WILSONS ADVISORY

**Date** 16 December 2024

**Theme** Company Update

**Sector** Healthcare

**Company**

Immutep Limited (IMM)

# Preparedness for approval in 1L mHNSCC

We maintain our OVERWEIGHT rating and PT of $1.05/sh on Immutep. The prospect of an accelerated approval (AA) for Efti in combination with KEYTRUDA, treating first line metastatic head and neck cancer (mHNSCC) patients with PD-L1 negative tumours took a step forward this week with the TACTI-003-B update. Median overall survival (mOS) hasn't been reached yet but looks on track to thrash the KEYTRUDA+EXTREME combo which serves as SoC (i.e hopeful of a 3+ month benefit). The wider that mOS gap the better, because although the surrogate endpoints we might look to for an AA (e.g. objective response, durability) also have great deltas (albeit in a cross-trial comparative sense versus KEYNOTE-048, remembering that TACTI-003-B was single arm) the sample size here is tiny. In favour: 'small n' AA predicates in oncology, the existing mHNSCC therapeutic options are dire and Efti is an incredibly safe molecule to administer. Upside from an AA is about 20% (to $1.25/sh) via our model; but possibly more because proximity to first revenues would be a profound phase shift for IMM's stock appeal.

| | |
|---|---|
| **Recommendation** | **OVERWEIGHT** |
| 12-mth target price (AUD) | $1.05 |
| Share price @ 13-Dec-24 (AUD) | $0.37 |
| Forecast 12-mth capital return | 187.7% |
| Forecast 12-mth dividend yield | 0.0% |
| **12-mth total shareholder return** | **187.7%** |

| | |
|---|---|
| Market cap ($m) | 530.2 |
| Enterprise value ($m) | 348.3 |
| Shares on issue (m) | 1,453 |
| Sold short (%) | 2.2 |
| ASX All Ords weight (%) | 0.0 |
| Median turnover/day ($m) | 1.0 |

## Key Points

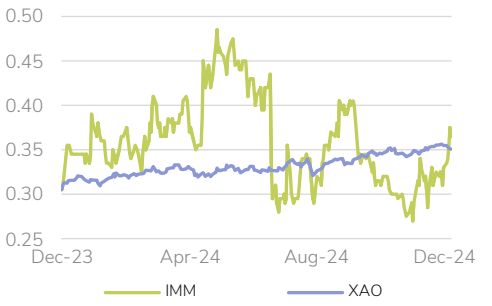
**TACTI-003-B updated results.** The steadily climbing complete response (CR) rates are what investors (and regulators) should be focusing on. The latest data cut (12.9% CR by RECIST1.1) is now quadruple that seen in KEYNOTE-048, the most relevant comparator study (KEYTRUDA+ the 'EXTREME' chemo combo). The median duration of response of 9.3 months is already 2.6 months ahead of that standard of care (6.7 months). We assess the Efti+KEYTRUDA combination is on track for at least 15 months mOS, noting that in a group of 31 evaluable patients the 16th 'event' will define the outcome. A clear 3+ month mOS benefit versus KEYNOTE-048 would start positioning Efti+KEYTRUDA for 'superiority' as the argument for an AA. A small efficacy population is a caveat to consider but we provide 'small n' AA predicates to help assess.

**A worthy development option targeting US$450M peak sales in CPS<1 mHNSCC.** MSD's further involvement in Phase III will be welcomed but is contingent on striking a new agreement with Immutep. Their enthusiasm for this indication is impossible to predict and could take various forms; from opting in to a full blown campaign (e.g. taking TACTI-004 as a template, remembering the efficacy in the 2L and considering prospects for future expansion into locally advanced disease and even neoadjuvant HNSCC settings, where Efti is mechanistically appealing); or opting out, happy to 'do no harm' as a passive beneficiary of KEYTRUDA upside, stemming from Immutep's targeted success in the CPS<1s. It's important to say at this point that independent commercialisation should be and is the base case on which mHNSCC contributes to our Immutep forecasts and valuation. In this report we also assess Immutep's organisational and technical preparedness for a briefer path to first commercial revenue, if that's where TACTI-003-B leads them. The business is in excellent shape for that, behind the scenes.

