

Immutep Ltd (IMMP)

Immutep Presents Updated Data from Ongoing TACTI-Mel Study

Yesterday, Immutep (Nasdaq: IMMP) presented updated data from parts A and B of TACTI-Mel, the ongoing Phase I study of IMP-321 in combination with Merck's (NYSE: MRK) *Keytruda* (pembrolizumab) for patients with metastatic melanoma. The presentation can be accessed [here](#). As a reminder, Part A previously demonstrated an ORR of 33% in 18 evaluable patients when evaluating response from day 1, cycle 5, which marks the beginning of combination dosing and Part B previously demonstrated a 50% ORR in 6 evaluable patients. Notably, the updated data featured long-term follow-up of patients in part A, with durable responses going beyond 33 months as well as more mature data from Part B extending beyond 8 months. Additionally, this morning the Company announced dosing of the first patient in TACTI-002, a Phase II study evaluating the IMP-321 + *Keytruda* combination in patients with HNSCC and NSCLC.

- The TACTI-Mel Trial Design.** TACTI-mel is an open-label, phase I study of IMP-321 in combination with *Keytruda* in patients with unresectable or metastatic melanoma. Part A of the study enrolled 18 patients with “suboptimal” responses to checkpoint therapy in 3 dose cohorts. These patients received the combination starting at day 1, cycle 5 of *Keytruda* therapy. Part B enrolled 6 patients to receive the combination from day 1, cycle 1 at the dose determined in part A. These patients also received 2mg/kg dosing of pembrolizumab.
- Updated Data from Parts A and B.** Tumor responses in this trial were evaluated by immune-related response criteria (irRC) in place of conventionally used RECIST guidelines. The Company previously reported an ORR of 33% in part A, when evaluating response from cycle 5 of *Keytruda* following the initiation of combination therapy. ORR when evaluating from the beginning of the trial was 61%. Notably, 1 iCR was reported. Longer-term follow-up showed durable on-going responses beyond 33 months. Efficacy data from Part A is summarized in **Figure 1**. Immutep additionally presented more mature data from Part B. As shown in **Figure 2**, 3 PRs were noted for an ORR of 50%. Treatment is ongoing in 4 patients, all greater than 6 months. Additionally, the Company presented some initial data on blood pharmacodynamics. Dosing with IMP-321 led to increases in IFN- γ concentrations and showed increases in CD4⁺ and CD8⁺ activated T-cells from baseline.

Expected Upcoming Milestones

- Q1 2019 – Initiation of INSIGHT-004 in advanced solid malignancies.
- H2 2019 – Primary progression free survival data from AIPAC in TNBC.
- 2019 – Initial data from TACTI-002 and INSIGHT-004.

