Biotechnology

IMMP - NASDAQ November 11, 2020

Intraday Price 11/11/20	**$1.98**
Rating:	Buy
12-Month Target Price:	*(prior $2.00)* $4.00
52-Week Range:	$0.53 - $3.10
Market Cap (M):	97.6
Shares O/S (M):	49.3
Float:	NA
Avg. Daily Volume (000):	395.2
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	8,713	9,148
H2	7,715	9,439	9,911
FY	17,287	18,151	19,059

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

The Data for Efti in Lung and H&N Continues to Build – Raising PT to $4, from $2

Summary

- **Immutep reported positive interim data at the Society for Immunotherapy of Cancer (SITC) on 11/9 from its ongoing P2 TACTI-002 combination trial evaluating eftilagimod alpha (efti) and KEYTRUDA in patients with 1L and 2L non-small cell lung cancer (NSCLC) and 2L head and neck (H&N) squamous cell carcinoma (HNSCC).**
- **Two patients with 1L NSCLC and three with 2L HNSCC exhibited a Complete Response (CR), and overall (ITT) objective response rates (ORR) of 36.1% and 46.4%, respectively. The positive data and continued safety in these indications continues to build. We are factoring in lung cancer and H&N cancer into our model, which serves to raise our price target to $4, from $2.**
- **IMMP shares have rebounded since reaching a 52-week low in March stemming from the efti miss in breast cancer in March, as well as impacts from COVID-19 across the markets in March as well. While breast cancer is still an active program, and we look forward to the San Antonio Breast Cancer Symposium in December for an update, the efti programs in lung and H&N cancers continue to evolve and report positive efficacy and safety data, becoming the lead programs for the company. In addition, the LAG-3 space overall, led by Bristol (BMY - NR) which has 30+ clinical programs in over 10K+ patients, continues to move closer to possibly becoming the next blockbuster checkpoint market behind the PD1/PD-L1s and CTLA4s. Combined, we see unlocked opportunity in IMMP.**

Details

TACTI-002 overview. 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 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 purpose of the phase 2 combination study is to evaluate the therapeutic potential of efti and KEYTRUDA, an anti-PD-1 monoclonal antibody, in up to N=109 patients with first-line and second-line NSCLC and HNSCC. The trial is made of three treatment arms: 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 200 mg of pembrolizumab every three weeks. The primary objective of the study will be the objective response rate (ORR).

First Line NSCLC. Among the intent-to-treat (ITT) population, an ORR of 36.1% was noted. In addition to two patients exhibiting CR, there were 11 partials (PR) as well as 11 patients who exhibited stable disease (SD) and nine in which progressive disease (PD) was noted. Three patients were not evaluable. Among the N=36 patients assessed, a disease control rate (DCR) of 66.7% was observed. 61% of patients experienced a target lesion decrease. Among patients with ≥1% PD-L1, an ORR of 44% (11/25) was noted, which compares favorably to the ORR of ~27% noted among a comparable patient population administered pembrolizumab alone. ORR for the <50% PD-L1 subgroup was 31.6%, comparing favorably to the ORR of <20% noted among a similar patient population receiving pembrolizumab exclusively. The superior ORRs exhibited by patients in all PD-L1 subgroups treated with efti suggest synergistic potential with pembrolizumab. At the data cutoff point, 11 patients were still undergoing therapy, six of whom for 12+ months. Progress-free survival (PFS) data points so far are positive. *(continued on page 2)*

Patients in the 1L NSCLC cohort are highly similar, but are derived from two stages. Patients in Stage 2 exhibit a median age nearly ten years older than those in Stage 1. Additionally, 84% of patients in Stage 2 exhibited an ECOG status of 1, indicative of greater susceptibility to the impacts of deteriorating health.

Second-line NSCLC. Among this difficult to treat subgroup of stage 1 patients, 85% of patients were PD-L1 low expressors (PD-L1<50%). Best response noted of PD-1/PD-L1 therapy was SD/PD among 61% of patients, potentially leading to primary resistance. In the 1L setting, the majority of patients were treated with chemotherapy and concomitant PD-1/PD-L1. Four patients (17.4%) were either stable or responding for 6+ months; two additional patients have been receiving therapy for 2+ months. Of note, ≥50% of patients were alive at the 12-month mark, a superior outcome to what is typically seen with standard of care (SOC) chemotherapy, in which 50% of patients are expected to reach the six-month mark. Based on this positive interim data, the DMC recommended the initiation of a "Stage 2" component in this arm.

Second-line HNSCC. At the 10/8 data cutoff, 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 are still undergoing treated, seven for six or more months, with positive progressive-free survival (PFS) and overall survival (OS). Five patients were not evaluable.

