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Biotechnology
Company Update
March 6, 2024
BUY
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Immutep Ltd.

Next Is Dose Optimization for BC Program; Reiterate Buy

IMMP (NASDAQ)

Company & Market Data	
Closing Price (as of 03/05/2024)	$2.61
Rating:	BUY
Price Target:	$8.30
52 Week Range:	$1.50 - $3.90
Shares Outstanding (MM):	118.9
Market Capitalization (MM):	$310
Cash (MM):	$70.5
Fiscal Year End:	Jun

*Cash $ as of December 31, 2023.

Estimates			
EPS	**2022A**	**2023A**	**2024E**
H1	—	$(0.24)	$(0.18)
H2	—	$(0.21)	$(0.18)
Full Year	$(0.39)	$(0.45)	$(0.36)
Revenue (MM)	**2022A**	**2023A**	**2024E**
H1	—	$1.7	$0.0
H2	—	$1.8	$0.0
Full Year	$4.7	$3.5	$0.0

Ratios			
P/E	NA	NA	NA

* Revenue (MM):In $AUD
* EPS:In $AUD

Chart data: Bloomberg

Immutep announced initial clinical data from the safety lead-in portion of the Phase 2/3 AIPAC-003 trial evaluating eftilagimod alpha (efti, soluble LAG-3 protein) in combination with paclitaxel for the treatment of metastatic HR+, HER2 negative/low breast cancer (BC) and triple-negative breast cancer (n=6 patients).

No concerning safety signals were observed, moving into the dose escalation.

This is the first data from the 90mg dose (high dose) of efti paired with paclitaxel (pacli), previous data assessed 30 mg (low dose).

- Among the six patients from the open-label, safety lead-in phase evaluating the 90mg dose of efti in combination with weekly pacli, a 50% ORR (1/6 CR, 2/3 PR) and 100% DCR (6/6) were achieved.
- These six patients were heavily pre-treated and had exhausted all endocrine therapy including CDK4/6 inhibitors.
- The combination of efti (90mg) and pacli revealed no treatment-emergent serious adverse events and all TEAEs during the safety observation period to date have been mild.

Following the completion of the safety lead-in portion, randomized Phase 2 dose optimization is underway. Currently, the Phase 2 portion of the trial has enrolled 23 patients (target 58 patients), and we expect to see further data updates in 2024. After Phase 2 dose optimization, the trial will advance to Phase 3 randomized, double-blinded, placebo-controlled portion with the selected dose.

What has been shown previously?

Previously, the Phase 2b AIPAC trial evaluated efti (30mg) paired with paclitaxel compared to pacli alone in patients (n=227) with HR+, HER2-negative metastatic breast cancer (mBC). Efti plus chemotherapy showed a significant survival benefit (our note) in predefined patient populations (+7.5 mos, +19.6 mos, +6.9 mos, +4.8 mos, and +4.2 mos in patients < 65 years, low monocytes, high NLR, diagnosed less than 5 years ago, and luminal B, respectively).

Recall, low dose efti (30mg)+paclitaxel demonstrated a 48% ORR (n=114, 1% CR, 47% PR) and 85% DCR compared with 38% ORR (n=112, 2% CR, 37% PR) and 76% DCR in the pacli alone group. Compared to this data (Phase 2b AIPAC trial, efti 30mg, n=114), efti (90mg)+paclitaxel (n=6) demonstrated consistent ORR (50% vs. 48%) and favorable DCR (100% vs. 85%).

Our view.

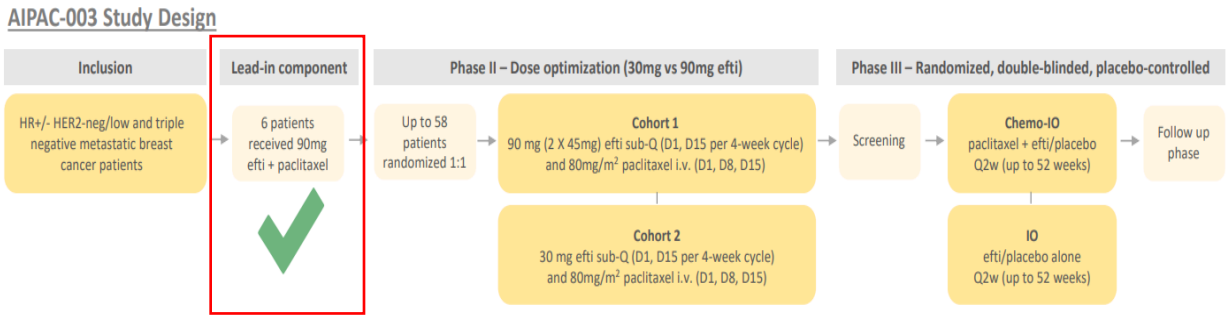
While we recognize significantly lower patient numbers with the high dose, we like there are no toxicity signals and there is a trend with favorable SD/DCR. The approved drugs to treat 2L(+) breast cancer received the nod from the agency based on the PFS primary endpoint, demonstrating improvements ranging from +1.5 mos to +10.9 mos (see Exhibit 2 for detailed comparison).