**Valuation.** Maintain O/W. SOTP valuation of $1.05/sh comprises: a) Efti 1L NSCLC ($0.75/sh); b) Efti in mBC ($0.21/share); and c) Efti in HNSCC ($0.09/sh). Unrisked $6.57/sh. An accelerated approval in HNSCC (potentially deliverable in 18 months) would elevate HNSCC component to $0,21/sh (Efti launch drawn forward two years; p [success] 52%→100%). Group PT would move to $1.25/sh with early revenue obviating capital demand from FY26e.


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


**12-mth price performance ($)**




| | 1-mth | 6-mth | 12-mth |
|---|---|---|---|
| **Abs return (%)** | 17.7 | (11.0) | 19.7 |
| **Rel return (%)** | 15.9 | (17.0) | 4.1 |

| Financial summary (Y/E Jun, AUD) | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|
| Sales ($m) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| EBITDA norm ($m) | (38.8) | (44.2) | (50.9) | (45.0) | (35.0) |
| Consensus EBITDA ($m) | | | (64.7) | (77.9) | (53.0) |
| EPS norm (cents) | (4.5) | (3.6) | (4.3) | (2.7) | (2.1) |

| Key changes | | 25-Jul | After | Var % |
|---|---|---|---|---|
| EBITDA | FY25E | (51.9) | (50.9) | 2% |
| norm | FY26E | (45.0) | (45.0) | 0% |
| ($m) | FY27E | | (35.0) | |
| EPS | FY25E | (4.5) | (4.3) | 5% |
| norm | FY26E | (2.8) | (2.7) | 3% |
| (cents) | FY27E | | (2.1) | |
| Price target | | 1.05 | 1.05 | 0% |
| Rating | | O/W | O/W | |

Source: Company data, Wilsons Advisory estimate, Refinitiv, IRESS.
All amounts are in Australian Dollar (A$) unless otherwise stated.

## Business Description

Immutep (IMM:ASX) is a clinical stage Australian biopharma operating in the immuno-oncology (IO) sector with their portfolio of LAG-3 directed biologics. Immutep have four assets under development, all with strong IP protection; two of which are out-licensed (LAG525 - Novartis, IMP731 - GSK) with attached milestone and royalty revenue optionality, with the remaining two (Efti and IMP761) being developed in-house for a range of oncology (incl. HNSCC, NSCLC, mBC) and autoimmune indications.

## Catalysts

a) achievement of clinical trial endpoints; b) partnership opportunities; c) regulatory approvals (including IND approvals); d) corporate activity.

## Investment Thesis

We maintain our OVERWEIGHT rating and PT of $1.05/sh on Immutep. The prospect of an accelerated approval (AA) for Efti in combination with KEYTRUDA, treating first line metastatic head and neck cancer (mHNSCC) with PD-L1 negative tumours took a step forward this week with the TACTI-003-B update. Median overall survival (mOS) hasn't been reached yet but looks on track to thrash the KEYTRUDA+EXTREME combo which serves as SoC (i.e hopeful of a 3+ month benefit).

## Risks

a) adverse clinical trial outcomes; b) negative regulator interactions; c) competitive intensity of immuno-oncology field; d) available capital.

| P&L ($m) | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|
| Sales | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| EBITDA norm | (38.8) | (44.2) | (50.9) | (45.0) | (35.0) |
| EBIT norm | (40.8) | (46.4) | (53.6) | (48.0) | (38.3) |
| PBT norm | (39.9) | (42.7) | (51.9) | (46.8) | (36.9) |
| NPAT norm | (39.9) | (42.7) | (51.9) | (32.7) | (25.8) |
| NPAT reported | (39.9) | (43.5) | (51.9) | (32.7) | (25.8) |
| EPS norm (cents) | (4.5) | (3.6) | (4.3) | (2.7) | (2.1) |
| DPS (cents) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

| Growth (%) | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|
| Sales | n/m | n/m | n/m | n/m | n/m |
| EBITDA norm | 18.6 | 14.0 | 15.3 | (11.6) | (22.2) |
| NPAT norm | 15.3 | 7.1 | 21.6 | (37.0) | (21.1) |
| EPS norm (cents) | 9.8 | (20.4) | 20.2 | (37.0) | (21.1) |
| DPS (cents) | n/m | n/m | n/m | n/m | n/m |

