WILSONS

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Theme Alert

Sector Healthcare

Company

Immutep Limited (IMM)

A registrational trial within 12 months!

Recommendation OVERWEIGHT

12-mth target price (AUD) $0.91

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Announcement Highlights

Immutep hosted a webinar this morning to present SITC data from their Phase II NSCLC trial with Efti (TACTI-002), initial data from their triple combo (*Efti + anti-PD-1 + chemo*) trial (INSIGHT-003) and provide updates on their pipeline and strategy as they progress into 2023. As we recently reported, the data from Efti combined with Keytruda in 1L NSCLC highlights compelling efficacy superiority when benchmarked to existing SoC options, with interim durability of response tracking well, in addition to safety. We anticipate first overall survival (OS) data from TACTI-002 in 2023. Today we also saw positive biomarker data supportive of Efti's unique mechanism of action, that is positively differentiated from anti-LAG-3 mAbs (i.e. relatlimab).

The notable webinar takeaway for us was the first mentions of what late stage progression of NSCLC trials with Efti may look like. An adaptive Phase II/III design potentially involving chemotherapy combinations is in scope. Timelines provided anticipate a registrational trial start in 2H 2023. This would mark the 2nd (potential) registrational study for IMM, remembering their Phase IIb TACTI-003 study has the potential to support approval. One further, and exciting, takeaway was the unveiling of a new program focused on small molecule anti-LAG-3 agents (currently preclinical), which looks to displace current biologics (i.e. relatlimab). Despite its early nature, this is another example of a unique and potentially highly valuable asset attractive to big pharma looking to enter the LAG-3 space with a differentiated offering (which are lacking). It further rounds out IMM's LAG-3 focused portfolio as far and away the most comprehensive, and continues to support our view of Immutep's strategic value in the IO sector.

Wilsons' View

Initial analysis

Registrational study commencement 2H 2023. Immutep confirmed ongoing regulator discussions with an expectation to confirm trial design in 1H 2023 and initiate a registrational NSCLC trial in 2H 2023. An adaptive trial design (Phase II/III) does confer benefits including; a) the ability to progress both established Efti + Keytruda combo in RCT design as well as the earlier triple combo in parallel; b) potential interim readouts that guide continued trial progression; and c) lower potential R&D expense as adaptive studies often require fewer participants. Taking this approach, the early INSIGHT-003 data can inform the final SoC comparator arms despite it being less validated on the efficacy front at present. Initial comments suggest overall survival (OS) as a potential primary endpoint and a focus on TPS ≥1% PD-L1 subgroups only (in line with their recent Fast Track Designation) optimising success likelihood.

The big question remains if this new trial will be in formal partnership with MSD (per the TACTI studies) or if Immutep will pursue this standalone. As at end Sept 2022 Immutep had ~$74M in cash and equivalents, noting their ongoing R&D expense line currently supports their Phase IIb TACTI-003 trial in HNSCC, TACTI-002 follow up, IMP761 development and a new preclinical program based on anti-LAG-3 small molecule development. IMM also reiterated ongoing investment in manufacturing scale up activities for both IMP761 (their novel LAG-3 agonist) as well as Efti (preparing for late-stage/commercial development).

Biomarker data supportive of MOA. Statistically significant increases in immune biomarkers (IFN-γ, CXCL10) versus baseline both 3- and 6- months post treatment support Efti's mechanism of action (MOA). With increased IFN-γ published as a related objective tumour response marker, and CXCL10 related to tumour immune stimulation (COLD → HOT). These data align to IMM's Phase IIb AIPAC study which importantly showed an absence of these changes in placebo cohorts.

Earnings implications

None.

Investment view

We maintain our OVERWEIGHT investment view on Immutep with $0.91/sh risked PT.

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