The primary endpoint of AIPAC-003 is OS. While the previous Phase 2b AIPAC trial did not show clear PFS improvements, significant survival benefits were evident in five predefined patient populations. It is encouraging to see the early efficacy of efti (90mg)+ pacli with a tolerable safety profile. We expect to see which dose is safe and more efficacious in this randomized Phase 2 portion of the AIPAC-003 trial.

Key potential catalysts. We see multiple value inflection points for IMMP including:

- The final design of TACTI-004, a Phase 3 registrational trial in 1L NSCLC, is anticipated in 1H24.
- Initial data from TACTI-003, the first placebo-controlled trial evaluating efti+pembro in 1L HNSCC, is expected in 1H24.
- Initial data from the investigator-initiated Phase 2 EFTISARC-NEO trial evaluating efti in combination with pembro and radiotherapy in soft tissue sarcoma in 1H24.
- Additional data from the Phase 2/3 AIPAC-003 trial evaluating efti+paclitaxel in metastatic breast cancer in 2024.

Exhibit 1. AIPAC-003 Study Design



Source: Company SEC Filings

Exhibit 2. Selected Approval Drugs to Treat Breast Cancer

Drug	Orserdu	Trodelvy		Enhertu		Kadcyla
Active Ingredient	elacestrant	sacituzumab govitecan-hziy		fam-trastuzumab deruxtecan-nxki		trastuzumab emtansine
MoA	ER antagonist that binds to estrogen receptor-alpha (ERα)	Trop 2-directed antibody-drug conjugate		HER2-directed antibody-drug conjugate		HER2-directed antibody-drug conjugate
Patients	ER+, HER2-negative, estrogen receptor 1 gene (ESR1) mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy	HR+,HER2-negative breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting	Triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease	HER2-positive breast cancer who have received a prior anti-HER2-based regimen	HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy	HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.
Treatment	Orserdu vs. Fulvestrant or an AI	Trodelvy vs. Chemo	Trodelvy vs. Chemo	Enhertu vs. Physician's Choice	Enhertu vs. Chemo	Kadcyla vs. Lapatinib+Capecitabine
Number	115 vs. 113	272 vs. 271	267 vs. 262	406 vs. 202	373 vs. 184	495 vs. 496
PFS	*3.8 mos vs. 1.9 mos; HR=0.55, p=0.0005	*5.5 mos vs. 4.0 mos; HR=0.661; p=0.0003	*4.8 mos vs. 1.7 mos; HR=0.43; p<0.0001	*17.8 mos vs. 6.9 mos; HR=0.36, p<0.0001	*9.9 mos vs. 6.1 mos; HR=0.5, p<0.0001	*9.6 mos vs. 6.4 mos; HR=0.65, p<0.0001
OS	83% vs. 74% (12 mos)	14.4 mos vs. 11.2 mos; HR=0.789; p=0.02	11.8 mos vs. 6.9 mos; HR=0.51; p<0.0001	39.2 mos vs. 26.5 mos; HR=0.66, p=0.0021	23.4 mos vs. 16.8 mos; HR=0.64, p=0.001	*30.9 mos vs. 25.1 mos; HR=0.682, p=0.0006
ORR		21% vs. 14%; p=0.0348		70% vs. 29%	52% vs. 16%	44% vs. 31%

* Primary Endpoint

Source: FDA.gov and Ladenburg Thalmann Research

Investment Risks

IMMP is subjected to many of the risks associated with investing in micro- to mid-cap biotech companies. In our view, the primary risks to an investment in IMMP shares include, but are not limited to:

Clinical risk. Although efti holds a great promise as an APC activator, there is an inherited risk in drug development. Immutep's efti has shown compelling results in multiple indications such as non-small cell lung cancer, head, and neck cancer; however, it has not yet been tested in a pivotal setting. In addition, none of the current data showed head-to-head comparison to a placebo control arm in the clinical setting. Despite the promise, we recognize further data validation will be key. Thus, similar to the situation with the anti-PD-L1 landscape, it remains to be clinically demonstrated which indication retaining or removing activity is better for the efficacy and safety profile.