Analysts

Sam Slutsky
(212) 915-2573
sslutsky@lifescicapital.com

Nicole Bezuevsky
(646) 876-5059
nbezuevsky@lifescicapital.com

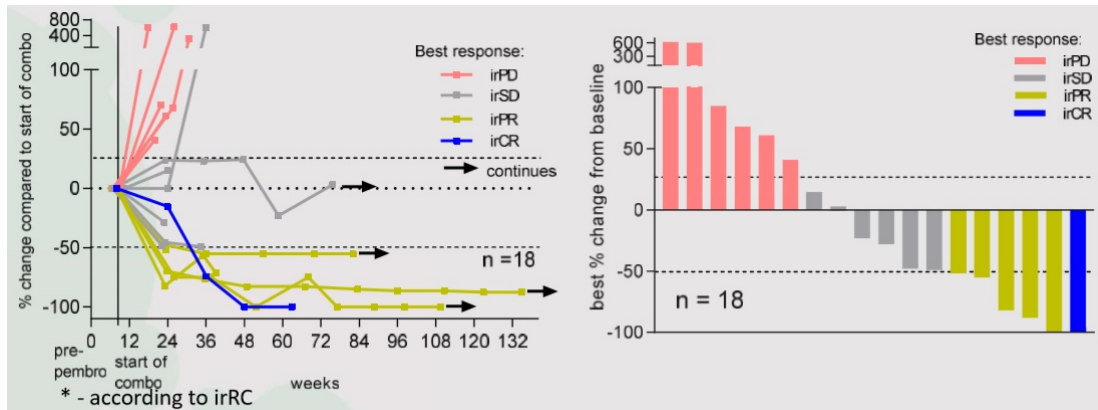
Market Data

Price	\$2.33
Market Cap (M)	\$79
EV (M)	\$53
Shares Outstanding (M)	33.8
Fully Diluted Shares (M)	43.7
Avg Daily Vol	46,228
52-week Range:	\$1.70 - \$4.21
Cash (M)*	\$26.0
Net Cash/Share	\$0.77
Annualized Cash Burn (M)	\$17.3
Years of Cash Left	1.5
Debt (M)	\$0.0
Short Interest (M)	0.11
*	

Financials

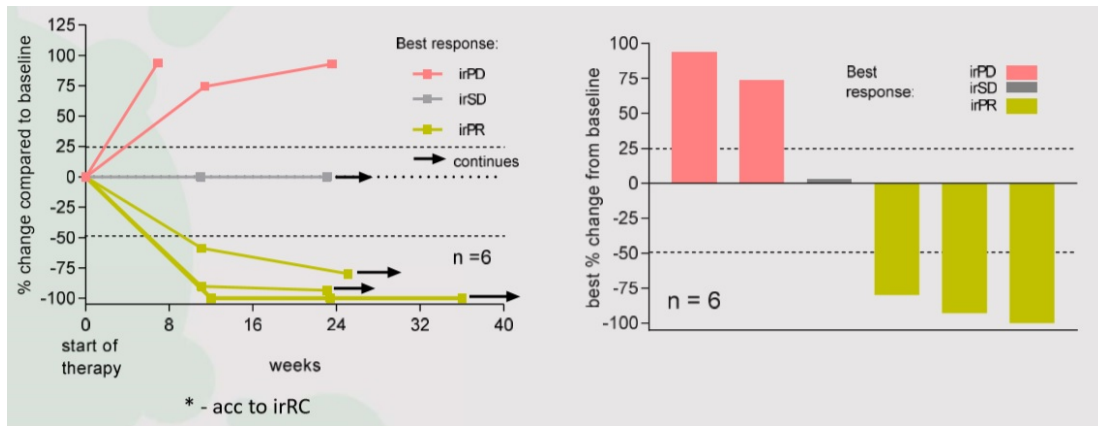
FY Jun	2017A	2018A	2019A
EPS H1	(0.19)	(0.18)	NA
H2	NA	NA	NA
FY	(0.41)	(0.49)	NA

Figure 1. Efficacy Results from Part A



Source: Company Presentation, World Immunotherapy Congress USA 2019

Figure 2. Efficacy Results from Part B



Source: Company Presentation, World Immunotherapy Congress USA 2019

- First Patient Dosed in TACTI-002 in HNSCC and NSCLC.** This morning, Immutep announced the dosing of the first patient in the Phase II trial, [TACTI-002](#), evaluating the combination of IMP-321 with *Keytruda* in patients with head and neck squamous cell carcinoma (HNSCC) and non-small cell lung cancer (NSCLC). The study will follow a Simon two-stage design and enroll up to 109 patients. All patients will be dosed with the standard *Keytruda* dose of 200mg every 3 weeks in combination with 30mg of IMP-321 every 2 weeks for the first 8 cycles, and then every 3 weeks starting with cycle 9. The primary endpoint is ORR. Secondary endpoints include response duration, disease control rate, PFS and OS. Response-related endpoints will be evaluating with either iRECIST or RECIST 1.1 criteria. As a reminder, this study is being completed as part of a trial collaboration and supply agreement with Merck. Initial data are expected before YE 2019.
- Busy Year Ahead for 2019.** The Company plans one more trial evaluating IMP-321, INSIGHT-004, in early 2019. INSIGHT-004 will serve as an amendment to the ongoing investigator-initiated INSIGHT trial and will evaluate IMP-321 in combination with Pfizer's (NYSE: PFE) *Bavencio* (avelumab) in patients with advanced solid malignancies. No trial design details have been provided at this time, but the study is anticipated to enroll ~12 patients. Initial data readouts for INSIGHT-004 and TACTI-002 could come throughout 2019. Additionally, primary progression-free survival data for the 226 patients in the AIPAC metastatic breast cancer trial are anticipated for H2 2019. The trial is evaluating the combination of IMP-321 and paclitaxel chemotherapy in triple-negative breast cancer. The preliminary data from the 15-patient safety run-in stage showed 7 PRs and 6 SDs. As both TACTI-002 and AIPAC will demonstrate results on substantially larger datasets of 100+ patients, these readouts should provide good insights on the activity of IMP-321.

