Biotechnology

IMMP - NASDAQ November 17, 2021

Closing Price 11/16/21	**$4.07**
Rating:	Buy
12-Month Target Price:	$8.00
52-Week Range:	$1.75 - $7.95
Market Cap (M):	347.5
Shares O/S (M):	85.4
Float:	NA
Avg. Daily Volume (000):	368.5
Debt (M):	$6.2
Dividend:	$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	June

Total Expenses ('000)

	2020A	2021A	2022E
H1	9,572	9,707	9,399
H2	7,715	7,462	9,799
FY	17,287	17,169	19,198

Immutep is listed on the ASX (IMM) and with ADR's traded on NASDAQ (IMMP). 1 ADR= 10 shares of common stock.

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Immutep Limited

Buy

AIPAC Presentation at SITC Builds on Prior Data, Prepping to Go Pivotal in mBC

Summary

- **Following its late-breaker presentation (on 11/12) at this year's s Society for Immunotherapy of Cancer (SITC) Conference, Immutep hosted an investor call yesterday, after the market close, to review the final AIPAC data as well as other ongoing programs.**
- **For us, the focus was on AIPAC: a P2b study of eftilagimod (soluble LAG-3) in combination with chemo in HR+/HER2- metastatic breast cancer (mBC). Here is what we know from before: (1) while not statistically significant, an overall survival (OS) benefit trend was seen in the overall study population in the efti group; however, (2) statistically significant OS benefit was observed in three patient subgroups with efti (see Details below). Important to note, these were predefined subgroups prior to data unblinding and not selected for with posthoc analyses.**
- **What's new? In the three patient subgroups, substantial survival benefit was observed in the efti group vs. control (that has sustained since the interim data readout in December 2020), leading to a final OS readout of: +19.6 months for the low monocyte group; and +7.5 months for patients <65 years of age with efti vs. comparator. The luminal B group also saw an OS benefit of +4.2 months with efti (see Exhibit 2). Taken together, we believe the data should renew investor confidence in an efti's/chemo combination and provide a path forward for efti in mBC.**
- **Given these positive results, Immutep will initiate a Phase 3 study in mBC (AIPAC-003), pending regulatory discussions and feedback from the FDA and EMA on the trial design.**
- **Conclusion. Shares of IMMP have appreciated (YTD +30% vs. XBI -12%) as the promise of a validated new checkpoint (since PD(L)1 and CTLA-4) appears to be on the horizon with Bristol's relalimab (LAG-3 inhibitor) PDUFA approaching on March 19, 2022. With its own LAG-3 assets for both autoimmune disease and cancer treatments, and lead drug efti in multiple combination trials, at a market cap of ~$350M, we believe there is still considerable upside to IMMP shares. Reiterate Buy.**

Details

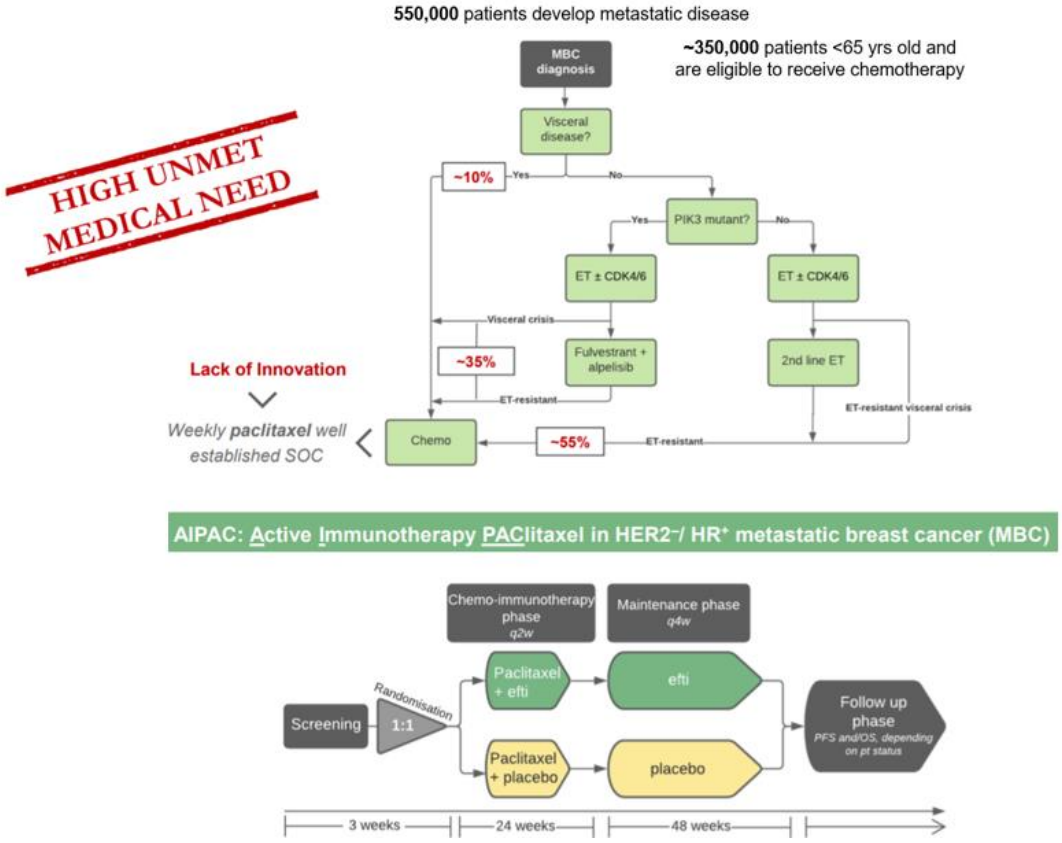
Active Immunotherapy Paclitaxel (AIPAC) P2b study design. The multi-center, double-blind, placebo-controlled, randomized trial (N=227) evaluated eftilagimod alpha (efti) in combination with paclitaxel standard of chemotherapy in patients with metastatic breast cancer. A total of 227 patients with HER2- HR+ metastatic breast cancer were randomized (1:1): efti + paclitaxel (n=114) vs. placebo + paclitaxel (n=113). Patients received weekly paclitaxel on days 1, 8, and 15. On days 2 and 16 of each 4-week cycle, efti or placebo was administered, with treatment repeated for up to 6 cycles. After the cycles, patients went on to maintenance therapy with efti alone. The primary endpoint of the study was progression free survival (PFS), which was missed in March 2020 (though efti/chemo combination was numerically greater than SOC). Secondary endpoint was overall survival (OS) and overall response rate (ORR). ORR previously reported for the study arm was 48.3% vs. 38.4% in the control arm.

