WILSONS ADVISORY

Date 15 May 2025

Theme Alert

Sector Healthcare

Company

Immutep Limited (IMM)

INSIGHT-003 | Even in the arctic tumours

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Investment View

We maintain our OVERWEIGHT rating and $1.05/sh risked PT on Immutep. The combination of Efti, KEYTRUDA and doublet chemotherapy has achieved impressive ORR and DCR in the INSIGHT-003 study, besting all rival IO/chemo regimens. The data confirms Efti's differentiated mechanism and is a foretaste of what to expect from the pivotal Phase III in NSCLC (TACTI-004).

Announcement Highlights

Immutep have announced updated data from the INSIGHT-003 study in 1L non-small cell lung cancer (NSCLC) evaluating Efti in combination with KEUTRUDA (pembrolizumab) anti-PD-1 and chemotherapy (carboplatin and pemetrexed). This data cut-off date continues to build upon previous results with all evaluable patients (n=51) demonstrating 60.8% overall response rate (ORR) and 90.2% disease control rate (DCR). As an all-comers trial, evaluable patients are skewed towards low/no PD-L1 expression in their tumours with 92% PD-L1 TPS <50% and 43% PD-L1 <1%. These results continue to build confidence in Immutep's planned (n=750) TACTI-004 pivotal Phase III in 1L NSCLC, which features mOS and mPFS as dual primary endpoints.

Wilsons' View

Initial analysis

INSIGHT-003 continues to impress with a 60.8% ORR regardless of PD-L1 expression and is a substantial improvement over comparator trials. MSD's registration study KEYNOTE-189 (anti-PD-1+Chemo) achieved just 48% ORR in a 'hotter' PD-L1 population (32% v 8% TPS <50%). The INSIGHT-003 results are impressive due to the patient population being skewed towards TPS <50% which account for 2/3 of the 1L NSCLC population. Both absolute and relative efficacy deltas were highest in the coldest tumours (TPS < 1% - 35% of incident mNSCLC). ORR and DCR improved with increasing PD-1 TPS with DCR reaching 100% in the 4 patients with TPS >50%. These data bode well for TACTI-004, which is far and away MSD's most ambitious potential extension for KEYTRUDA as the only Phase III collaboration in 1L mNSCLC that is PD-L1 agnostic[1].

Figure 1: Selected comparator trials relevant to INSIGHT-003 interpretation

	Efti + anti-PD-1 + doublet chemo	**pembrolizumab + doublet chemo**	**atezolizumab + doublet chemo**	**nivolumab + chemo**	**relatlimab/nivolumab + chemo**
Targets	APC activator + Anti-PD-1 + chemo	Anti-PD-1 + chemo	Anti-PD-L1 + chemo	Anti-PD-1 + chemo	Anti-LAG-3 + Anti-PD-1 + chemo
Study	**INSIGHT-003**	**KEYNOTE-189**	**IMpower130**	**RELATIVITY-104**	
Indication	advanced/metastatic non-squamous NSCLC	advanced/metastatic non-squamous NSCLC	advanced/metastatic non-squamous NSCLC	advanced/metastatic NSCLC	advanced/metastatic NSCLC
Phase	II (IIT)	III	III	II	II
Therapy Line	1st	1st	1st	1st	1st
n	51	410	483	151	158
PD-L1 TPS <1%	43%	68%	81%	49%	47%
PD-L1 TPS 1-49%	49%			NR	NR
PD-L1 TPS ≥ 50%	8%	32%	19%	NR	NR
ORR (all PD-L1)	**60.8%**	**48.0%**	**49.2%**	**38.5%**	**46.7%**
ORR TPS <1%	54.5%	32.3%	NR	44.8%	50%
ORR TPS 1-49%	64.0%	49.0%	NR	NR	NR
ORR TPS ≥50%	75.0%	62.1%	NR	NR	NR
mPFS (all PD-L1)	**12.7 months**	**8.8 months**	**7.0 months**	**8.3 months (NSQ only)**	**6.0 months (NSQ only)**
DCR (all PD-L1)	**90%**	**84.6%**	**79.6%**	**NR**	**NR**
DCR TPS <1%	86.4%	NR	NR	NR	5.6 months
DCR TPS 1-49%	92.0%	NR	NR	NR	NR
DCR TPS ≥50%	100.0%	NR	NR	NR	NR
mOS	**32.9 months**	**22.0 months**	**18.6 months**	**not reached**	**not reached**

NR: Not reported

Source: Immutep, Kristensen CA et al. ESMO presentation; 15 Sept 2024, Wilsons Advisory.

Earnings implications

No changes. INSIGHT-003 data strongly supports the 1L NSCLC component ($0.67/share) of our risked, sum-of-parts PT ($1.05/share).

[1] The MK-2870-007 collaboration with Kelun Biotech (ADC construct sacituzumab tirumotecan) and MK-1084-004 with Taiho (KRAS G12C inhibitor) are both limited to TPS ≥ 50%.

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