Risk to Investment

We consider an investment in Immutep to be a high-risk investment. Immutep is a development stage company with no history of taking a treatment to market, and currently with no FDA approved drugs in its portfolio. There are several other companies trying to target the same indications as Immutep, and the cancer treatment pipeline is especially crowded with competitors. Immutep lead program has not yet generated pivotal data and has limited clinical data to date. Furthermore, early indications of efficacy do not necessarily translate into positive late-stage results. As with any company, Immutep may be unable to obtain sufficient capital to fund planned development programs. There are regulatory risks associated with the development of any drug and Immutep may not receive FDA approval for its candidates despite significant time and financial investments. Regulatory approval to market and sell a drug does not guarantee that the drug will penetrate the market, and sales may not meet the expectations of investors.

Analyst Certification

The research analyst denoted by an “AC” on the cover of this report certifies (or, where multiple research analysts are primarily responsible for this report, the research analyst denoted by an “AC” on the cover or within the document individually certifies), with respect to each security or subject company that the research analyst covers in this research, that: (1) all of the views expressed in this report accurately reflect his or her personal views about any and all of the subject securities or subject companies, and (2) no part of any of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst(s) in this report.

DISCLOSURES

Neither the research analyst(s), a member of the research analyst's household, nor any individual directly involved in the preparation of this report has a financial interest in the securities of the subject company/companies.

LSC (or an affiliate) has received compensation from Immutep Ltd for producing this research report. LSC is paid a monthly payment of \$1,000 from the Affiliate for preparing and distributing research pertaining to each subject company under contract with the Affiliate. The subject company of this report is covered by this arrangement between LSC and the Affiliate, and LSC has therefore indirectly received compensation from the subject company for publishing this report. No explicit or implicit promises of favorable research coverage have been made to the subject company by LSC or the Affiliate. Neither LSC nor the Affiliate has promised any specific research content as an inducement for the receipt of business or compensation.

LSC (or an affiliate) has provided non-investment banking securities-related services, non-securities services, and other products or services other than investment banking services to Immutep Ltd and received compensation for such services within the past 12 months.

Neither LSC nor any of its affiliates beneficially own 1% or more of any class of common equity securities of the subject company/companies.

This research contains the views, opinions and recommendations of LifeSci Capital, LLC (“LSC”) research analysts.

Additionally, LSC expects to receive or intends to seek compensation for investment banking services from the subject company/companies in the next three months.

LSC does not make a market in the securities of the subject company/companies.

LSC is a member of FINRA and SIPC. Information used in the preparation of this report has been obtained from sources believed to be reliable, but LSC does not warrant its completeness or accuracy except with respect to any disclosures relative to LSC and/or its affiliates and the analyst's involvement with the company that is the subject of the research. Any pricing is as of the close of market for the securities discussed, unless otherwise stated. Opinions and estimates constitute LSC's judgment as of the date of this report and are subject to change without notice. Past performance is not indicative of future results. This material is not intended as an offer or solicitation for the purchase or sale of any financial instrument. The opinions and recommendations herein do not take into account individual client circumstances, objectives, or needs and are not intended as recommendations of particular securities, companies, financial instruments or strategies to particular clients. The recipient of this report must make his/her/its own independent decisions regarding any securities or financial instruments mentioned herein. Periodic updates may be provided on companies/industries based on company specific developments or announcements, market conditions or any other publicly available information. Additional information is available upon request.

Please visit <http://www.lifescicapital.com/equity-research/> for disclosures related to each company that is a subject of this report. Alternatively, please contact us by telephone at (646) 597-6991 or by mail at LifeSci Capital LLC, Attn: Compliance, 250 West 55th Street, Suite 3401, New York, NY 10019 to obtain disclosures relating to any of the companies that are the subject of this report.

No part of this report may be reproduced in any form without the express written permission of LSC. Copyright 2019.