Exhibit 1. Positive interim-data readout from ongoing phase 2 TACTI-002 trial. Superior ORRs were exhibited among 1L NSCLC patients in all PD-L1 subgroups as well as those with 2L HNSCC, compared to those seen among comparable populations treated with pemrolizumab exclusively, indicative of synergistic potential. Additionally, survival data from the 2L NSCLC cohort compared favorably to SOC chemotherapy, with ≥50% of patients in the 2L NSCLC cohort alive at 12-months, compared to 50% of patients alive at six months on chemotherapy alone.

	Part A 1st line NSCLC	Part B 2nd line NSCLC	Part C 2nd line HNSCC
Tumour response - iBOR per iRECIST	**Stages 1 & 2 N (%) Total (N=36)**	**Stage 1 N (%) Total (N=23)**	**Stage 1 & 2 N (%) Total (N=28)**
Complete Response (iCR)	2 (5.6)	0 (0)	3 (10.7)
Partial Response (iPR)	11 (30.6)	1 (4.4)	7 (25.0)
Stable Disease (iSD)	11 (30.6)	7 (30.4)	3 (10.7)
Progressive Disease (iPD)	9 (25.0)	14 (60.9)	10 (35.7)
Not evaluable	3 (8.3)	1 (4.4)	5 (17.9)
Disease Control Rate (DCR)	**24 (66.7)**	**8 (34.8)**	**13 (46.4)**
Objective Response Rate (iORR) ITT*	**13 (36.1)**	**1 (4.4)**	**10 (35.7)**
Objective Response Rate in eval. pts	**13 (39.4)**	**1 (4.5)**	**10 (43.5)**

*Intention-to-treat (ITT) analysis of the results of an experiment is based on the initial treatment assignment and not on the treatment eventually received. ITT analysis is intended to avoid various misleading artifacts that can arise in intervention research such as non-random attrition of participants from the study or crossover.

Source: Immutep Press Release

Exhibit 2. Characteristics of stage 1 and 2 patients in cohort A. Patients in Stage 2 had a higher median age (almost 10 years) than those in Stage 1. Additionally, 84% of patients in Stage 2 had an ECOG status of 1, compared to ~30% of patients in Stage 1.

Baseline Characteristics	Stage 1 (N=17) N (%)	Stage 2 (N=19) N (%)	Stage 1+2 (N=36) N (%)
Median age, years (range)	**65 (53-76)**	**74 (60-84)**	68.5 (53-84)
ECOG 0 ECOG 1	12 (70.6) **5 (29.4)**	3 (16) **16 (84)**	15 (41.7) 21 (58.3)
Squamous (SQ) Non-squamous (NSQ)	10 (58.8) **7 (41.2)**	5 (26) **14 (73)**	15 (41.7) 21 (58.3)

Source: Immutep Press Release

Exhibit 3. Similar proportion of 1L NSCLC patients in both stages exhibited progressive disease. Stage 1 patients exhibited superior data in terms of PR. The data suggests that combination therapy may benefit patients in both stages.

Tumour response (iRECIST)	Stage 1 (N=17) N (%)	Stage 2 (N=19) N (%)	Stage 1+2 (N=36) N (%)
Complete Response	1 (5.9)	1 (5.3)	2 (5.6)
Partial Response	8 (47.1)	3 (15.8)	11 (30.6)
Stable Disease	4 (23.5)	7 (36.8)	11 (30.6)
Progressive Disease	4 (23.5)	5 (26.3)	9 (25.0)
Not Evaluable	0 (0)	3 (15.8)	3 (8.3)
Overall Response Rate ITT			**13 (36.1)**
[95% CI interval]			**[20.8-53.8]**
Overall Response Rate (evaluable patients only)			**13/33 (39.4)**
Disease Control Rate			**24 (66.7)**

Source: Immutep Press Release

MODELING ASSUMPTIONS

1. We assume Eftilagimod Alpha (efti) will be approved for non-small cell lung cancer (NSCLC) and second-line head and neck squamous cell carcinoma (HNSCC) in 2024 in the US and EU.
2. We assume an an increase in incidence of 1% for both indications in the US and EU.
3. We assume NSCLC will maintain a prevalence of 85% of all lung cancer cases.
4. We assume that 75% of patients diagnosed with NSCLC will require second-line treatment.
5. We assume that HNSCC will maintain a prevalence of 90% of all head and neck cancers.
6. We assume that 25% of HNSCC patients will require second-line therapy.
7. We assume efti will be priced at $150,000 in the US and $70,000 in the EU.
8. A risk adjustment of 75% is applied based on stage of development, clinical trial risk, and other factors.
9. In light of the relative lack of new data regarding IMP731 and IMP701, we have moved out our estimated commercialization year to 2025 and increased our risk adjustment to 90%, from 75% (not shown).

