

Biotechnology

IMMP - NASDAQ	March 16, 2021
Closing Price 3/15/21 Rating: 12-Month Target Price: 52-Week Range: Market Cap (M): Shares O/S (M): Float: Avg. Daily Volume (000): Debt (M): Dividend: Dividend Yield: Risk Profile:	\$2.74 Buy \$8.00 \$0.53 - \$7.95 135.0 49.3 NA 1,314.2 \$6.2 \$0.00 0.0% 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							
Prior		18,151	19,059							



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Immutep Limited

Buy

Success in 2L H&N Cancer Leads to Second Collaboration to Move into 1L – Reiterate Buy

Summary

- Immutep announced a second collaboration agreement with Merck (known as "MSD" ex-US, ex-Canada) for a P2b trial (TACTI-003) evaluating eftilagimod (efti) in combination with Keytruda in 1L head and neck (H&N) squamous cell carcinoma (HNSCC). Recall the company had earlier success in 2L HNSCC patients in the ongoing P2 TACTI-002 trial, which formed the bases of the expansion into 1L and this second collaboration.
- The TACTI-002 trial is also being conducted via a collaboration agreement with Merck (MRK - NR). The trial is evaluating the efficacy of efti+Keytruda in 1L and 2L non-small cell lung cancer (NSCLC) and 2L HNSCC. Earlier data from the 1L NSCLC cohort was also positive, driving expansion to another N=74 patients. The willingness of a big player like Merck to collaborate with Immutep speaks to the validity of the efti platform, and in-part de-risks the efti story.
- Over 2021, we expect updates around multiple programs, including TACTI-002, AIPAC and the path forward in breast cancer, and now the start of a P2b in 1L H&N. Positive updates should continue to support a higher valuation.

Details

Efti and Keytruda — a "one-two punch" combination treatment. Both Efti and Keytruda serve to heighten the immune system's response to cancer. However, each drug goes about it from two different angles. Efti is predicated on the LAG-3 immune modulation control mechanism, which could play a role in the T-cell immune response. 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 cells urface. 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). Coming in from the other angle, Keytruda is an anti-PD-1 monoclonal antibody designed to "unblind" the patient's immune system to cancer cells. This differentiated combination of attenuating immune evasion mechanisms combined with the stimulation of T-cells via antigen presentation could provide superior therapeutic benefit to patients.

The upcoming TACTI-003 builds upon earlier success observed in TACTI-002. Positive early-stage safety and efficacy data was noted in 2L HNSCC patients in the TACTI-002 trial (N=109), which is evaluating the therapeutic potential of efti +Keytruda in three different indications: 1L NSCLC, 2L NSCLC, and 2L HNSCC. During the first eight, three-week cycles, patients are administered 30 mg of efti every two weeks; starting at cycle 9, patients receive efti every three weeks. In addition, patients receive 200mg of pembrolizumab every three weeks. The primary objective of the study will be the objective response rate (ORR).

At the 10/8 data cutoff, in the 2L HNSCC cohort, an ORR of ~36% was observed among the intent-to-treat (ITT) population of Stage 1 and 2 N=28 patients, comparing favorably to KEYNOTE studies with comparable patient populations, in which an ORR of ~15% was noted, highlighting synergistic potential. Three patients exhibited CR, seven PR, three SD, and 10 PD. A disease control rate of 46.4% was observed. Responses were also noted in patients with low PD-L1 status, a subgroup of patients who typically fail to respond to PD-L1 therapy. Of the 28 patients assessed, 10 were still undergoing treated, seven for six or more months, with positive progressive-free survival (PFS) and overall survival (OS). Five patients were not evaluable.

