goetzpartners SECURITIES

FLASH NOTE

Immutep Limited (IMM-AU)

Data highlights efti efficacy and potential central role in cancer therapy

OUTPERFORM

Target Price AUD1.350
Current Price AUD0.565

KEY TAKEAWAY

Data presented SITC (Society for Immunotherapy of Cancer) not only further supports eftilagimod alpha ("efti") efficacy in metastatic breast ("mBC") and head and neck ("HNSCC") cancers, but also highlights a potential central role for efti across cancer therapy. Interim overall survival ("OS") from the AIPAC was already positive, this final data is slightly improved with a clear 2.9 month increase in OS with efti+ paclitaxel. While this was not statistically significant, there was a significant increase in quality of life ("QoL") across the population and in OS in large patient subgroups amounting to 60% of the population. This included patients <65 years, those pre-treated with CDK 4/6 treatment, with luminal B or particularly with a low starting monocyte count where there was an impressive 19.6-month OS increase. Further data from Phase IIa TACTI-002 supported the efficacy of efti-pembrolizumab ("efti-pembro") combination in HNSCC. These data not only support the continued development of efti in mBC in the AIPAC-03 Phase III and HNSCC in TACTI-003 Phase 2b, but also the broad potential of efti combinations in cancer therapy. Safe and well tolerated efti is already showing synergy with anti-PD-L1 and chemo, we believe analysis of the mBC subgroups could lead to additional combinations; particularly with agents that impact monocyte activity. We reiterate and maintain our OUTPERFORM recommendation and AUD$ 1.350 target price.

Firm basis to move to Phase 3 in mBC: There is now a strong basis for movement into Phase 3, with significant increases in final OS of 7.5, 5.3, 4.2, and 19.6 months in patients <65years, CDK 4/6 pre-treated, with luminal B or with low starting monocytes respectively. Although management is cautious in providing guidance on design with regulatory discussions ongoing, given that CDK 4/6 treatment is now standard and the impact of efti on QoL across the population, a standard of care ("SoC") all comers trial seems likely with close monitoring of the responsive patient groups. While AIPAC failed to achieve significance across the patient population, the AIPAC-03 Phase 3 will extend paclitaxel dosing beyond the six cycles used in Phase 2. This could boost the overall response. Given the strength of the AIPAC Phase 2 data and adoption of CDK 4/6 as SoC, we are optimistic for a positive outcome.

Strong results from TACTI-002 support Phase 2b entry: Encouraging results from their TACTI-002 phase IIa trial has been reported HNSCC patients, with overall Response Rate (ORR) in 29.7% of 2nd line HNSCC patients responding to the combination therapy of efti and pembrolizumab, with 13.5% having a complete response. All responses were durable, with no patients with a response progressing within 9 months. Also encouraging is the strong ORR (40.7%) in the patient subgroup traditionally considered poorly responsive to anti-PD-1/PD-L1 therapy (PD-L1 ≥1 group), highlighting potential of efti to expand utility of anti-PD-1/PD-L1 therapy in indications that poorly respond to monotherapy. The Phase IIb TACTI-003 received fast-track designation from the US FDA. Recruitment is now open in the US and Ukraine, with further sites expected to open in coming months; primary completion anticipated H1/2023E.

Expanding clinical development in the Chinese market: Immutep's Chinese partner EOC Pharma, announced plans to initiate a clinical study of efti in combination with an anti-PD-1 therapy in H1/2022E. This new trial builds on EOC's Phase II trial combining efti with chemotherapy in mBC. This is supported by the recent award of a patent in China for use of efti and anti-PD-1 / anti-PD-L1 combinations until 2036.

Potential for broad effective combinations drives long term value Although immediate focus is on AIPAC mBC and TACTI HNSCC / NSCLC programmes, we see real potential value from a broad range of efti combinations across multiple indications. Safe and well tolerated, data indicates the drug may find synergy with a broad range of drugs with different MoAs such as CCL2 inhibitors which modulate monocytes.

EQUITY RESEARCH

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COMPANY DESCRIPTION

Immutep (known as Prima BioMed until November 2017) is an Australian clinical-stage biotechnology company that develops immunotherapies for cancer and autoimmune diseases. Immutep is the global leader in the understanding of and in developing therapeutics that modulate Lymphocyte Activation Gene-3 (“LAG-3”). LAG-3 was discovered in 1990 at the Institut Gustave Roussy by Dr Frédéric Triebel, Immutep's Chief Scientific Officer and Chief Medical Officer. The company has three assets in clinical and one asset in preclinical development. The lead product candidate is eftilagimod alpha ("efti"), a first-in-class antigen presenting cell ("APC") activator being investigated in combination with chemotherapy or immune therapy for advanced breast cancer and melanoma. Immutep is dual-listed on the Australian Stock Exchange (“IMM”) and on the NASDAQ Global Market (“IMMP”) in the US (American Depository Receipts), and has operations in Europe, Australia, and the US. The company has licensing deals with Novartis, GSK and EOC (China only), and clinical trial collaboration and supply agreements with Merck & Co. and Merck KGaA / Pfizer, the latter for lead asset efti.