| Margins and returns (%) | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|

| Interims ($m) | 2H23A | 1H24A | 2H24A | 1H25E | 2H25E |
|---|---|---|---|---|---|
| Sales | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| EBITDA norm | (18.8) | (22.2) | (22.0) | (25.4) | (25.5) |
| EBIT norm | (19.9) | (23.2) | (23.2) | (26.8) | (26.9) |
| PBT norm | (19.3) | (21.2) | (21.5) | (25.9) | (26.1) |
| NPAT norm | (19.3) | (21.2) | (21.5) | (25.9) | (26.1) |
| NPAT reported | (19.3) | (21.2) | (22.3) | (25.9) | (26.1) |
| EPS norm (cents) | (2.2) | (1.8) | (1.8) | (2.1) | (2.1) |
| DPS (cents) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

| Stock specific | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|
| R&D expense (m) | (34.4) | (39.6) | (50.0) | (25.0) | (35.0) |
| Licensing revenue (m) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

| Balance sheet ($m) | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|
| Cash & equivalents | 123.4 | 181.9 | 132.3 | 147.8 | 122.8 |
| Current receivables | 8.0 | 7.4 | 5.0 | 0.0 | 0.0 |
| Current inventory | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| PPE | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Intangibles | 9.5 | 8.2 | 8.2 | 8.2 | 8.2 |
| Other assets | 6.5 | 4.0 | 5.7 | 3.4 | 4.9 |
| Total assets | 147.4 | 201.6 | 151.3 | 159.6 | 136.0 |
| Current payables | 9.0 | 9.6 | 9.5 | 6.6 | 6.6 |
| Total debt | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other liabilities | 1.8 | 2.3 | 2.0 | 2.6 | 1.6 |
| Total liabilities | 11.0 | 12.1 | 11.7 | 9.4 | 8.4 |
| Minorities | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Shareholders equity | 136.5 | 189.5 | 139.6 | 150.2 | 127.6 |

| Cash flow ($m) | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|
| Operating cash flow | (35.4) | (34.8) | (49.4) | (31.3) | (24.8) |
| Maintenance capex | (0.1) | (0.0) | (0.0) | (0.0) | (0.0) |
| Free cash flow | (35.4) | (34.9) | (49.4) | (31.3) | (24.9) |
| Growth capex | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Acquisitions/disposals | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Dividends paid | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other cash flow | (1.2) | (7.0) | (0.2) | (3.2) | (0.2) |
| Cash flow pre-financing | (36.6) | (41.8) | (49.6) | (34.5) | (25.0) |
| Funded by equity | 80.1 | 100.3 | 0.0 | 50.0 | 0.0 |
| Funded by cash/debt | (123.5) | (158.7) | 49.6 | (65.5) | 25.0 |

| Liquidity | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|
| Cash conversion (%) | 93.6 | 87.2 | 100.3 | 103.4 | 106.6 |
| Net debt ($m) | (123.4) | (181.9) | (132.3) | (147.8) | (122.8) |
| Net debt / EBITDA (x) | 3.2 | 4.1 | 2.6 | 3.3 | 3.5 |
| ND / ND + Equity (%) | (945.6) | n/m | n/m | n/m | n/m |
| EBIT / Interest expense (x) | 44.4 | 12.5 | 31.5 | 38.5 | 27.0 |

| Valuation | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|
| EV / Sales (x) | n/m | n/m | n/m | n/m | n/m |
| EV / EBITDA (x) | n/m | n/m | n/m | n/m | n/m |
| EV / EBIT (x) | n/m | n/m | n/m | n/m | n/m |
| P / E (x) | n/m | n/m | n/m | n/m | n/m |
| P / BV (x) | 3.2 | 2.3 | | | |
| FCF yield (%) | (8.2) | (8.0) | | | |
| Dividend yield (%) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Payout ratio (%) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Weighted shares (m) | 892.5 | 1,200 | 1,214 | 1,214 | 1,214 |

Source: Company data, Wilsons Advisory estimate, Refinitiv, IRESS.
All amounts are in Australian Dollar (A$) unless otherwise stated.