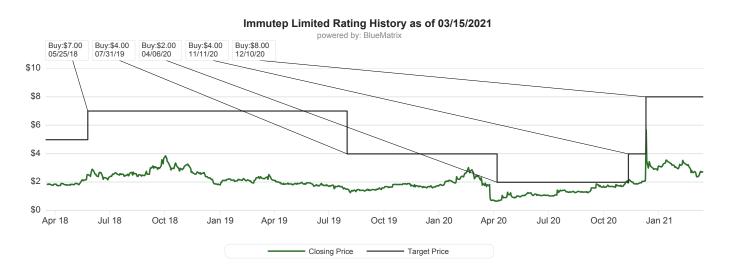
The Phase 2b TACTI-003 trial (N=160) will evaluate the efficacy of efti and Keytruda in N=160 patients with 1L HNSCC compared to those who receive Keytruda in a single-agent capacity. The first patient is expected to enroll in mid-2021.

Immutep Limited (IMMP)

Model update. On 2/23, the company reported 1H21 results with a net loss of (\$15.3M) and ended the period with \$42.3M in cash on the balance sheet.

Income Statement (\$'000, USD)																	
Immutep I: YE June 30	2017A	2018A	2019A	2020A	1H-2021A	2H-2021E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Revenue (000's)																	
,																	
Eftilagimod Alpha - Breast Cancer (US)										_	58.192	176,322	237.447	299,776	339,107	366,962	395.3
Eftilagimod Alpha - Breast Cancer (EU)									_	_	49,075	148,696	200,244	252,808	285,977	309,467	333,4
Eftilagimod Alpha - Lung Cancer (US)										67.547	139,174	215,066	295,414	349,986	391,909	436,044	499,1
Eftilagimod Alpha - Lung Cancer (EU)										69,082	142,336	219,952	302,126	357,938	400,812	445,950	510,4
Eftilagimod Alpha (IMP321) - HNSCC (US)										17.635	30,279	43.670	57,843	66,211	71.621	77,298	83.2
Eftilagimod Alpha (IMP321) - HNSCC (EU)										18,934	32,510	46,889	62,106	71,091	76,899	82,994	89,3
Etiliagii ilou Alpria (livir 321) - HN3CC (EU)										10,934	32,510	40,009	62,100	71,091	70,099	02,994	09,3
Total Revenues	-				-	-			-	173,198	451,565	850.594	1.155.180	1,397,810	1,566,325	1,718,716	1,910,9
License revenue		1,947	95	4,492						,	,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	.,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,	,,,,,,,
Miscellaneous income	616	746	785	168	149		149										
Grant Income	2,553	2,379	2,953	3,584	1,555		1,555										
Milestones and Royalties:	2,000	2,010	2,000	0,001	1,000		1,000										
milestories and regulates.																	
IMP321 (Melanoma)					_	_	_	_	-	_	_	_	_	_	_	_	_
IMP731 (Psoriasis)					_	_	_	-	-	_	4,157	8,564	10,588	13,634	15,919	19,294	21,8
IMP701 (Solid tumors)					_	_	_	_	_	_	512	791	1,086	3,357	3,688	4,156	4.8
CVac											312	731	1,000	0,007	5,000	4,100	4,0
Cvac																	
Total Revenues	3,169	5,072	3,833	8.244	1.704	-	1,704		_	173,198	456,234	859,949	1,166,854	1,414,801	1.585.932	1,742,165	1.937.7
Expenses															, ,		
Cost Of Goods Sold									_	51,959	136,870	257,985	291,713	353,700	396,483	348,433	387,5
%Gross Margin									70%	70%	70%	70%	75%	75%	75%	80%	80%
Research & Development	5,585	7,392	11,282	12,238	6,497	6,682	13,179	13,838	14,530	15,256	16,019	16,820	17,661	18,544	19,471	20,445	21,4
R&D % Rev's	3,303	7,352	11,202	12,230	0,437	0,002	13,179	13,030	14,550	13,230	10,019	10,020	17,001	10,544	15,471	20,443	21,4
	3,347	5,359	4,329	0.004	2,400	2,076	4,476	4,700	4,935	5,181	5,440	5,712	5,998	6,298	0.040	0.040	7.0
General & Administrative Expense	3,347	5,359	4,329	3,801	2,400	2,076	4,476	4,700	4,935	5,181	5,440	5,712	5,998	6,298	6,613	6,943	7,2
SG&A %																	
