WILSONS ADVISORY

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Theme Alert

Sector Healthcare

Company

Immutep Limited (IMM)

Summit data relevance limited

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Investment View

We maintain our OVERWEIGHT rating on Immutep and $1.05 risked PT. Whilst we concede that ivonescimab's efficacy versus Keytruda is impressive, there are a multitude of caveats that render it far less relevant to IMM's upcoming TACTI-004 trial, notably the exclusion of cold tumours. We also note, the new data presented aligns with what Efti achieved in earlier Phase II programs.

Announcement Highlights

Summit therapeutics (NASDAQ:SMMT) have released further data from their Phase III HARMONi-2 trial (n=389) which compared their bispecific anti-PD-1/VEGF inhibitor to MSD's Keytruda in 1L advanced NSCLC. This data follows on from topline commentary back in May where Summit (and Akesco) announced having beaten Keytruda – a feat not previously achieved. The recent data, presented yesterday at the World Conference on Lung Cancer in San Diego, demonstrated a median progression free survival benefit of ivonescimab of ~5.3 months over Keytruda monotherapy (mPFS 11.1 months for ivonescimab vs 5.8 months for Keytruda). This was a statistically significant benefit (p<0.0001) with a Hazard Ratio (HR) of 0.51 meaning the bispecific reduced the risk of disease progression or death by 49%. ORR was 50% for the bispecific vs 38.5% for Keytruda. Data was consistent across squamous and non-squamous subgroups, and across both low (PD-L1 TPS 1-49%) and high (PD-L1 TPS≥50%) subgroups, noting the trial did not recruit PD-L1 negative (TPS <1%) patients. Safety comparisons did not demonstrate any meaningful difference between the groups. This data is impactful given it is the first time we have seen Keytruda bested in a Phase III lung cancer trial. Overall survival (OS) data will still be forthcoming in time.

Wilsons' View

Initial analysis

Caveats to the HARMONi-2 trial data. There are a number of key caveats/differences to the data from this trial in the context of comparing to Immutep's TACTI-004 program. This trial was relatively small (n=389) and recruited exclusively Chinese patients. The trial was focused on less advanced disease – being advanced NSCLC, vs metastatic (focus of TACTI-004), and only recruited patients with PD-L1 positive tumours (TPS ≥1%). Clinician commentary on the data appears to focus on the fact that this is compared to Keytruda monotherapy, and that there is a desire to see it compared to Keytruda plus chemotherapy which is the far more dominant current SoC therapy in NSCLC. We note that there is a chequered history of Chinese developed anti PD-L1/PD-1s in terms of their ability to translate data and approvals from the Chinese market to the US with Innovent's sintilimab, Jiangsu HengRui's camrelizumab and Coherus Biosciences' topiralimab relevant examples we have previously noted. We can see Summit/Avesco pursuing follow on trial programs now in US sites, we expect to ensure they avoid some of the challenges predecessors have faced with providing FDA with Chinese-only patient data in the past. The dual inhibition of PD-1 and VEGF has also been pursued in the past (with combo treatments) with limited success.

Reminder on TACTI-004. Immutep are pursuing metastatic 1L NSCLC in their Phase III registrational TACTI-004 trial, combining Efti with Keytruda plus chemotherapy and enrolling all patients regardless of PD-L1 expression (incl. PD-L1 negative patients; ~35% cohort). Their trial will be conducted at global sites including a significant majority at US sites. We anticipate this trial to initiate by end CY24 aiming to recruit n=750 patients. Notably, Summit's follow-on trials seek to compare ivonescimab to Keytruda plus chemotherapy (as the most broadly used SoC in NSCLC) but appear focused only in PD-L1 positive patients (noting that the HARMONi-7 trial to initiate in early 2025 is focused only on PD-L1 high (TPS ≥50%) patients; ongoing programs all PD-L1 positive focused only).

mPFS and ORR data comparison to TACTI-002. We would remind readers that the TACTI-002 program demonstrated a mPFS of 11.2 months in a comparable population (TPS ≥1%) with Efti plus Keytruda in 1L NSCLC, with an ORR of 48% - both metrics matching what has been achieved here with ivonescimab (noting this was from a smaller n=114 Phase II non-randomised program).

Increases competitive landscape and pressure on MSD; more trials in pipeline. This does of course place more pressure on the Keytruda franchise as the dominant 'unbeatable' agent in NSCLC. We continue to view Efti as a strategically important asset for MSD noting it has the ability to expand into the 'cold' tumour population (PD-L1 negative) which remains unique to registrational Phase III's in metastatic NSCLC. The ongoing HARMONi-3 trial initiated late last year is focused on later stage patients, in exclusively North American sites, and is comparing ivonescimab with chemotherapy to Keytruda with chemotherapy. This trial we expect to have far more relevance to TACTI-004 with the key caveat continuing to be the focus on PD-L1 positive tumours.

Earnings implications

None.

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