# TACTI-003-B: warming to an accelerated approval bid in HNSCC

## TACTI-003-B update

**An inexorable march towards a survival benefit in CPS<1 HNSCC patients.** Part B data from the TACTI-003 Phase IIb trial in PD-L1 negative (CPS<1) 1L mHNSCC patients is maturing in a convincing way. Although the data is 'small n' and uncontrolled, the deltas Efti (in combination with KEYTRUDA) has opened up over international standards or care look promising indeed. Much still depends on where Part B's ultimate mOS lands. Here we speculate, but the steadily climbing complete response (CR) rates are what investors (and regulators) should be focusing on. The latest data cut (12.9% CR by RECIST1.1) is now quadruple that seen in KEYNOTE-048, the most relevant comparator study (see **Figure 1**, at right), where the highest CR in the CPS<1 subgroup was 3% (KEYTRUDA + EXTREME). The median duration of response of 9.3 months is already 2.6 months ahead of that standard of care (6.7 months). We assess the Efti + KEYTRUDA combination is on track for at least 15 months mOS, noting that in a group of 31 evaluable patients the 16th 'event' will define the outcome. A clear 3+ month mOS benefit versus KEYNOTE-048 would start positioning Efti+KEYTRUDA's 'superiority' as the argument for an accelerated approval. It feels like Part B is well past the fallback position of arguing for a chemo-free alternative with better safety (Grade ≥3 AEs 15% for the Efti combo vs 72%) and equivalent efficacy. The outlook for a supportive mOS result remains hopeful.

**Figure 1: Updated TACTI-003 data versus KEYNOTE-048 data in 1L mHNSCC**

| Comparison of relevant trial programs in 1L mHNSCC | | | | |
|---|---|---|---|---|
| | **Efti + pembrolizumab** | **Pembrolizumab** | **Pembro+ chemo** | **Cetuximab + chemo** |
| | **IO - IO** | IO monotherapy (SOC only in 'hot' tumours) | IO - Chemo (now SOC) | 2L SOC or for cold tumour patients |
| **Checkpoint target** | **PD-1 + LAG-3** | PD-1 | PD-1 | NA |
| **Study** | **TACTI-003 Part B** | Keynote-048 | Keynote-048 | Keynote-048 |
| **Phase** | IIb | III | III | III |
| **Therapy Line** | 1st | 1st | 1st | 1st |
| **n** | 31 | 301 | 281 | 278 |
| **Demographics** (% male) | 74% | 83% | 80% | 87% |
| **HPV status** (% positive) | 12.9%^ | 21% | 21% | 22% |
| **Current smoker** | 26% | * | * | * |
| **Median age** | 64 | 62 | 61 | 61 |
| **PD-L1 CPS <1** | 100% | 15% | 15% | 15% |
| **CPS 1-19** | 0% | 41% | 40% | 45% |
| **CPS ≥ 20** | | 44% | 45% | 40% |
| Median PFS | 5.8 months | 2.1 months | 4.9 months | 5.2 months |
| HR (for progression) | NR | p>0.05 | 0.84 (p>0.05) | - |
| PF at 6 months | NR | 25% | 45% | 45% |
| **Median OS** | **not reached** | **11.6 months** | **13.0 months** | **10.7 months** |
| mOS CPS ≥1 | not reached | 7.9 months | 11.3 months | NR |
| **OS at 12 months (CPS<1)** | 67% | 39% | NR | NR |
| **Median Duration of response** | 9.3 months | 2.6 months | 6.7 months | 4.3 months |
| **ORR (total)** | **35.5%** | **16.9%** | **36.0%** | **36.0%** |
| ORR CPS <1 | 35.5% | 5.4% | 30.8% | 39.5% |
| ORR CPS ≥1 | - | 19% | 36% | 36% |
| ORR CPS 1-19 | - | 14.5% | 29.3% | 33.6% |
| ORR CPS ≥20 | - | 23% | 38% | 43% |
| DCR (total) | 58.1% | 44% (32% for CPS<1) | 64% | 70% |
| Complete response (CPS<1) | 13% | 0% | 3% | 2% |
| **Response criteria** | RECIST v1.1 | RECIST v1.1 | RECIST v1.1 | RECIST v1.1 |
| **Treatment-related Adverse Events (AEs)** | | | | |
| Discontinuation AEs | 6% | 0% | 8% | 9% |
| Grade ≥3 AEs | 15% | 17% | 72% | 69% |
| AEs leading to death | 0% | 1% | 4% | 3% |

^in patients with oropharyngeal tumours only. * only current + former smoker prevalence reported, not in a LFL manner with TACTI-003 reporting thus far. NR: Not reported.
Source: Immutep, MSD, Wilsons Advisory.

