WILSONS

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Theme Alert

Sector Healthcare

Company

Immutep Limited (IMM)

Efti to enable expansion of Keytruda's TAM

Recommendation OVERWEIGHT

12-mth target price (AUD) $0.91

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Announcement Highlights

Immutep have released updated final data from Part B of their TACTI-002 Phase II trial evaluating lead candidate, Efti, in combination with MSD's anti-PD-1 blockbuster, Keytruda. The updated data presented at the ESMO European Lung Cancer Conference is from 2L patients with metastatic NSCLC that had previously failed anti-PD-1 monotherapy +/- chemotherapy. Median overall survival (OS) of 9.9 months compares well to a 6-9-month OS range with 2L chemotherapy, of course noting the material benefit in this ~10-month OS being achieved without the use of chemo (and its associated side effect profile). Importantly, the ability for the Efti combination to stablise disease was demonstrated in one third of patients (DCR=33.3%), with 39% of the cohort surviving through the 21-month timepoint (compares to 10-15% with SOC chemo). This third of stabilized patients is demonstration that despite being initially anti-PD-1/L1 resistant, some patients can be reverted back to responders using Efti – which is a critical proof of principle. Finally, the safety and AE profile of the Efti+ Keytruda combination was maintained, with no new safety signals or treatment tolerability discontinuations. Efti continues its efficacy stride.

Wilsons' View

Initial analysis

Data solidifies Efti proof of principle and can revert resistance in 1/3rd of patients, which is key for TAM expansion of current anti-PD-1 blockbusters. Positive efficacy data from TACTI-002 supports Immutep's theory that activation of a more comprehensive immune response (innate + adaptive) will be more efficacious against tumours, than via targeting T-cells alone. The Part B data continues to support this. This new data follows on from the last interim readout from mid-2022, where Immutep reported median OS of 9.7months and DCR of 30.6% (vs 33% reported here). This tells us that the one third DCR figure is stable and that there is potential for Efti to expand the addressable market for Keytruda by ~20-30% - given that Keytruda is not typically used in a 2L NSCLC setting (with chemotherapy the 2L go-to option). As we have continued to note, this is a critical differentiator of IMM's approach to the IO market – in that they are not seeking to replace or cannibalise current blockbuster IO's (such as Keytruda or Opdivo) - but rather expand their use case into other patient segments (i.e. low PD-L1 expression) or lines of therapy (i.e. refractory 2L) making for a far more attractive strategic acquisition.

Around the grounds in IO; more TIGIT failures. We continue to keep an eye on the latest happenings in the IO landscape. Notably, MSD's Phase II program in mNSCLC (KeyVibe-002), combining Keytruda with a new anti-TIGIT drug vibostolimab, failed to improve upon progression free survival (PFS) versus chemotherapy alone in a 2L setting (akin to the patient cohort described above – having failed chemo + IO in 1L). MSD are pursuing 10 other clinical programs with this anti-TIGIT asset. It looks as though they will now pursue a triple combination (Keytruda+anti-TIGIT+chemo)- akin to what Immutep are investigating in the INSIGHT-003 trial program. The MSD failure highlights that this novel anti-TIGIT asset (a competitor to Efti) was not able to demonstrate equivalent efficacy to 2L chemotherapy when combined with Keytruda in a 2L setting – which is what Efti has succeeded in doing (Part B TACTI-002 data).

NSCLC registrational trial progression continues. This new data continues to strengthen the clinical case for advancement of Efti in NSCLC. Immutep continue to finalise registrational trial design (Phase II/III) to evaluate Efti in combination with anti-PD-1 assets (including potential for a triple chemotherapy combination) in a 1L setting. We are anticipating updates on the outcomes of FDA discussions in the current quarter, which will provide more clarity as to trial timelines, but also financial requirements.

Earnings implications. No changes.

Investment view. We maintain our OVERWEIGHT rating and risked $0.91 per share PT on Immutep. Unrisked PT remains at $2.43 per share.

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