WILSONS ADVISORY

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Theme Alert

Sector Healthcare

Company

Immutep Limited (IMM)

TACTI-003: the real results

Recommendation OVERWEIGHT

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Announcement Highlights

Immutep announced topline data from their TACTI-003 trial in in first line head and neck squamous cell carcinoma (1L HNSCC). We should make this very clear: from the results released today Efti in combination with pembrolizumab (KEYTRUDA) demonstrated superior objective response rates (ORR) compared to KEYTRUDA alone, regardless of level of PD-L1 expression (including Cohort A and B: CPS < 1, CPS ≥ 1, CPS 1-19, CPS ≥ 20). Given the size of the trial, (n=58 and n=60 in combo and monotherapy arms respectively), we had low expectations that the trial would show statistical significance, given it was not powered to do so. The aberration of higher ORR in the KEYTRUDA monotherapy arm in the CPS 1-19 group (33.3% vs 14.5% based on historical data) does invite questions regarding if the data is 'clear enough' for accelerated approval (AA) (with a larger Phase III to be conducted alongside commercialization) however clear factors enhancing the KEYTRUDA arm (gender, smoking status, HPV status etc.) have highlighted why in this population, this may have been the case, and again not uncommon given the size of the trial. The market is also completely ignoring that Immutep have announced that data from Part B (CPS <1, 'cold tumour' cohort) has substantially improved from early data release in April - ORR of 26.9%, which already demonstrated >5x vs KEYTRUDA monotherapy in this cohort. Management's early guidance to ORR of ~34% (regardless of expression level), would suggest that this 26.9% number is >35%. The market has yet again misread Immutep and should represent an obvious buying opportunity.

Wilsons' View

Initial analysis

Figure 1: Objective response rates (ORR) by PD-L1 expression levels

	Efti + pembrolizumab	Pembrolizumab monotherapy
High PD-L1 expression (CPS ≥20)	31.0% (n=29)	18.5% (n=27)
Low PD-L1 expression (CPS 1-19)	34.5% (n=29)	33.3% (n=33)
Any PD-L1 expression (CPS ≥ 1)	32.8% (n=58)	26.7% (n=60)
Negative PD-L1 expression (CPS < 1)	26.9%* (N=26)	N/A

*based on April data release. Source: Immutep.

Our expectations for this study were to see benefit in one or two of the PD-L1 cohorts within Part A (PD-L1 CPS 1-19 or CPS>20) in terms of a meaningfully greater ORR response over Keytruda monotherapy – with no added safety burden. Our prior ballpark thinking was an ORR of +10% vs a historical control ballpark ORR of 20% (Keynote-048 trial ORR was 16.9%), equating to the ORR we saw in the 2L TACTI-002 trial of ~30% (of course noting differences between 1L and 2L populations). The expectation to see statistical significance was low purely based on the size of the trial and it not being adequately powered to potentially see differences.

Earnings implications

None. The results today were in line with expectations. To note our ROV for Efti in HNSCC incorporates 55% probability of moving to accelerated approval (incorporating a A$35M Phase III trial which is required regardless)s. Our commercialisation timeline for HNSCC is for first revenues from FY28e noting that an AA would bring this closer and hence be beneficial to valuation.

Investment view

We maintain our OVERWEIGHT rating and $1.13/sh PT for Immutep.

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