 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. Immutep Pipeline of LAG-3 Assets. Immutep has 4 LAG-3 related products undergoing development in Immuno-oncology and autoimmune disease: Eftilagimod (Efti, lead candidate), IMP731, IMP701, and IMP761. The company retains the global rights (ex-China) for Efti, and has partnerships with leading global pharma companies such as Merck (MSD - NR), Pfizer (PFE - NR), GSK (GSK - NR), and Novartis (NVS - NR), as well as with Eddingpharm (PRIVATE - NR) for Efti Commercialization in China. More recently (Jan. 2019), Immutep announced a collaboration with Cytlimic to evaluate efti as part of a cancer vaccine. Novartis retains the rights for IMP701, where they are developing it as LAG525 and GSK retains the rights for IMP731.



Source: Immutep presentation

Exhibit 2. LAG-3 Therapeutic Landscape. Immutep is one of the leading companies in the LAG-3 therapeutic landscape with a total of 11 clinical trials investigating an Immutep product. The only company with a larger LAG-3 pipeline is Bristol-Meyer Squibb (BMY-NR) with 23 trials ongoing.



Source: Immutep Presentation

Exhibit 3. Increase in LAG-3 Development. Investment in LAG-3 development by Pharma and Biotech has demonstrated a continuing trend of growth. The number of ongoing clinical trials has ballooned from 1 in 2013 to 47 in 2019, which, in our view, is indicative that the pharmaceutical industry sees the value in LAG-3 as a potential addition to the checkpoint landscape.



Source: Immutep Presentation

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) results in an increase of antigen presentation to cytotoxic CD8 T cells (tumor killing); (2) negative regulation of the LAG-3+ 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

Income Statement (\$'000, USD)		•	Jan-Jun								
Immutep I: YE June 30	2017A	1H-2018A	2H-2018A	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenue (000's)											
Total Revenues	-	-	-	-	-	-	-	-	-	-	-
License revenue		1,910	37	1,947							
Miscellaneous income	616	246	501	746							
Grant Income	2,553	981	1,398	2,379							
Milestones and Royalties:											
IMP321 (Breast cancer)							5,659	14,575	44,426	57,141	65,615
IMP321 (Melanoma)						-	-	-	10,580	20,652	30,732
IMP731 (Psoriasis)						893	2,761	4,741	22,518	35,902	47,798
IMP701 (Solid tumors)						1,541	4,669	8,016	18,996	24,462	30,241
CVac											
Tatal Damana	0.400	0.400	4 000	5 070		0.404	40.000	07.000	00.500	400.450	474.005
Total Revenues	3,169	3,136	1,936	5,072	-	2,434	13,089	27,332	96,520	138,156	174,385
Expenses Cost Of Goods Sold											
COGS % Sales											
	5 505	3,439	2.052	7,392	7,762	0.450	0.550	8.986	9,435	9,907	10 402
Research & Development R&D % Rev's	5,585	3,439	3,953	7,392	7,762	8,150	8,558	8,960	9,435	9,907	10,402
	2.247	2,957	2 402	5,359	5,627	5 000	6 204	6.514	6,840	7 100	7 5 4 4
General & Administrative Expense SG&A %	3,347	2,957	2,402	5,359	5,627	5,908	6,204	6,514	6,840	7,182	7,541
	1,702	662	677	1,339	1,406	1,476	1,550	1,627	1,708	1,794	1 00/
Depreciation and amortization	1,702	002	077	1,559	1,400	1,470	1,550	1,027	1,700	1,794	1,884
Total expenses	10,633	7,058	7,032	14,090	14,795	15,534	16,311	17,127	17,983	18,882	19,826
Oper. Inc. (Loss)	(7,464)	(3,922)	(5,096)	(9,019)	(14,795)	(13,100)	(3,222)	10,205	78,537	119,274	154,559
Other income and expenses											
Interest income	80	28	103	131							
Loss on foreign exchange	333	28	211	239							
Finance cost			-								
Changes in fair value of comparability milestone			-								
Net Change in fair value of financial liability	(579)	320	(961)	(641.47)							
Loss on fair value change of warrants			(141)	(141)							
Loss on disposal of assets			-								
Exchange differences on the translation of foreign operations			-								
			-								
Total other income	(165)	375	(788)	(412)	-	-	-	-	-	-	-
Pre-tax income	(7,629)	(3,547)	(5,884)	(9,431)	(14,795)	(13,100)	(3,222)	10,205	78,537	119,274	154,559
Pretax Margin											
Taxes (or benefits)	738	0	(1)	(1)				1,020	11,781	21,469	30,912
Tax Rate								10%	15%	18%	20%
Exchange differences on the transations of foreign operations	209	375	954	1,329							
GAAP Net Income (loss)	(7,101)	(3,547)	(5,885)	(9,432)	(14,795)	(13,100)	(3,222)	9,184	66,756	97,805	123,647
Total Comprehensive Income (loss)	(7,101)	(3,172)	(4,931)	(8,103)	(14,795)	(13,100)	(3,222)	9,184	66,756	97,805	123,647
GAAP -EPS	(0.32)	(0.15)	(0.25)	(0.40)	(0.58)	(0.46)	(0.11)	0.30	2.20	3.22	4.06
Wgtd Avg Shrs (Bas) - '000s	22,111	23,608	23,990	23,799	25,414	28,404	30,213	30,273	30,334	30,394	30,455
Wgtd Avg Shrs (Dil) - '000s	22,111	23,608	23,990	23,799	25,414	28,404	30,213	30,273	30,334	30,394	30,455

Source: Company reports and Maxim

DISCLOSURES



Maxim	Group LLC Ratings Distribution		As of: 01/30/19
		% 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.	83%	35%
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.	16%	24%
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	1%	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: 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 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) High volatility of the company's stock price.

RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

Speculative – <u>Fundamental Criteria</u>: 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. <u>Price Volatility</u>: 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 – <u>Fundamental Criteria</u>: 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. <u>Price Volatility</u>: 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 – <u>Fundamental Criteria</u>: 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 – <u>Fundamental Criteria</u>: 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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