**Supporting arguments**. Also supporting the bid for an accelerated approval is the genuine lack of options for these patients, given that KEYTRUDA is the only immune checkpoint inhibitor to have shown a benefit over cetuximab/5-FU/platinum (EXTREME regimen). The failures of nivolumab/ipilimumab (in CheckMate 651[1]) and durvalumab ± tremelimumab (KESTREL[2], EAGLE[3]) are testament to how resistant HNSCC is to treatment[4]. Worse, approximately 50% of patients in the CPS<1 HNSCC cohort either refuse or are otherwise ineligible for chemotherapy (e.g. advanced age, low performance status). KEYTRUDA monotherapy is not approved, offering just 7.9 months mOS in this population.

**Small sample size the caveat.** There are no hard and fast rules on sample size for accelerated approvals. As per FDA's guidance, accelerated approvals are governed by the severity, rarity or prevalence of a serious or life-threatening condition and the availability or lack of alternative treatments. Predicate accelerated approvals based on single-arm trials with ORR or DoR as the approvable endpoint(s) include: a) **larotrectinib** (Loxo/Bayer; 2018
; solid tumours with NTRK gene fusion) approved based on efficacy in the first 55 patients (176 patient safety package); b) **trastuzumab deruxtecan** (Daiichi Sankyo; 2022; HER2-mutated NSCLC) approved with a primary efficacy population of 52 patients; c) the same molecule, approved this year (2024) for HER2-positive (ICH3+) solid tumours (n=192); and d) **dostarlimab-gxly** (GSK; 2021; for mismatch repair deficient recurrent or advanced solid tumours) approved on an efficacy population of 209 patients.

[1] Haddad, R. I., *et al.* (2023) *Nivolumab plus ipilimumab versus EXTREME regimen as first-line treatment for R/M HNSCC: the final results of CheckMate 651* J. Clin. Oncol. 20: 2166 – 2180. Trial did not meet its primary endpoints of OS in all randomly assigned or CPS ≥ 20 populations.
[2] Psyrri, A., *et al.* (2023) *Durvalumab with or without tremelimumab versus the EXTREME regimen as first-line treatment for recurrent or metastatic squamous cell carcinoma of the head and neck: KESTREL, a randomized, open-label, phase III* study Ann. Oncol. 34: 262 – 274.
[3] Ferris, R. L., *et al.* (2020) Durvalumab with or without tremelimumab in patients with recurrent or metastatic head and neck squamous cell carcinoma: EAGLE, a randomized, open-label phase III study Ann. Oncol. 31: 942 – 950.
[4] Daste, A., *et al.* (2024) *Immunotherapy for head and neck squamous cell carcinoma: current status and perspectives* Immunotherapy 16: 187 – 197.

## Thoughts on process from here

**Closing out TACTI-003-B | EOP2 meeting | Phase III trial planning.** TACTI-003 has been conducted by Immutep, under a collaboration and supply agreement with MSD, signed in 2021. Our understanding of the agreement is that Immutep has freedom to operate should it elect to move forward and conduct Phase III trials with a view to commercialising Efti, targeting an 'in combination with pembrolizumab' marketing label, with or without MSD's involvement. In that sense, the next series of interactions with FDA (e.g an end of Phase II meeting as a natural opportunity to explore the accelerated approval idea and seek guidance with respect to Phase III) are for Immutep to manage and benefit from.

