Immutep Limited

Data From TACTI-002 Continues to be Positive, Activity In the Space Bodes Well for Immutep

Summary

- Immutep reported further positive interim data on 4/27 from its ongoing TACTI-002 trial (from Parts A and C) at this year’s American Association for Cancer Research (AACR) Virtual Annual Meeting.
- Recall, TACTI-002 is a collaboration with Merck (MRK - NR), evaluating efti in combination with Keytruda (pembrolizumab) in a multicenter, open-label P2 study in two cancer types (lung and head and neck).
- TACTI-002 is looking at all patient tumor types (low, medium, and high PD-L1 expression). While small in patient number, efti + pembro continue to demonstrate overall response rates (ORR) that are numerically greater than historical pembro alone in both lung and head and neck cancers. We remain encouraged by the combination data. Given the challenge of demonstrating durability and survival benefit in these cancers, combination will be key to address the void, in our view.

Details

AACR data presented. Key to remember is that responses observed in TACTI-002 to date are regardless of PD-L1 expression.

- 1L non-small cell lung cancer (NSCLC, Part A): Albeit in a relatively small patient size (N=17), ORR was 53%; thus deepening from the earlier reported ORR of 47% in February and 41.2% ORR reported in September, with 71% of patients exhibiting tumor shrinkage. The data compares favorably to (historical) Keytruda monotherapy where response rates with high PD-L1 expressors are ~40%, whereas responses with all-comers (varying PD-L1 distribution) are even lower at ~20%-25%. Additionally, although median progression free survival (PFS) has not yet been reached, PFS reported is 8+ months.
- 2L head and neck (HNSCC, Part C): 33% ORR was seen in head and neck, which is consistent with a prior interim look. For reference, Keytruda was approved based on an ORR of 16% lasting for ≥6 months for 82% of patients and chemo in the same patient type has an ORR of 10.1%. Furthermore, 44% of patients had observable target tumor shrinkage. Median PFS has not yet been reached.

Activity in the space: Coincidentally, Regeneron (REGN - NR) and Sanofi (SNY - NR) also announced on 4/27 that its P3 trial comparing Libtayo (PD-1) monotherapy to platinum doublet chemotherapy in 1L lung cancer was stopped early, having met the primary endpoint of overall survival. Although this would make Libtayo only the second PD-1 inhibitor to show survival benefit in 1L lung cancer other than pembro and is positive news for the space, the study enrolled patients that had high PD-L1 expression (i.e. positive for PD-L1 in ≥50% of tumor cells). As such, there remains an unmet need for the treatment of >60% of patients where PD-1/PD-L1 inhibitors are not effective.

The Phase 2 TACTI-002 study (collaboration with Merck) is evaluating efti in combination with PD-1 inhibitor, Keytruda (pembrolizumab) in two cancer types, enrolling N=109 (74 enrolled to date) across 12 sites in the US, EU, and Australia. The primary endpoint of the P2 study is an objective response rate (ORR) in accordance with iRECIST. The study design has three cohorts (Parts A, B, C): Part A: 1L NSCLC in PDX naive - Stage 1 is fully enrolled (17/17); Stage 2 is recruiting; Part B: 2L NSCLC in PDX refractory - Stage 1 is nearing enrollment completion (17/23 last reported); Stage 2 to begin enrollment thereafter. Part C: 2L in head and neck (HNSCC) in PDX naive - Stage 1 is fully enrolled (18/18); Stage 2 recruitment is ongoing.
Financial update. Immutep completed a ~$7.8M (A$12M) equity financing on 4/28; 96M shares at 12.5c (A$) per share, representing 960K ADSs. Immutep expects the additional funds to extend its runway to the end of CY21.
<table>
<thead>
<tr>
<th>Income Statement ($'000, USD)</th>
<th>July-Dec</th>
<th>Jan-Jun</th>
</tr>
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<tbody>
<tr>
<td>Revenue (000's)</td>
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<td>-</td>
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<tr>
<td>Total Revenues</td>
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<tr>
<td>License revenue</td>
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<td>Miscellaneous income</td>
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<td>Milestones and Royalties:</td>
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<tr>
<td>IMP321 (Melanoma)</td>
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</tr>
<tr>
<td>IMP731 (Psoriasis)</td>
<td>893</td>
<td>893</td>
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<tr>
<td>IMP701 (Solid tumors)</td>
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<td>1,541</td>
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<td>CVac</td>
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<tr>
<td>Expenses</td>
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<tr>
<td>Cost Of Goods Sold</td>
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<tr>
<td>Research &amp; Development</td>
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<tr>
<td>General &amp; Administrative Expense</td>
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<td>Depreciation and amortization</td>
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<tr>
<td>Total expenses</td>
<td>19,633</td>
<td>14,090</td>
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<tr>
<td>Pre-tax income</td>
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<td>(9,431)</td>
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<td>Pretax Margin</td>
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<td>Taxes (or benefits)</td>
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<td>(1)</td>
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<td>Tax Rate</td>
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<tr>
<td>GAAP Net Income (loss)</td>
<td>(7,101)</td>
<td>(9,345)</td>
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<tr>
<td>Total Comprehensive Income (loss)</td>
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<td>(8,103)</td>
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<td>GAAP EPS</td>
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<td>0.34</td>
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<td>Wgtd Avg Shrs (Bas) - '000s</td>
<td>22,111</td>
<td>23,799</td>
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<tr>
<td>Wgtd Avg Shrs (Dil) - '000s</td>
<td>22,111</td>
<td>23,799</td>
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Source: Company reports and Maxim Group LLC
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 each LAG-3 product, initially with IMP701 and IMP731 in 2020 and followed by IMP321 in 2023 (breast cancer). 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) 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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