

Biotechnology

IMMP - NASDAQ December 10, 2020

Closing Price 12/9/20	\$2.16
Rating:	Buy
12-Month Target Price:	(prior \$4.00) \$8.00
52-Week Range:	\$0.53 - \$3.10
Market Cap (M):	106.5
Shares O/S (M):	49.3
Float:	NA
Avg. Daily Volume (000):	278.8
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



EVENT INFORMATION

Immutep Conference Call

Phase 2b AIPAC data to be presented
Today, December 10, 4:30pm ET

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Immutep Limited

Buy

Efti Was Out in Breast Cancer...Or Was it? Update from Ongoing SABCS meeting, Raising PT to \$8

Summary

- The San Antonio Breast Cancer Symposium (SABCS) is ongoing and yesterday (12/9), there was significant activity in the space, including from Immutep, whose update on its P2b program in metastatic breast cancer (mBC) (efti + chemo vs. placebo + chemo) last night has resulted in IMMP shares up over 100% in the pre-market. So...wasn't efti essentially out of breast cancer following the miss on PFS back in March? Most thought so, including us, but not Immutep, nor did its China-based partner EOC Pharma (private).
- The data around overall survival, particularly in pre-defined subgroups, suggests efti is having a meaningful and significant impact. The improvement in the ITT was 2.7 months but in patients under 65 years of age, which was 2/3 of the efti-treated patients, that improvement rose to 7.1 months. In low-monocyte count patients, the improvement was 9.4 months. There is more data to come in 1Q21 and concurrent with the SABCS data, EOC Pharma also announced it will start a new P2 efti trial in mBC in 1Q21 as well. IMMP conference call to discuss is today at 4:30pm ET ([LINK](#)).
- Given the data in March, we had previously removed an indication for efti in mBC from our model. However, considering the SABCS update, EOC's activity and the continued demonstration of efti's potential and progression in lung and H&N cancers, we factor back in mBC into our model. We apply a 75% risk adjustment in mBC based on clinical trial risk, stage of development, and the prior data. Immutep is also well-capitalized with ~\$38M in cash on the balance sheet. The net result is our PT increases to \$8, from \$4.

Details

Phase 2b AIPAC combination study overview. The trial is evaluating eftilagimod alpha (efti) in combination with paclitaxel chemotherapy in patients with HER2-/HR+ metastatic breast cancer. The trial is made up of two stages, a safety run-in stage, in which the Phase 2 dose of efti in conjunction with paclitaxel was determined, followed by the randomization stage. N=227 patients are randomized 1:1 to a combination of efti with frontline paclitaxel (n=114) vs. paclitaxel + placebo (n=112). Patients were treated with six cycles of therapy for four weeks comprising weekly 80 mg/m² doses of paclitaxel on days 1, 8, and 15 in addition to either 30mg efti or placebo on days 2 and 16 of each 4-week cycle. This will then be followed by a maintenance phase in which responsive or stable patients will receive a 30mg dose of efti or placebo every four weeks.

The primary endpoint of the study was progression free survival (PFS), which was missed in March of 2020. While the efti combination was numerically greater against SOC, it was not statistically significant. At 6-months, 63% of patients treated with efti +paclitaxel were progression-free vs. 54% of patients that received paclitaxel plus placebo (HR=0.93; p=0.341). Additionally, the overall response rate (ORR) for the study arm was 48.3% vs. 38.4% in the control arm. However, key secondary endpoints include overall survival (OS), adverse events (AEs), and duration of response (DOR) which is the subject of the data presented at SABCS 12/8 -12/12.

Phase 2b AIPAC trial update at SABCS, 12/9. Among the total patient population, as of the September 24 data cutoff date, a median overall survival (mOS) of 20.2 months was observed compared to 17.5 months in the active comparator arm (p=0.14, HR=0.83), not a statistically significant difference, but still meaningful. The delta on mOS then starts to widen as different pre-defined subgroups are evaluated for mOS. In patients under the age of 65 mOS delta was 21.9 vs. 14.8 months (p=0.012, HR=0.62). This actually represented 66.7% of the efti treated patients. Additionally, among patients with a low monocyte count, mOS was 22.4 months vs. 12.9 months (p=0.02, HR=0.47). We would note that this group is relatively

small, making up ~22% of efti treated patients. Among 48.8% of patients with a more aggressive and immunogenic luminal B type of breast cancer, an mOS of 16.3 months was noted compared to 12.6 months in the comparator arm ($p=0.077$, $HR=0.69$). It was also noted that it appeared that the control group experienced significant deterioration in QoL, whereas deterioration was not observed in the efti group. This readout was the first OS data at ~60% of events. Final data readout expected mid-2021 where we could see these OS deltas widen further and see also if the observed changes in QoL continue.

A significant increase in CD8 T cells in patients treated with efti and chemotherapy appeared to correlate with improved OS outcomes, providing proof-of-concept of efti's mechanism of action as an antigen presenting cell activator (APC activator). This then supports the rationale that tumor cell killing with chemotherapy is inducing immune activity which is enhanced by the APC-activating ability of efti. Recall it's a soluble LAG3, a checkpoint target that continues to gain traction in the space, led by groups like Bristol (BMY - NR) and Immutep, which has multiple large pharma partners for its LAG3 candidates.

New study coming in from partner EOC Pharma (private). Concurrent with the SABCS data came the announcement that China-based partner EOC Pharma plans commence phase 2 metastatic breast cancer study. The trial will enroll up to 152 patients in China and will take place across 20 clinical trial sites in the country over 24 months. Efti in combination with paclitaxel will be evaluated in HER2-/HR+ metastatic breast cancer patients who have progressed after undergoing endocrine therapy. EOC Pharma expects to enroll and dose its first patient in 1Q21.

DISCLOSURES

Immutep Limited Rating History as of 12/09/2020

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Maxim Group LLC Ratings Distribution		As of: 12/09/20	
		% 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%	54%
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%	49%
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, eftilagomod (efti) (royalty-free) in 2025 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 – 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.

Low – Fundamental Criteria: 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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ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST



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