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Equity Research Alert

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24 March 2022

Immutep Limited (IMM)

IO non-responder patients saved by Efti

Announcement highlights

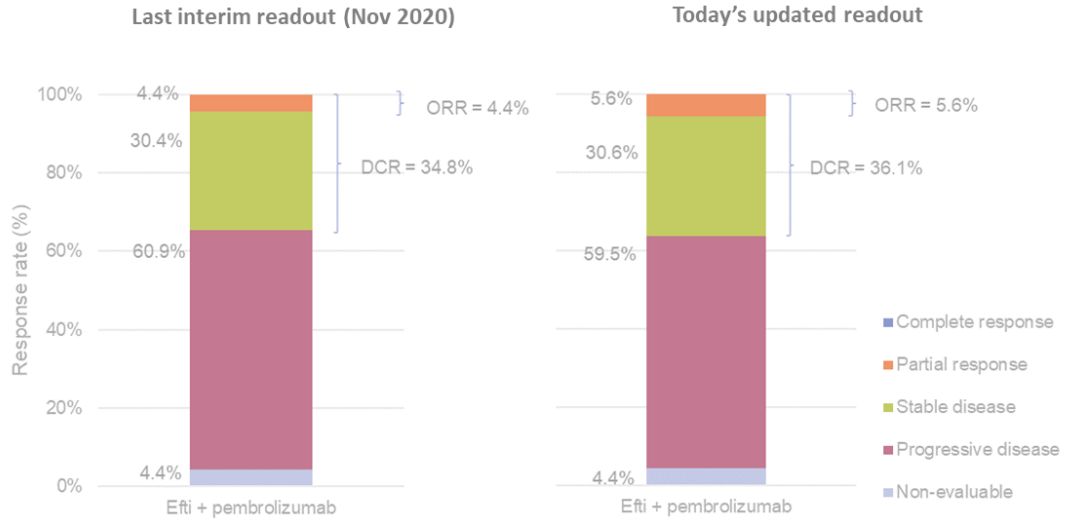
Immutep have released updated interim data from Part B of their TACTI-002 Phase II study, related to the efficacy of their lead asset Efti in patients with metastatic, treatment-resistant, 2nd line non-small cell lung cancer (NSCLC). The last readout from this study was back in November 2020. Immutep have released an abstract for the ESMO European Lung Cancer Congress (ELCC) in which they will present the data on April 1st to their oncology peers. Data shows that >35% of patients continue to have halted progression and/or improved tumour burden as a result of Efti addition to their previously failed pembrolizumab treatment. Importantly this effect has been maintained since the Nov 2020 readout showing sustained, durable responses (which are often hard to achieve with IO drug treatments). This data, despite being from a small patient subset (n=36), is key to highlighting the power of Efti in being able to broaden the use case for blockbuster IO drugs like Keytruda, extending their addressable market and the proportion of patient responders (including those who lack key checkpoint expression, i.e. PD-L1 negative). This is central to our investment thesis on Immutep.

Wilsons' view

Initial analysis

Data continues to strengthens clinical case – efficacy maintained over time. The data revealed in the latest Part B TACTI-002 readout continues to support the thesis that Efti is able to turn 'cold' tumours 'hot' again via its unique mechanism as an Antigen Presenting Cell (APC) activator. Data showed that the combination of Efti + pembrolizumab was able to control cancer progression (halt or improve it) in 36.1% of patients indicating that the benefit patients have received is sustained ≥12 months on (**Figure 1**). Whilst an ORR of 5.6% (2/36) is small on an absolute basis it is critical to understand that these patients are those that have failed/not-responded to current first line SOC therapy with anti-PD-1 agents (i.e. pembrolizumab, nivolumab etc) and/or chemotherapy. This leaves these patients with limited options. Here Immutep have shown that by the addition of Efti to an anti-PD-1 agent they are able to 'rescue' an additional 36% of patients that would otherwise have tumour progression – which is powerful and relevant for pharma that continue to struggle with IO resistance and low overall treatment response rates (20-30%). The durability of patient responses is a significant win for Immutep confirmed by this data readout.

Figure 1. Updated data readout from TACTI-002 Part B of Efti + pembrolizumab (Keytruda) in 2nd line NSCLC PD-1/PD-L1 non-responders



Source: Immutep, Wilsons.

Importantly, this tumour stabilisation did not come at the expense of safety. The updated interim data shows safety and tolerability of the Efti + pembrolizumab combination in line with previously reported data. Two patients (5.6%) discontinued treatment due to adverse reactions. This is critical also to the future of Efti in an IO-IO combination setting, where the incremental efficacy benefit must far outweigh any additive toxicity of a second agent (i.e. Efti in this case) – which it does in this case. The same has not been seen with other combinations in the past (i.e. addition of anti-CTLA-4 agents to anti-PD-1s has led to worsened safety/tolerability profiles in some instances).

Responses achieved in cohort lacking PD-1 expression. As a reminder, the TACTI-002 Part B enrolled patients on an all-comers basis – i.e. they were not restricted to only those with positive PD-L1 checkpoint expression. It is key to note that current approvals of Keytruda are restricted to patients that express its checkpoint target (PD-1) (~65% patients max). This leaves a significant portion of patients (~35%) with no access to Keytruda in mNSCLC. The data presented today by Immutep included 13 of 36 (36%) patients with no PD-L1 expression. Being able to achieve disease control in a cohort irrespective of PD-L1 expression is important for the expansion of anti-PD-1 therapies and their addressable market.

Efti has the potential to expand the TAM for Keytruda by >30%. As we have previously assessed, we see the true value of Efti in its ability to extend and expand the addressable market for pembrolizumab (Keytruda®) – hence why it is so attractive to large anti-PD-1 players like Merck (MSD). This data shows just in one cancer indication how Efti is able to reinvigorate the immunogenic cancer response that was previously unresponsive to effectively increase the 'responder' patient pool for Keytruda by >35%. This brings the potential for players like MSD to a) increase the number of patients who respond to Keytruda; b) increase the spectrum of cancers that may be made more immunogenic; and c) achieve longer survival for Keytruda patients which has the ability to increase sales per patient.

Earnings implications

None. This data further solidifies our view in the attractiveness of Efti in the NSCLC indication as a potential game-changer for existing anti-PD-1 drugs such as Keytruda.

Investment view

We maintain our OVERWEIGHT rating and $0.91 per share risked PT on Immutep. As a reminder, ~55% of our risked valuation lies with the opportunity for Efti in the NSCLC indication.

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