



FLASH NOTE

Immutep Limited (IMM-AU)

FDA fast-tracks efti as chemo alternative in NSCLC

OUTPERFORM

Target Price AUD2.000

Current Price AUD0.270

KEY TAKEAWAY

FDA has granted Fast Track to eftilagimod alpha ("efti") in combination with Merck's anti-PD-1 therapy pembrolizumab ("pembro"), for first line treatment in NSCLC. Already with FDA Fast Track in head and neck cancer ("HNSCC"), the expedited review process was awarded based on the phase 2 data from the TACTI-002 study, indicating efti-PD-1 / L1 (PD-X) combinations could provide a safer and better tolerated alternative to the chemotherapy SoC in first line NSCLC, substantially expanding treatment responsive populations and decreasing toxicity-linked treatment discontinuation. Through Fast Track designation FDA acknowledges the potential benefits of efti-pembro combo over existing therapies. Allowing for more frequent meetings with the FDA and streamlining the trial design and approval process, a welcome lift as IMM plan for phase 3 efti-pembro NSCLC trial. Often speeding approvals, Fast Track takes IMM closer to the potential \$6bn opportunity in NSCLC. Other perks can include Rolling Review, Accelerated Approval and Priority Review. IMM has provided a constant flow of positive efti data across indications, including HNSCC and AIPAC metastatic breast ("mBC") phase 2b trial providing improvements in overall survival. We anticipate efti total peak sales of at least \$8bn; valuing the company at c.AUD 1.7bn (AUD 2.03 / share). The share price has been hit by market turbulence and flight from risk, but efti looks an attractive asset as PD-X patents expire. Financed to 2024E and with more data in the pipeline, IMM looks dramatically undervalued, in our view. We reiterate both our OUTPERFORM recommendation and our AUD \$2.00 target price.

Safer and better tolerated alternative to chemo: Governed by PD-L1 status,

PD-X- chemo is the current 1st line SoC for 70% of late-stage NSCLC patients. Pembro-efti combinations delivered a 42% overall response rate ("ORR") and 9.3-month median progression free survival ("mPFS") compared to 50% and 7.2 month with pembro-chemo SoC respectively. Avoiding the severe acute and long-term side effects, efti could provide an alternative to chemo for the majority of NSCLC patients.

Potential to expand responsive patient population: Safe and well tolerated, efti has already shown signs of synergy with chemo in the AIPAC Phase 2 in metastatic breast cancer ("mBC"). INSIGHT-003 is testing the additional first line impact of efti-PD-X-chemo triple therapy in NSCLC due to report first data Q4/2022E.

NSCLC opportunity in excess of \$6bn: The bulk of Merck's \$17.2bn pembro revenues come from NSCLC. With increased penetration from the substitution for chemo and triple therapy, we estimate that global peak revenues in NSCLC could reach \$6.5bn, with Fast Track designation hoping to expedite this launch.

Approaching PD-X patent expiry feed pharma appetite: Key patents are due to expire on PD-X products including pembrolizumab. Under threat from biosimilars, large pharma will be hungry for new products to protect and extend their proprietary markets; few other PD-X combos have delivered, and the chemo combo is not sufficient to extend patents.

Further opportunities in solid cancers: While NSCLC will be the focus for Phase 3, IMM will continue to explore opportunities in HNSCC and mBC. The ongoing TACTI-002 and -003 trials will continue to generate efti-PD-X combo data in HNSCC, where, with the right data, FDA Fast Track status could open the door to accelerated approval. Given the encouraging overall survival data, IMM will continue to talk to regulators and potential partners about the development of efti in breast cancer; the efti mBC programme in China should hopefully in any case move forwards.

EQUITY RESEARCH

DR. CHRIS REDHEAD
Research Analyst
T +44 (0) 203 859 7725
chris.redhead@goetzpartners.com

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 efitlagimod 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

Analyst Certification

I, Dr. Chris Redhead, hereby certify that the views regarding the companies and their securities expressed in this research report are accurate and are truly held. I have not received and will not receive direct or indirect compensation in exchange for expressing specific recommendations or views in this research report.