SITC data highlights. Efti immunotherapy agent in combination with paclitaxel showed sustained OS responses across the board, particularly in the predefined subgroups (see Exhibit 2). Efti/combo was safe and tolerable. We believe efti's benign safety profile could pave the way for multiple combinations in different combinations. Below are the final AIPAC results:

(continued on page 2)

- Overall patient population: Subjects in the efti group had a median OS (mOS) of 20.4 months compared with 17.5 months in the comparator group, for a survival benefit of +2.9 months (HR = 0.88; *p* = 0.197). This was an increase of 0.2 months from the prior topline results reported in December 2020.
- Subgroup <65 years of age: Subjects in the efti group showed a mOS of 22.3 months compared to 14.8 months in the comparator group, for a survival benefit of +7.5 months (HR = 0.66; p = 0.017). This was an increase of 0.4 months from prior.
- Low monocyte count (<0.25/nl) at start of study: Subjects in the efti group reported a mOS of 32.5 months compared to 12.9 months in the comparator group, for a survival benefit of +19.6 months (HR = 0.44; p = 0.008). This was an increase of 10.1 months from prior.
- Luminal B: Subjects in the efti group reported a median OS of 16.8 months compared to 12.6 months in the comparator group, for a survival benefit of +4.2 months (HR = 0.67; p = 0.049). This was an increase of 0.5 months from prior.

Exhibit 1. Epidemiology and AIPAC study trial design. Breast cancer is the most frequently diagnosed cancer, ~70% of which includes a diagnosis of HR-/HER2+. In advanced/metastatic cancer, 1L treatment involves predominantly a combination of endocrine therapy with a CDK4/6 inhibitor. Once patients progress following CDK4/6 therapy, soc is chemo, which is insufficient in a majority of patients. **AIPAC Study.** In the AIPAC trial, patients received weekly paclitaxel on days 1, 8, and 15. On days 2 and 16 of each 4-week cycle, efti or placebo was administered, with treatment repeated for up to 6 cycles. After the cycles, patients went on to maintenance therapy with efti alone.



Source: Modified Immutep company presentation SITC 2021.

How the pivotal trial (AIPAC-003) design may differ. Since AIPAC was a European trial design, chemo paclitaxel was discontinued at 6 months. Given that an effect on PFS was initially observed when efti was administered in combination with paclitaxel, which shrank with the removal of paclitaxel (therein eliminating any PFS advantage), Immutep is expecting to combine both until progression (at least in the US study design). This strategy may demonstrate both an improvement in OS as well as PFS. That said, since OS is typically the standard primary endpoint in trials evaluating end-stage patients, the primary endpoint is also expected to be OS over PFS in the pivotal study. However, whether the study will be enriched for more than one subgroup has yet to be determined. Immutep is expected to initiate a Phase 3 study in mBC (AIPAC-003), pending regulatory discussions and feedback from the FDA and EMA on the trial design.