Exhibit 4. Eftilagimod Alpha (IMP321) - Lung Cancer US Market Model.

Eftilagimod Alpha (IMP321) - Lung Cancer (US)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Incidence of lung cancer	228,150	230,432	232,736	235,063	237,414	239,788	242,186	244,608	247,054	249,524	252,020	254,540	257,085	259,656
Increase in incidence		1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Patients with non-small cell lung cancer (NSCLC)	193,928	195,867	197,825	199,804	201,802	203,820	205,858	207,917	209,996	212,096	214,217	216,359	218,522	220,708
1L Market Penetration							0.20%	0.30%	0.50%	1.00%	1.20%	1.50%	1.70%	2.00%
Patients with 2L NSCLC	145,446	146,900	148,369	149,853	151,351	152,865	154,393	155,937	157,497	159,072	160,662	162,269	163,892	165,531
2L Market Penetration							0.20%	0.30%	0.50%	1.00%	1.20%	1.50%	1.70%	2.00%
Total NSCLC patients treated							721	1,092	1,837	3,712	4,499	5,679	6,501	7,725
Cost of Therapy							$ 150,000	$ 153,000	$ 156,060	$ 159,181	$ 162,365	$ 165,612	$ 168,924	$ 172,303
Price increase								2%	2%	2%	2%	2%	2%	2%
Revenue ('000)							$ 108,075	$ 167,009	$ 286,754	$ 590,829	$ 730,406	$ 940,580	$ 1,098,184	$ 1,330,999
Risk							75%	75%	75%	75%	75%	75%	75%	75%
Revenue ('000)							**$27,019**	**$41,752**	**$71,689**	**$147,707**	**$182,602**	**$235,145**	**$274,546**	**$332,750**

Source: Maxim estimates

Exhibit 5. Eftilagimod Alpha (IMP321) - Lung Cancer EU Market Model.

Eftilagimod Alpha (IMP321) - Lung Cancer (EU)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Incidence of lung cancer	500,000	505,000	510,050	515,151	520,302	525,505	530,760	536,068	541,428	546,843	552,311	557,834	563,413	569,047
Increase in incidence		1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Patients with non-small cell lung cancer	425,000	429,250	433,543	437,878	442,257	446,679	451,146	455,658	460,214	464,816	469,464	474,159	478,901	483,690
1L Market Penetration							0.20%	0.30%	0.50%	1.00%	1.20%	1.50%	1.70%	2.00%
Patients with 2L NSCLC	318,750	321,938	325,157	328,408	331,693	335,009	338,360	341,743	345,161	348,612	352,098	355,619	359,175	362,767
2L Market Penetration							0.20%	0.30%	0.50%	1.00%	1.20%	1.50%	1.70%	2.00%
Total NSCLC patients treated							1,579	2,392	4,027	8,134	9,859	12,447	14,247	16,929
Cost of Therapy							$ 70,000	$ 71,400	$ 72,828	$ 74,285	$ 75,770	$ 77,286	$ 78,831	$ 80,408
Price increase								2%	2%	2%	2%	2%	2%	2%
Revenue ('000)							$ 110,531	$ 170,803	$ 293,269	$ 604,252	$ 747,000	$ 961,949	$ 1,123,134	$ 1,361,238
Risk							75%	75%	75%	75%	75%	75%	75%	75%
Revenue ('000)							**$27,633**	**$42,701**	**$73,317**	**$151,063**	**$186,750**	**$240,487**	**$280,783**	**$340,310**

Source: Maxim estimates

Exhibit 6. Eftilagimod Alpha (IMP321) – HNSCC US Market Model.

Eftilagimod Alpha (IMP321) - HNSCC (US)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Incidence of Head and Neck Cancer	65,630	66,286	66,949	67,619	68,295	68,978	69,668	70,364	71,068	71,779	72,496	73,221	73,954	74,693
Increase in incidence		1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
HNSCC	59,067	59,658	60,254	60,857	61,465	62,080	62,701	63,328	63,961	64,601	65,247	65,899	66,558	67,224
Patients with 2L HNSCC	14,767	14,914	15,064	15,214	15,366	15,520	15,675	15,832	15,990	16,150	16,312	16,475	16,640	16,806
Market Penetration							1.00%	3.00%	5.00%	7.00%	7.30%	7.50%	7.70%	8.00%
Total NSCLC patients treated							157	475	800	1,131	1,191	1,236	1,281	1,344
Cost of Therapy							$ 150,000	$ 153,000	$ 156,060	$ 159,181	$ 162,365	$ 165,612	$ 168,924	$ 172,303
Price increase								2%	2%	2%	2%	2%	2%	2%
Revenue ('000)							23,513	72,669	124,772	179,956	193,336	204,632	216,433	231,657
Risk							75%	75%	75%	75%	75%	75%	75%	75%
Revenue ('000)							**$5,878**	**$18,167**	**$31,193**	**$44,989**	**$48,334**	**$51,158**	**$54,108**	**$57,914**