Meaning of goetzpartners Research Ratings

goetzpartners securities Limited ("GPSL") publishes investment recommendations, which reflect the analyst's assessment of a stock's potential relative return. Our research offers 4 recommendations or 'ratings':

OUTPERFORM - Describes stocks that we expect to provide a relative return (price appreciation plus yield) of 15% or more within a 12-month period.

NEUTRAL - Describes stocks that we expect to provide a relative return (price appreciation plus yield) of plus 15% or minus 10% within a 12-month period.

UNDERPERFORM - Describes stocks that we expect to provide a relative negative return (price appreciation plus yield) of 10% or more within a 12-month period.

NON-RATED – Describes stocks on which we provide general discussion and analysis of both up and downside risks but on which we do not give an investment recommendation.

Companies Mentioned in this report

- (BIOTECHNOLOGY)
- (BIOTECH)
- (MERCK)
- Immutep Limited (IMM-AU)

Valuation Methodology

GPSL's methodology for assigning recommendations may include the following: market capitalisation, maturity, growth / value, volatility and expected total return over the next 12 months. The target prices are based on several methodologies, which may include, but are not restricted to, analyses of market risk, growth rate, revenue stream, discounted cash flow (DCF), EBITDA, EPS, cash flow (CF), free cash flow (FCF), EV/EBITDA, P/E, PE/growth, P/CF, P/FCF, premium (discount)/average group EV/EBITDA, premium (discount)/average group P/E, sum of the parts, net asset value, dividend returns, and return on equity (ROE) over the next 12 months.

Frequency

This research will be reviewed at a frequency of 3 months. Any major changes to the planned frequency of coverage will be highlighted in future research reports.

Conflicts of interest

GPSL is required to disclose any conflicts of interest which may impair the firm's objectivity with respect to any research recommendations contained herein. Please click on the link to view the latest version of our [Conflicts of Interest policy](#).

We are also required to disclose any shareholdings of the firm or our affiliates in any relevant issuers which exceed 5% of the total issued share capital or any other significant financial interests held:

GPSL shareholdings in relevant issuers >5% - None.

GPSL wishes to disclose that it is party to a formal client agreement with Immutep Limited relating to the provision of advice and equity research services.

To avoid potential conflicts of interest arising, restrictions on personal account dealing are placed on analysts and other staff. The firm's personal account dealing policy expressly prohibits staff and / or relevant connected persons from dealing in the securities of a relevant issuer. Analysts must not trade in a manner contrary to their published recommendation or deal ahead of the publication of any research report.

If our contractual relationship with a client ceases, then please be advised that GPSL will no longer publish equity research on the specific client and any recipients of our equity research publications should not rely on our forecasts / valuation that have previously been published in the last full company research publication. Please note that GPSL will not publish a cessation of coverage notice to the market. Also, in accordance with the provision of MiFID2 – if any of our clients are not contractually paying GPSL to write and publish equity research, then we will not publish any future equity research publications to the market on the issuer until all of our unpaid fees have been fully paid.

To comply with the regulatory requirement to disclose. We disclose the monthly proportion of recommendations that are OUTPERFORM, NEUTRAL, UNDERPERFORM and NON-RATED. We also disclose a summary of the history of our analysts' investment recommendations (in accordance with EU MAR rules effective 3rd July 2016). goetzpartners publishes this information on the following link: [Research Summary](#).

This is a marketing communication. For professional investors and institutional use only. The information herein is considered to be an acceptable minor non-monetary benefit as defined under FCA COBS 2.3A19(5). GPSL is authorised and regulated by the Financial Conduct Authority (FRN 225563). GPSL does and seeks to do business with companies / issuers covered in its research reports. As a result, investors should be aware that GPSL may have a conflict of interest that could affect the objectivity of this research report. Investors should consider this research report as only a single factor in making their investment decision. GPSL has a formal client relationship with Immutep Limited.

