

Immutep Limited (IMM)

A coveted ASCO spot for Efti

Announcement highlights

Immutep released their Appendix 4C today with operational update. Importantly Immutep announced this week they have secured a coveted oral presentation position at ASCO (American Society of Clinical Oncology) annual meeting in June (3-7th in Chicago), where they will report on updated results (interim) from their TACTI-002 Phase II trial of Efti in combination with Merck's Keytruda as a 1st line therapy in advanced/metastatic non-small cell lung carcinoma (NSCLC). This is in addition to a poster presentation focused on interim data for their Phase IIb TACTI-003 trial in advanced/metastatic head and neck squamous cell carcinoma (HNSCC). Further details will be made available including data with the abstract release on May 26th (5pm ET). Final data release will be during the ASCO meeting (June 3rd & June 6th).

Immutep finished 3Q22 with \$87.2M net cash, which will support their ongoing clinical trial programs (TACTI-002, TACTI-003, INSIGHT) in addition to providing R&D capital for progression of their Phase III program in metastatic HR+/HER2- breast cancer (AIPAC-002). Immutep spent \$8.13M on R&D during the quarter which included manufacturing spend for Efti and IMP761 to support clinical programs.

Wilson's view

Initial analysis

Oral presentation at ASCO places TACTI-002 abstract within top ~5%. Winning a coveted oral presentation spot at ASCO, the world's largest and most influential cancer conference is a win for Immutep and speaks to the interest levels in their NSCLC TACTI-002 data from the panel of assessing clinicians. It is our understanding there are only ~260 spots for oral presentations each meeting with ~6,200 applications (2019 ASCO data). Oral presentations are chosen for abstracts where the data is deemed to be highly relevant and interesting for attendees, with poster presentations rounding out a further 1,900 positions (~30% success rate).

ASCO the place to unveil key results with the entire pharma industry watching. ASCO is an event that is broadly attended by the clinical, as well as investment and pharmaceutical industries, with significant clinical data readouts often unveiled at this annual meeting. ASCO is of intense focus for the pharmaceutical industry as this is where key data readouts are unveiled that often prompt deal making or partnerships. Whilst this is not Immutep's first ASCO experience, their continued ability to be selected to present their data on this stage is supportive of their broadening industry exposure which is amplified given the recent BMS approval of anti-LAG-3 relatlimab in March.

NSCLC opportunity is ~50% of our valuation. Lung cancer is the second most abundant cancer globally with ~84% of lung cancers being NSCLC. Tobacco smoking has been a huge driver of NSCLC incidence with incredibly high mortality rates associated with metastatic disease (7% 5-year survival rate). Initial pembrolizumab (Keytruda) monotherapy approval in mNSCLC was granted in April 2019 which has now become standard of care, alongside other anti-PD-1 therapies including atezolizumab (anti-PD-L1) and nivolumab. Acquired resistance to these anti-PD-1/L1 therapies is a key issue the industry is attempting to combat with rates climbing north of 50% of patients by ~24months of therapy (**Table 1**).

Table 1. Acquired resistance rates to anti-PD-1/PD-L1 therapies in NSCLC is high

Indication	Checkpoint inhibitor	Trial	Acquired resistance rate	Timeframe (median)
NSCLC	Pembrolizumab	Keynote 001	41-57%	61 months
		Keynote 042	52%	24 months
	Nivolumab	CheckMate 017, 057, 063, 003	64%	48 months
	Atezolizumab	OAK	55%	28 months

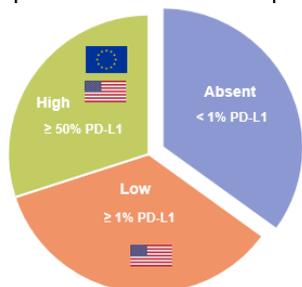
Source: Adapted from Schoenfeld & Hellmann¹.

¹ Schoenfeld & Hellmann. 2020. Acquired Resistance to Immune Checkpoint Inhibitors. *Cancer Cell*. 37(4): 443-455.

Acquired resistance renders these therapies effectively useless in half of the patient population after this period where they fall back to chemotherapy approaches which are often ineffective and/or toxic. We value the opportunity for Efti in NSCLC as being worth \$0.53/share based on a licensing deal assessment which assumes peak royalty revenues of ~\$350M and \$470M in milestone payments. Our evaluation of potential peak sales for Efti in mNSCLC exceeds US\$2.5B across US and EU5 markets.

Expansion of a blockbuster's addressable market. We continue to view the opportunity for Efti as sizable given its ability to extend (efficacy) and expand (patient pool) the addressable market for anti-PD-1 blockbusters, i.e. pembrolizumab (Keytruda) with annual sales of US\$17B in FY21. The ability for Efti to re-engage the immune system's attack functions on tumours (effectively re-igniting the anti-tumoural effect of Keytruda) is key to our positive thesis, and in achieving this in a patient group that is not pre-selected for PD-L1 expression. As a reminder, current Keytruda approvals in 1st line mNSCLC only apply to ~65% of total patient pool in USA and ~30% total patient pool in Europe. Patients with high ($\geq 50\%$ TPS) or low ($\geq 1\%$ TPS) PD-L1 expression in their tumours are indicated for Keytruda therapy only (**Figure 1**). The TACTI-002 trial – including the data to be presented at ASCO on June 3rd – focuses on including this remaining 35% of patients with no detectable PD-L1 expression ($\leq 1\%$ PD-L1 TPS). Interim data thus far supports the premise that the addition of Efti can improve survival outcomes even in low PD-L1 expressing patients – this is the key to expanding Keytruda's addressable market by >30%. The upcoming TACTI-002 readout should further develop this idea.

Figure 1. Keytruda monotherapy approvals in mNSCLC (1st and 2nd line) based on PD-L1 tumour expression status.
At present ~35% of mNSCLC patients are not addressed by Keytruda therapy – Efti could capture a portion of this segment.



Source: FDA, EMA, Wilsons.

Earnings implications

None.

Investment view

We maintain our OVERWEIGHT rating and \$0.91 per share risked PT on Immutep. Our unrisks PT is \$2.33 per share.

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