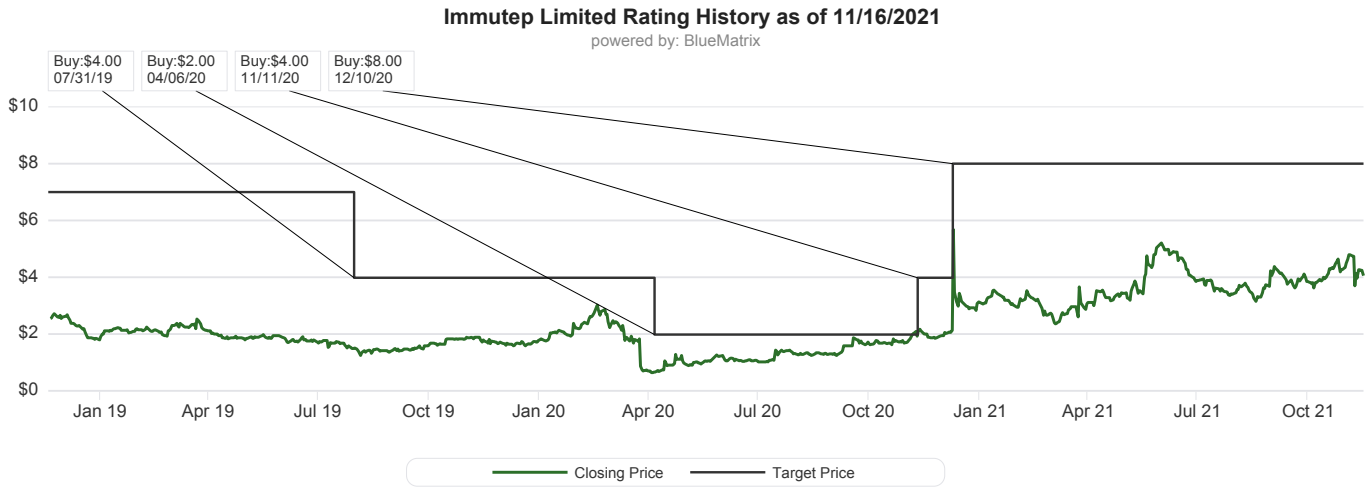
Exhibit 2. AIPAC results - efti/chemo combination is durable. Statistically significant survival benefit was observed for three key patient groups in final Phase 2b AIPAC study results. Patients saw sustained responses since the prior data readout on December 2020. Here, the study cut off was May 14, 2021. The minimum follow-up was 22 months.

	Reported: % of patients in efti group	December 2020 Paclitaxel + Placebo	December 2020 Paclitaxel + Efti	December 2020 OS benefit	November 2021 Paclitaxel + Placebo	November 2021 Paclitaxel + Efti	November 2021 OS benefit	Additiional OS benefit
Total Population (N=226)	100%	17.5	20.2	**+2.7** HR = 0.83 p = 0.14	17.5	20.4	**+2.9** HR = 0.88 p = 0.197	**+0.2** months
Subgroup								
< 65 years age (n=147)	66.7%	14.8	21.9	**+7.1** HR = 0.62 p = 0.012	14.8	22.3	**+7.5** HR = 0.66 p = 0.017	**+0.4** mos
Low monocyte counts (n=47)	21.9%	12.9	22.4	**+9.5** HR = 0.47 p = 0.02	12.9	32.5	**+19.6** HR = 0.44 p = 0.008	**+10.1** mos
Luminal B type (n=83)	48.8%	12.6	16.3	**+3.7** HR = 0.69 p = 0.077	12.6	16.8	**+4.2** HR = 0.67 p = 0.049	**+0.5** mos

Source: Immutep company reports SITC 2021.

Company overview: *Immutep is a clinical-stage biotechnology company that is focused on developing LAG-3 both as an immune stimulator and an immune suppressor, for cancer and for autoimmune diseases, respectively. The company's lead product candidate is eftilagimod alpha (efti), a soluble LAG-3 fusion protein, that is being evaluated in combination with chemotherapy or immune therapy for multiple advanced cancers. The company also has licensing deals with large pharma for additional LAG-3 products: GSK'781 with GlaxoSmithKline (GSK - NR) and LAG525 with Novartis (NVS - NR).*

DISCLOSURES



Maxim Group LLC Ratings Distribution		As of: 11/16/21	
		% 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.	**89%**	**53%**
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.	**11%**	**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*		

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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 (NYSE Biotechnology Index) as the relevant index.

Valuation Methods

IMMP: We forecast sales for efti in metastatic breast cancer in 2025 (EU, US) and in 2027 (China), in non-small-cell lung cancer in 2025 (EU, US), and in head and neck in 2024 (EU, US). We assume royalty revenues for LAG525 in 2025 (EU, US) and for GSK'781 in 2027 (EU, US). We use a 30% discount rate and attribute equal weighting to our FCF, discounted EPS and SOTP to derive our 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 is domiciled in Australia; (7) 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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