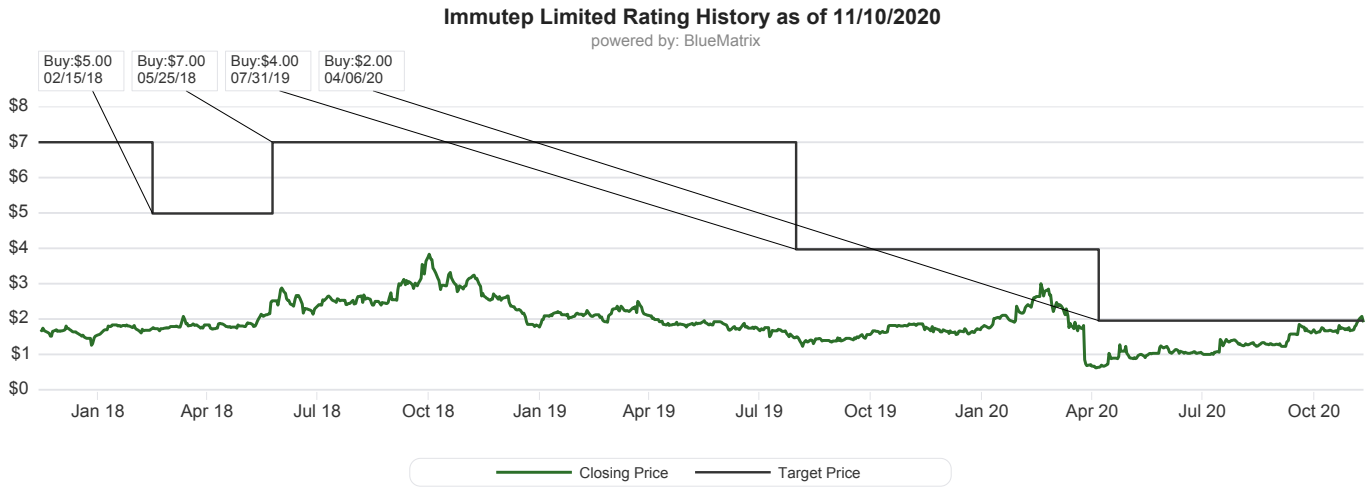
Source: Maxim estimates

Exhibit 7. Eftilagimod Alpha (IMP321) – HNSCC EU Market Model.

Eftilagimod Alpha (IMP321) - HNSCC (EU)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Incidence of Head and Neck Cancer	151,000	152,510	154,035	155,575	157,131	158,703	160,290	161,892	163,511	165,146	166,798	168,466	170,151	171,852
Increase in incidence		1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
HNSCC	135,900	137,259	138,632	140,018	141,418	142,832	144,261	145,703	147,160	148,632	150,118	151,619	153,136	154,667
Patients with 2L HNSCC	33,975	34,315	34,658	35,004	35,355	35,708	36,065	36,426	36,790	37,158	37,530	37,905	38,284	38,667
Market Penetration							1.00%	3.00%	5.00%	7.00%	7.30%	7.50%	7.70%	8.00%
Total NSCLC patients treated							361	1,093	1,840	2,601	2,740	2,843	2,948	3,093
Cost of Therapy							$ 70,000	$ 71,400	$ 72,828	$ 74,285	$ 75,770	$ 77,286	$ 78,831	$ 80,408
Price increase								2%	2%	2%	2%	2%	2%	2%
Revenue ('000)							$ 25,246	$ 78,024	$ 133,967	$ 193,218	$ 207,584	$ 219,712	$ 232,384	$ 248,729
Risk							75%	75%	75%	75%	75%	75%	75%	75%
Revenue ('000)							**$6,311**	**$19,506**	**$33,492**	**$48,305**	**$51,896**	**$54,928**	**$58,096**	**$62,182**

Source: Maxim estimates

DISCLOSURES



Maxim Group LLC Ratings Distribution		As of: 11/10/20	
		% 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.	**81%**	**52%**
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.	**19%**	**48%**
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*		

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.

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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, as well as IMP321 (royalty-free) in 2025 for 1L and 2L NSCLC, as well as 2L HNSCC. 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 – 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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ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

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