WILSONS ADVISORY

Date 14 November 2024

Theme Alert

Sector Healthcare

Company

Immutep Limited (IMM)

INSIGHT-003 | Flexing in 1L NSCLC

Dr Shane Storey
shane.storey@wilsonsadvisory.com.au
Tel. +61 7 3212 1351

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 survival data 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). As a reminder, this trial is evaluating Efti, in combination with anti-PD-1 therapy (i.e. KEYTRUDA) and doublet chemotherapy (carboplatin and pemetrexed). Mature data from 21 evaluable patients treated with this triple combo has built upon the strong initial response rates shared at ESMO last year. At a minimum follow-up period of 22 months, median overall survival (mOS) is 32.9 months and median progression free survival (mPFS) is 12.7 months. Both results sit well ahead of rival IO/chemo regimens in the treatment of 1L NSCLC, based on cross-trial comparisons. As an all-comers trial (patients unselected for PD-L1 status), INSIGHT-003 ended up being enriched for patients with low/no PD-L1 expression in their tumours (81% with <50%; 33% with <1%). Achieving such impressive survival in the most difficult patients gives us confidence Efti can expand the TAM and responder rates for anti-PD-1 blockbusters like Keytruda. The results also 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 possibly the study that convinced MSD to launch TACTI-004. INSIGHT-003 is a compelling study on account of its all-comers nature and striking results in patients with low/no PD-L1 expression (TPS <50%). These patients represent 35% of all mNSCLC and are the largest unmet need in oncology's largest indication. At ESMO last year, the INSIGHT-003 investigators reported that two thirds of patients responded with over 90% of them experiencing an improvement or stabilisation of disease. The ESMO data (reviewed here) was powerful enough to give MSD (and Immutep) the confidence to include TPS < 1% patients in the TACTI-004 study. This matured INSIGHT-003 dataset has shed light on survival, with mOS and mPFS well ahead of comparator IO/chemo regimens (see our side-by-side comparator table in **Figure 1**). 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]. As a reminder, the inclusion of chemotherapy will also make TACTI-004 popular with trialists. Such prodigious survival results (read alongside what we know from TACTI-002) should prompt curiosity as to what a chemo-free Efti/KEYTRUDA combo might achieve in this important patient population.

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-1 + chemo	Anti-PD-1 + chemo	Anti-LAG3 + Anti-PD-1+ chemo
Study	INSIGHT-003	KEYNOTE-189	IMpower130	RELATIVITY-104	
Reference	NCT03252938	NCT02578680	NCT02367781	NCT04623775	
Indication	advanced/metastatic non-squamous NSCLC			advanced/metastatic NSCLC	
Phase	II	III	III	III	III
Therapy Line	1st	1st	1st	1st	1st
n	21	410	483	151	158
PD-L1 TPS <50%	81%	62%	81%	NR	NR
PD-L1 TPS ≥ 50%	19%	26%	32%	NR	NR
PD-L1 TPS < 1%	33%	NR	NR	49%	47%
DCR (all PD-L1)	**87.5%**	**85%**	**80%**	**NR**	**NR**
mPFS (all PD-L1)	**12.7 months**	**9.0 months**	**7.0 months**	**8.3 months (NSQ)**	**6.0 months (NSQ)**
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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Wilsons Advisory contact

For more information please phone: 1300 655 015 or email: publications@wilsonsadvisory.com.au