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Equity Research Alert

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Immutep Limited (IMM)

AIPAC final data as expected: Phase III supported

Announcement highlights

Immutep have released final overall survival (OS) data from the Phase IIb AIPAC study of their lead LAG-3 asset, Efti, in combination with paclitaxel chemotherapy in metastatic breast cancer patients (with $HR^+/HER2^-$ subtype). The final OS data is incrementally positive from the latest published data with further gains in survival observed across the three patient subgroups of focus in the trial. The significant benefits with the addition of Efti in these patient subgroups continues to support Immutep's plans for their registration global Phase III study (EU & US sites) which is currently in preparation (which has already received a positive opinion from EMA). Today's update is a positive for Immutep's breast cancer program.

Wilsons' view

Initial analysis

Table 1. Final Overall Survival (OS) data from the AIPAC Phase IIb study of Efti in combination with chemotherapy in metastatic $HR^+/HER2^-$ breast cancer

	Median OS benefit		NOTES
	Previous data	Updated FINAL data	
Total population	+2.7 months HR=0.83 (p=0.14)	+2.9 months HR=0.88 (p=0.197)	As expected, non-significant benefit at total group level.
<65 years old subgroup	+7.1months HR=0.62 (p=0.012)	**+7.5 months HR=0.66 (p=0.017)**	Benefit extended, significance maintained.
Low monocyte subgroup	+9.4 months HR=0.47 (p=0.02)	**+19.6 months HR=0.44 (p=0.008)**	Benefit extended, significance maintained.
Luminal B subgroup	Not reported	**+4.2 months HR=0.67 (p=0.049)**	Significant benefit seen. Follows PFS benefit previously reported.

Source: Immutep

Significant OS benefit observed in three pre-defined subgroups; key to inform Phase III design. Importantly, we have seen the significant clinical benefit of the Efti combination maintained out to the final analysis that has incorporated 72.5% of events. The key patient trial subgroups (<65 years, Luminal B and Low monocyte) all showed significant benefit versus placebo and support Phase III trial progression. Hazard ratios (HR) in the ≥0.67 range signal a clear clinical benefit of the combination in these subgroups versus chemotherapy alone.

Total group OS benefit incrementally improved at final cut off but still didn't reach significance; not unexpected in our view. We have seen a market overreaction we expect to the total population OS data not reaching significance (p=0.197). This result is not at all unexpected in our view as noted in our prior research, and we focus (as Immutep are) on the <65 years subgroup as the key patient cohort informing the registration Phase III trial patient inclusion and future approvable label.

Low monocyte subgroup of patients experienced an extreme benefit. We note an incredibly impressive benefit in patients with low monocyte count, with an additional 10months OS benefit since the last interim analysis (+19.6 months total, p=0.008). As we have previously discussed, we are unsure as to how to interpret this population and their relevance to an approvable label, notwithstanding how excellent the data is. Further mechanistic understanding of why Efti is so beneficial in these patients will be key to further development of Efti in broader cancer cohorts.

Reactionary share price movements provide a buying opportunity. We note the US market traded ADRs as being down overnight. We expect this is due to cursory views of the total population data not hitting significance. We note this was never expected and statistically very unlikely given the interim data readout – hence we view the associated market movements as ill-informed as to understanding the clinical data and importantly how it supports progression into a Phase III study which we expect is focused on patients 65 years and under.

Earnings implications

Results as expected and support our modelling of Immutep's breast cancer program.

Investment view

We maintain our OVERWEIGHT rating and $0.91 risked price target on Immutep. Immutep is also a member of Wilsons' Conviction Insights.

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