SCENARIOS

Base Case - GP Investment Case
Immutep generates further clinical data on efti and secures an outlicensing deal over the next 12 - 18 months.

Bluesky Scenario
N/A

Downside risk
Company is unable to generate further positive data on efti and fails to achieve licensing deal.

Peer Group Analysis

SWOT

Strengths: Global leadership position in LAG-3 with 4 LAG-3 related product candidates; many active clinical trials with readouts expected 2022E; strong performance of efti alongside many FDA-approved therapies; established collaborations with big players (Merck (MSD), Merck KGaA / Pfizer, Novartis and GSK).

Weaknesses: Sales growth in China dependent on EOC Pharma collaboration; single asset (efti) accounts for most of value and does not have strong efficacy data as a monotherapy; expired composition of matter patent means efti is only protected by use and formulation patents.

Opportunities: Provide a novel class of immunotherapy for use alongside many existing approved therapies across many cancer and auto-immune indications; efti may become the first immunotherapy licensed for use in MBC; M&A activity in the immune-oncology space.

Threats: Market entry by competitors and alternative therapies may erode sales; EMA and FDA approval for immune-oncology drugs subject to stringent criteria

INDUSTRY EXPECTATIONS

Immutep is developing immunotherapies for cancer, with a focus on the immune checkpoint LAG-3. The immune checkpoint inhibitor ("ICI") class has experienced rapid adoption since the launch of BMS's Yervoy (ipilimumab) in 2011, owing to their ability to elicit durable responses in 20 - 50% of patients for up to 10 years. The global ICI market was worth $16.8bn in 2018 and is expected to nearly triple by 2022E, driven largely by expanding use of existing therapies both in approved and new indications. The race is on to develop novel compounds with complementary mechanisms of action for combination therapy able to augment response rate without increasing toxicity, which, if successful, are expected to enjoy rapid uptake.

Important Disclosures: Non-Independent Research

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- (BIOTECH)
- (BIOTECHNOLOGY)
- (EOC PHARMA)
- Immutep Limited (IMM-AU)

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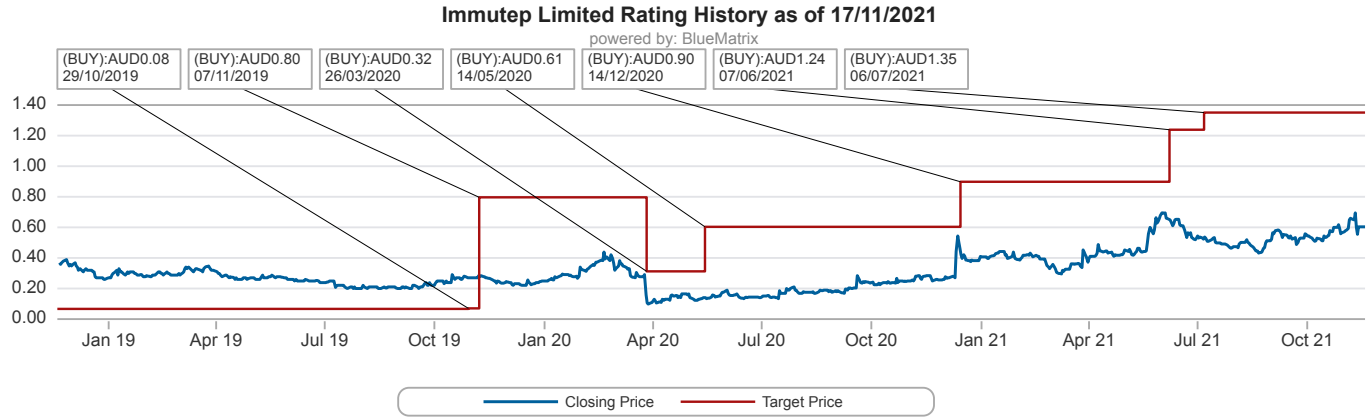

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GPSL has received compensation from Immutep Limited for the provision of research and advisory services within the previous twelve months.

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