WILSONS

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Theme Alert

Sector Healthcare

Company

Immutep Limited (IMM)

FastTrack for Efti in 1st line NSCLC

Recommendation OVERWEIGHT

12-mth target price (AUD) $0.91

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Announcement Highlights

Immutep have been granted Fast Track Designation (FTD) from the FDA for their combination of lead asset, Efti, with blockbuster anti-PD-1 pembrolizumab (Keytruda®) in 1L non-small-cell lung cancer (NSCLC). As a reminder, Immutep presented efficacy data at the May ASCO conference from their Phase II TACTI-002 trial showing impressive efficacy uplifts for this combination versus pembrolizumab monotherapy (1L). These designations and validation of the importance of Efti programs from regulators such as the FDA continues to build the corporate/strategic appeal of the Efti asset, and signals positive initial engagement with the FDA regarding progression of the Efti NSCLC program into late stage (Phase III) development.

Wilsons' View

Initial analysis

Fast Track detail. Being granted FTD from the FDA provides benefits including eligibility for an expedited Priority review (6 months vs standard 10 months), eligibility for Rolling Review (allowing for submission of documents as ready) and more engagement/interaction with the FDA during the development process which can be critical to ensuring pivotal trial design is optimised for approval success. In Immutep's case, FTD has been granted by the FDA for the Efti + pembrolizumab combo specifically for metastatic (Phase IIIB/IV) NSCLC patients with PD-L1 positive tumours (TPS ≥ 1%) that are not eligible for targeted EGFR- or ALK inhibitor therapies based on their tumour mutation profiles. The presence of EGFR and/or ALK mutations in NSCLC ranges by genetic heritage with some cohort studies showing ~10-20% mutation prevalence in Caucasian populations and much higher (~50% EGFR mutations) in Asian populations[1]. This however leaves a significant proportion of mNSCLC patients that are not amenable to these targeted therapies (within the FTD remit) that require improved 1st line options.

NSCLC opportunity. As a recap, we continue to view the key opportunity for Efti in 1st line NSCLC as two-fold; first to provide an efficacious chemotherapy-free option for patients, with superior efficacy to 1L anti-PD-1 (i.e. pembrolizumab) monotherapy. The ability to deliver equivalent/superior efficacy with a reduced adverse event profile is highly advantageous. Second, to expand the addressable population for 1L anti-PD-1 monotherapy which is currently restricted to ~65% of NSCLC patients USA and ~30-35% of NSCLC patients in Europe. The TACTI-002 data presented at ASCO earlier this year clearly showed the ability for Efti to boost overall response rate (ORR) in the PD-L1 absent (TPS <1%) and low (TPS 1-49%) populations by >2x when compared to 1L pembrolizumab in a comparable all-comers population (see Table 2 here).

Second FTD for Efti. As a reminder, IMM have already been awarded FTD status for their program with Efti in 1L HNSCC (TACTI-003 Phase IIb trial ongoing). These designations continue to provide external validation that regulators see the key opportunity Efti could potentially provide in these metastatic cancer populations which require improved treatment options, particularly for those with nil-low PD-L1 expressing tumours. We note granting of this designation by FDA may signal positive ongoing conversations with regards to Phase III trial planning in 1st NSCLC, following the announcement by IMM that progressing Efti in this indication is a key priority.

Earnings implications

No changes to our forecasts or modelling, noting that we model a licensing deal for the Efti opportunity in 1st line NSCLC as a value realisation mechanism (~2H23e).

Investment view

We maintain our OVERWEIGHT rating and risked $0.91/share price target on Immutep. The opportunity for Efti in NSCLC comprises ~55% of our current risked valuation, noting we do not include any other assets (IMP761, LAG525 or GSK2831781) in our valuation at present.

[1] Tan *et al.* 2022. Predicting EGFR mutation, ALLK rearrangement, and uncommon EGFR mutation in NSCLC patients by driverless artificial intelligence: a cohort study. *Respiratory Research.* 23:132.

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