Please see analyst certifications, important disclosure information, and information regarding the status of analysts on pages 3-5 of this research report.

Country-Specific Disclosures

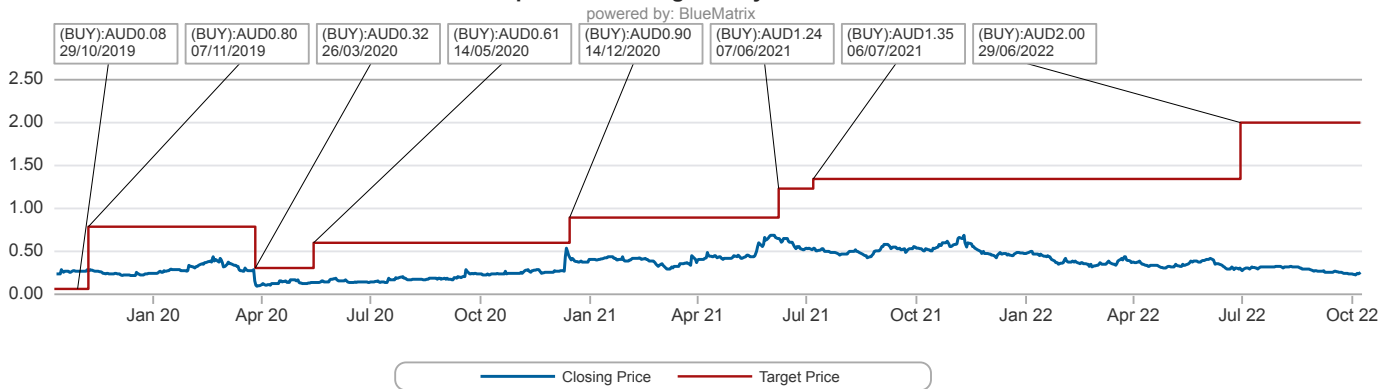
United Kingdom: goetzpartners securities Limited ("GPSL") is authorised and regulated by the Financial Conduct Authority ("FCA"); registered in England and Wales No. 04684144; Registered Office / Address: The Stanley Building, 7 Pancras Square, London, N1C 4AG, England, UK; telephone +44 (0)20 3859 7725. GPSL's FCA Firm Reference Number is: 225563. In the United Kingdom and European Economic Area, this research report has been prepared, issued and / or approved for distribution by GPSL and is intended for use only by persons who have, or have been assessed as having, suitable professional experience and expertise, or by persons to whom it can be otherwise lawfully distributed. It is not intended to be distributed or passed on, directly or indirectly, to any other class of persons. This marketing communication is classed as 'non-independent research' and, as such, has not been prepared in accordance with legal requirements designed to promote the independence of investment research. GPSL has adopted a Conflicts of Interest management policy in connection with the preparation and publication of research, the details of which are available upon request in writing to the Compliance Officer or on the web link above in the Conflicts of Interest section above. GPSL may allow its analysts to undertake private consultancy work. GPSL's conflicts management policy sets out the arrangements that the firm employs to manage any potential conflicts of interest that may arise as a result of such consultancy work.

Other EU Investors: This research report has been prepared and distributed by GPSL. This research report is a marketing communication for the purposes of Directive 2004/39/EC (MiFID). It has not been prepared in accordance with legal requirements designed to promote the independence of investment research, and it is not subject to any prohibition on dealing ahead of the dissemination of investment research. GPSL is authorised and regulated in the United Kingdom by the FCA in connection with its distribution and for the conduct of its investment business in the European Economic Area. This research report is intended for use only by persons who qualify as professional investors or eligible counterparties (institutional investors) in the applicable jurisdiction, and not by any private individuals or other persons who qualify as retail clients. Persons who are unsure of which investor category applies to them should seek professional advice before placing reliance upon or acting upon any of the recommendations contained herein.