Depreciation and amortization	1,702	1,339	1,278	1,248	811	681	1,492	1,566	1,645	1,727	1,813	1,904	1,999	2,099	2,204	2,314	2,4
Total expenses	10,633	14,090	16,889	17,287	9,707	9,439	19,146	20,104	21,109	74,123	160,142	282,421	317,371	380,641	424,771	378,135	418,7
Oper. Inc. (Loss)	(7,464)	(9,019)	(13,056)	(9,043)	(8,004)	(9,439)	(17,443)	(20,104)	(21,109)	99,074	296,091	577.529	849,483	1,034,160	1,161,162	1,364,030	1,518,9
Other income and expenses	(1,404)	(3,013)	(10,000)	(3,043)	(0,004)	(5,455)	(17,440)	(20,104)	(21,103)	33,014	250,051	377,323	043,403	1,004,100	1,101,102	1,004,000	1,010,0
Interest income	80	131	270	120	34		34										
	333	239	336				(600)										
Loss on foreign exchange	333	239	330	208	(600)												
Net change in fair value of warrants				(0)	(6,204)		(6,204)										
Finance cost				(6)													
Changes in fair value of comparability milestone																	
Net Change in fair value of financial liability	(579)	(641.47)	(678)	688	(506)		(506)										
Gain/Loss on fair value change of warrants		(141)	654	1,329													
Loss on disposal of assets																	
Exchange differences on the translation of foreign operations																	
			_														
Total other income	(165)	(412)	582	2,338	(7,276)	- (5. 15.5)	(7,276)	-	-	-	-	-	-				
Pre-tax income	(7,629)	(9,431)	(12,474)	(6,705)	(15,280)	(9,439)	(24,719)	(20,104)	(21,109)	99,074	296,091	577,529	849,483	1,034,160	1,161,162	1,364,030	1,518,9
Pretax Margin		1									l						
Taxes (or benefits)	738	(1)		(0)	(0)		(0)	-	-	4,954	29,609	57,753	84,948	124,099	139,339	177,324	197,4
																4000	l .
Tax Rate		4 000	550	(400)	(470)		(470)			5%	10%	10%	10%	12%	12%	13%	1
Exchange differences on the transaations of foreign operations	209	1,329	558	(100)	(478)	(0.400)	(478)	(00.40.4)	(04.400)	0.1.40	000 (00	540 7770	704.50	040.00	4 004 000	4 400 700	4.004
GAAP Net Income (loss)	(7,101)	(9,432)	(12,474)	(6,705)	(15,280)	(9,439)	(24,719)	(20,104)	(21,109)	94,121	266,482	519,776	764,534	910,061	1,021,822	1,186,706	
Total Comprehensive Income (loss)	(7,101)	(8,103)	(11,915)	(6,705)	(15,758)	(9,439)	(24,719)	(20,104)	(21,109)	94,121	266,482	519,776	764,534	910,061	1,021,822	1,186,706	1,321,5
GAAP -EPS	(0.32)	(0.40)	(0.49)	(0.17)	(0.24)	(0.15)	(0.38)	(0.29)	(0.29)	1.28	3.63	7.07	10.37	12.32	13.81	16.01	17.
Wgtd Avg Shrs (Bas) - '000s	22,111	23,799 23,799	25,414	38,899	64,872	64,937 64,937	64,905	69,002	73,112	73,258	73,405	73,552	73,699	73,846 73,417	73,994	74,142	74,2 73.4
Wgtd Avg Shrs (Dil) - '000s	22.111		25,414	38.899	64.872		64.905	69.002	73.112	73,258	73,405	73.418	73.417		73,417	73,417	

DISCLOSURES



Maxim	Group LLC Ratings Distribution		As of: 03/15/21
		% 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.	84%	55%
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%	50%
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: 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 reports in A\$; (7) 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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