Regulatory risk. The regulatory approval processes of the agencies (FDA or EMA) are lengthy, time-consuming, and inherently unpredictable. In the case of IMMP not obtaining regulatory approval for product candidates, its business will be materially adversely affected. If IMMP fails to comply with the U.S. or foreign regulatory requirements, regulatory authorities could withhold marketing or commercialization approvals, limit or withdraw any marketing or commercialization approvals the company may receive and subject the company to other penalties that could materially harm their business.

Competition risk. IMMP faces many direct and indirect competitions for its lead asset, efti. There are a large number of companies focusing on the development of APC activators, and also other assets in the indication efti being evaluated. All cancer indications IMMP is assessing including NSCLC, HNCLC, melanoma, and others, are highly competitive fields. If IMMP's products cannot demonstrate competitive differentiation from competing products, their commercial opportunities could be significantly impaired.

Financial risk. As with a majority of development-stage biotechnology companies, the ability to maintain sufficient funding is critical to the progress of pipeline candidates. Should the company experience problems raising sufficient capital, its development programs' progress could be significantly impeded, leading to both delays in development timelines as well as potential negative effects on investor confidence. Each of these could have a negative impact on the share price.

The company has a history of operating losses and may not achieve or maintain profitability in the future. The company us exposed to significant risks related to ongoing research and development efforts and might not be in a position to successfully develop any product candidate. Any failure to implement the company's business strategy could negatively impact business, financial condition and results of operations.

The company's status as an emerging growth company may reduce the amount of information available to investors.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact business, including non-clinical studies and clinical trials.

The company's ordinary shares may be considered a "penny stock" under SEC regulations which could adversely affect market trading in the company's ADSs. If the company is or becomes a passive foreign investment company (PFIC), then that would subject U.S. investors to adverse tax rules. Currency fluctuations may adversely affect the price of the ADSs relative to the price of the company's ordinary shares.

Australian takeovers laws may discourage takeover offers being made for the company or may discourage the acquisition of large numbers of the company's shares. Rights as a

holder of ordinary shares are governed by Australian law and Constitution which differ from the rights of shareholders under U.S. law. Holders of the company's ordinary shares or ADSs may have difficulty in effecting service of process in the United States or enforcing judgments obtained in the United States. The company is exposed to differing legal and tax laws in multiple jurisdictions, including complex transfer pricing rules in Australia.

APPENDIX A: IMPORTANT RESEARCH DISCLOSURES

ANALYST CERTIFICATION

I, Ahu Demir, 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, provided, however, that:

The research analyst primarily responsible for the preparation of this research report has or will receive compensation based upon various factors, including the volume of trading at the firm in the subject security, as well as the firm's total revenues, a portion of which is generated by investment banking activities.

Additional information regarding the contents of this publication will be furnished upon request. Please contact Ladenburg Thalmann, Compliance Department, 640 Fifth Avenue, 4th floor, New York, New York 10019 (or call 212-409-2000) for any information regarding current disclosures, and where applicable, relevant price charts, in regard to companies that are the subject of this research report.

COMPANY BACKGROUND

Immutep is a clinical-stage biotechnology company focused on the development of immune checkpoint LAG-3 (Lymphocyte Activating 3) therapeutics for oncology and autoimmune diseases. The lead asset Eftilagimod Alpha (efti or IMP321) is being assessed in combination with PD-1/PD-L1 agents or chemotherapy in numerous clinical trials in metastatic breast cancer, non-small-cell lung carcinoma (NSCLC), head and neck squamous cell carcinoma, solid tumors, melanoma, and soft tissue sarcoma. The second asset IMP761 is at the preclinical stage for autoimmune disease.

VALUATION METHODOLOGY

We value Immutep using a risk-adjusted discounted cash flow model. The DCF model is risk-adjusted for the probability of success of efti in clinical development. We used a probability estimate to account for financial, clinical, and regulatory risks. For our revenue estimates, we include HNSCC and mBC markets as the company plans to advance in these two indications. We included PD-1/PD-L1 agents in these indications and assume market penetration in the combination setting. We assigned a 50% probability of success in these indications. The model is based on data compiled by previous industry studies (Clinical Development Success Rates 2006-2015 by Bio (Biotechnology Innovation Organization), BioMedTracker, and Amplion). Using the Gordon Growth Method, we calculate a terminal value of $2.01 billion and arrive at our $8.30 price target.