U.S. PERSONS: This research report has been prepared by GPSL, which is authorised to engage in securities activities in England and Wales and to conduct designated investment business in the European Economic Area. GPSL is not a registered broker-dealer in the United States of America and therefore is not subject to U.S. rules regarding the preparation of research reports and the independence of research analysts. This research report is provided for distribution in the United States solely to "major U.S. institutional investors" as defined in Rule 15a-6 under the Securities Exchange Act of 1934.

Other countries: Laws and regulations of other countries may also restrict the distribution of this research report. Persons in possession of research publications should inform themselves about possible legal restrictions and observe them accordingly.

Immutep Limited Rating History as of 07/10/2022



Risks

This is a marketing communication as defined by the Financial Conduct Authority ("FCA"). The information herein is considered an acceptable minor non-monetary benefit as defined under FCA COBS 2.3A19(5). Information relating to any company or security is for information purposes only and should not be interpreted as a solicitation to buy or sell any security or to make any investment. The information in this research report has been compiled from sources believed to be reliable, but it has not been independently verified. No representation is made as to its accuracy or completeness, no reliance should be placed on it and no liability is accepted for any loss arising from reliance on it, except to the extent required by the applicable law. All expressions of opinion are subject to change without notice. Opinions, projections, forecasts or estimates may be personal to the author and may not reflect the opinions of goetzpartners securities Limited ("GPSL"). They reflect only the current views of the author at the date of the research report and are subject to change without notice. GPSL's research reports are not intended for Retail Clients as defined by the FCA. This research report is intended for professional clients only. Research reports are for information purposes only and shall not be construed as an offer or solicitation for the subscription or purchase or sale of any securities, or as an invitation, inducement or intermediation for the sale, subscription or purchase of any securities, or for engaging in any other transaction. The analysis, opinions, projections, forecasts and estimates expressed in research reports were in no way affected or influenced by the issuer. The authors of research reports benefit financially from the overall success of GPSL. The investments referred to in research reports may not be suitable for all recipients. Recipients are urged to base their investment decisions upon their own appropriate investigations. Any loss or other consequence arising from the use of the material contained in a research report shall be the sole and exclusive responsibility of the investor and GPSL accepts no liability for any such loss or consequence. In the

This is a marketing communication. For professional investors and institutional use only. The information herein is considered to be an acceptable minor non-monetary benefit as defined under FCA COBS 2.3A19(5). GPSL is authorised and regulated by the Financial Conduct Authority (FRN 225563). GPSL does and seeks to do business with companies / issuers covered in its research reports. As a result, investors should beware that GPSL may have a conflict of interest that could affect the objectivity of this research report. Investors should consider this research report as only a single factor in making their investment decision. GPSL has a formal client relationship with Immutep Limited.

Please see analyst certifications, important disclosure information, and information regarding the status of analysts on pages 3-5 of this research report.

event of any doubt regarding any investment, recipients should contact their own investment, legal and / or tax advisers to seek advice regarding the appropriateness of investing. Some of the investments mentioned in research reports may not be readily liquid investments which may be difficult to sell or realise. Past performance and forecasts are not a reliable indicator of future results or performance. The value of investments and the income derived from them may fall as well as rise and investors may not get back the amount invested. Some investments discussed in research publications may have a high level of volatility. High volatility investments may experience sudden and large falls in their value which may cause losses. Some of the information or data in this research report may rely on figures denominated in a currency other than that of GBP (the currency should be stated), the return may increase or decrease as a result of currency fluctuations. International investment includes risks related to political and economic uncertainties of foreign countries, as well as currency risk. To the extent permitted by applicable law, no liability whatsoever is accepted for any direct or consequential loss, damages, costs or prejudices whatsoever arising from the use of research reports or their contents.

GPSL record electronic and phone communications in accordance with FCA and MiFID2 regulations, they are monitored for regulatory and training purposes.

Compensation

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

IMM-AU

AUD2.000 | Company Update
9 October 2022

goetzpartners securities Limited

The Stanley Building, 7 Pancras Square, London, N1C 4AG, England, UK.

Tel: +44 (0)203 859 7725

www.goetzpartnerssecurities.com