WILSONS ADVISORY

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Theme Alert

Sector Healthcare

Company

Immutep Limited (IMM)

Dose it higher? Now an option

Recommendation **OVERWEIGHT**

Dr Melissa Benson
melissa.benson@wilsonsadvisory.com.au
Tel. +61 2 8247 6639

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

Madeleine Williams
madeleine.williams@wilsonsadvisory.com.au
Tel. +61 3 9640 3834

Announcement Highlights

Immutep have released initial data from their pilot phase study (n=6) exploring higher dosing of their lead oncology candidate Efti in $HR^{+}/HER2^{-/low}$ metastatic breast cancer patients (mBC). The study tested Efti in combination with chemotherapy at 3x higher dose of Efti than has been used in their prior trials (90mg vs 30mg). New data shows Efti continues to be safe and well tolerated even at this higher dosing with only mild severity AEs reported. This pilot was the lead-in to the larger Phase II/III AIPAC-003 trial in mBC which is now 40% enrolled in the Phase II arm (23/58). Clinically the combination of high dose (90mg) efti plus paclitaxel chemotherapy showed good clinical response with an overall response rate (ORR) of 50% and disease control rate (DCR) of 100% (including 1 complete response patient). This data is consistent with their published Phase IIb AIPAC trial. Important to note, these six mBC patients had exhausted all endocrine therapy options (including CDK4/6 inhibitors) and thus are a challenging patient cohort to treat with such strong initial response rates. Looking more broadly, this data gives IMM dosing optionality across all of their development programs - as they finalise their Phase III TACTI-004 NSCLC trial design expected to be announced very soon.

Wilsons' View

Initial analysis

Dosing optionality. The key takeaway from this data is really that Efti has an incredibly good safety profile with no significant change in AE profile even at a 3x higher dose. This is not the norm for IO assets, many of which we are seeing have an additive safety burden when in combination with other drugs/chemotherapy. This is a key differentiator for Efti and its future utility as a broad immune booster across oncology indications (and treatment combinations). Whilst the mBC clinical response data is certainly encouraging, the larger commercial relevance of this announcement is around the optionality it grants IMM in their TACTI-004 trial design. With this safety pilot now complete discussions around the use of a 90mg dose in the upcoming Phase III NSCLC trial can be had, we understand with no additional clinical safety data required to support use in TACTI-004. We will have to wait and see what IMM decide to do, and if they stick with 30mg dosing from their Phase II program or opt to boost the dose (to 90mg) in Phase III, which should allow enhanced immune stimulation. IMM are due to announce the finalised TACTI-004 trial design imminently.

Earnings implications

None.

Investment view

We maintain our OVERWEIGHT rating and $0.90/sh risked PT on Immutep. We are bullish on Efti's prospects and opportunity for share price re-rate in the coming 6 months with initial top line data from their Phase IIb TACTI-003 trial in HNSCC anticipated.

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Wilsons Advisory contact

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