RISKS

IMMP is subject to many of the risks associated with investing in micro- to mid-cap biotech companies. In our view, the primary risks to an investment in IMMP shares include, but are not limited to:

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STOCK RATING DEFINITIONS

Buy: The stock's return is expected to exceed 12.5% over the next twelve months.

Neutral: The stock's return is expected to be plus or minus 12.5% over the next twelve months.

Sell: The stock's return is expected to be negative 12.5% or more over the next twelve months.

Investment Ratings are determined by the ranges described above at the time of initiation of coverage, a change in risk, or a change in target price. At other times, the expected returns may fall outside of these ranges because of price movement and/or volatility. Such interim deviations from specified ranges will be permitted but will become subject to review.

RATINGS DISPERSION AND BANKING RELATIONSHIPS AS OF (March 6, 2024)

Rating	%	IB %
BUY	75.4	57.8
NEUTRAL	24.6	45.4
SELL	0.0	0.0

COMPANIES UNDER AHU'S COVERAGE

Aadi Bioscience, Inc. (AADI)
Cellectar Biosciences, Inc. (CLRB)
Evaxion Biotech A/S (EVAX)
Immutep Ltd. (IMMP)
Oryzon Genomics S.A. (ORY.SM)
Salarius Pharmaceuticals Inc. (SLRX)
Ayala Pharmaceuticals Inc. (ADXS)
Cyclacel Pharmaceuticals, Inc. (CYCC)
Immunocore Holdings plc (IMCR)
Onconova Therapeutics Inc. (ONTX)
Peak Bio, Inc. (PKBO)
Sonnet BioTherapeutics Holdings, Inc. (SONN)

COMPANY SPECIFIC DISCLOSURES

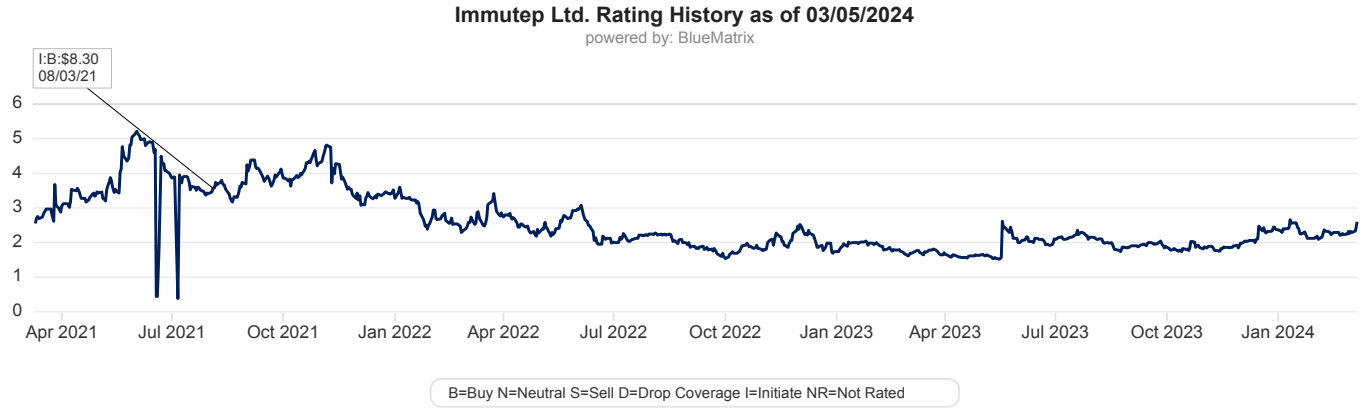
Ladenburg Thalmann & Co. Inc. intends to seek compensation for investment banking and/or advisory services from Immutep Ltd. within the next 3 months.

Ladenburg Thalmann & Co. Inc received compensation for investment banking services from Immutep Ltd. within the past 12 months.

Ladenburg Thalmann & Co. Inc had an investment banking relationship with Immutep Ltd. within the last 12 months.

Ladenburg Thalmann & Co Inc. acted in an advisory capacity for Immutep Ltd. in the last 12 months.

INVESTMENT RATING AND PRICE TARGET HISTORY



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