**MSD's involvement will be welcomed but is contingent on striking a new agreement with Immutep**. The agreement governing the TACTI-004 Phase III in 1L NSCLC (under which MSD is providing the pembrolizumab) is a potential model. A new transaction around Phase III HNSCC is obviously desirable but our sense is that MSD will want to weigh up how deeply it should go into this indication, given the encouraging (but uncontrolled) data from Part B and the randomised (but perplexing) results from Part A (as reviewed in our Jun-24 report, a striking benefit in CPS ≥ 20 patients; but equivocal results from the CPS 1-19 cohort, thanks to a surprising response to the pembrolizumab monotherapy control). Prior even to TACTI-003, MSD has had mixed results in HNSCC, in failing to secure a monotherapy label with KEYNOTE-048. The 1L label it has today (and only approved in combination with EXTREME) is already servicing up to 60-80% of patients, as the indication is limited to CPS ≥ 1[5]. Our peak sales estimate for Efti in HNSCC (CPS<1 cohort) is US$450M[6] (at 20% of HNSCC), MSD stands to make similar money from KEYTRUDA in that setting, which, in the context of a US$25B franchise, staring down biosimilar substitution from 2028, may or may not 'move the needle' for them.

**What does independent HNSCC reg development look like?** It's important to say at this point that independent commercialisation should be and is the base case on which HNSCC contributes to our Immutep forecasts and valuation. This includes a $35M R&D/opex envelope, ear marked for a pivotal Phase III trial limited to the CPS<1 subgroup. MSD's potential involvement could be upside (if limited to CPS<1) or even neutral/downside if their involvement went broader because that would likely take Immutep's share of program expenses beyond what we've budgeted for (notwithstanding the indication upside on offer). In any case, FDA will probably want to see the Phase III trial enrolling patients before considering an accelerated approval. If TACTI-003-B is considered sufficient to bring the accelerated approval into frame, the logistics from there are straightforward. Efti has already been granted Fast Track designation. The three components of a BLA seem near at hand: a) an efficacy package, the guts of which is summarised in this note; b) a safety package comprising hundreds of patients from this and other clinical trials; c) a commercial scale manufacturing scheme in the process of being characterised and validated, obviously leveraging the preparatory work Immutep and its partner WuXi Biologics has done in initiating TACTI-004.

**What if Efti is approved?** An approved Efti product presentation would sit separately from KEYTRUDA as a subcutaneous injectable, with an indication limited to combination therapy with pembrolizumab. It's customary for collaboration agreements to grant certain ongoing rights to co-developed data for subsequent marketing purposes so our starting assumption is that Immutep would be free to commercialise Efti using all data generated under the TACTI-003 agreement. Commercial development and sales often start (even for Pharma campaigns) using contractors like IQVIA (QuintilesIMS) providing both field sales and medical liaison product specialists.

[5] Our research identifies a wide range of estimates as to what proportion of 1L mHNSCC patients have CPS<1 (16-61%). Immutep references 20% based on MSD's KEYNOTE-048 study – noting that was convenience sampling and not a reflection of real-world incidence. A meta-analysis of 23 trials conducted in HNSCC reports a ~41% proportion of CPS<1 patients, with another six-study analysis suggesting 36%.

[6] Our peak sales estimate for Efti in HNSCC (CPS<1) is US$450M, treating approximately patients in those years. As a reminder, we model wholesale acquisition costs (WACs) of US$168K and US$100K for the Efti component of the combination in US and EU5 markets, respectively. The treatment schedule is taken directly from TACTI-003 and uses q2w dosing for the first 4 [6-week] cycles and q3w dosing thereafter (21 infusions in all, over the first 12 months on drug). With overall survival likely to exceed 12 months, there is likely some survivorship upside to our model. At 20% our estimate of 15,000 patients per year in 1L mHNSCC across US/EU supporting a TAM of US$1.3B feels conservative.

## Thoughts on valuation impact

**Timing and optionality.** If we posit a BLA filing in 2H25 (calendar) the package may be approvable by mid-2026 assuming the process is expedited with Priority Review. Commerciality would therefore be drawn forward at least two years from where it sits in our model today (2028 approval). **Figure 2** shows that we've already de-risked for TACTI-003-B but only ascribed a 52% p(success) to the accelerated approval event in mid-2026. After that, value development hinges on a confirmatory pivotal Phase III in 2H2028 and confirmation of market access milestones (principally pricing and reimbursement) approximately 18 months post-launch. As always with our real options-based valuations, value is ultimately driven by the underpinning market model, which as we've described, looks for US$450M peak sales. Risked program value is therefore $141.2M or $0.09 per share.

**Figure 2: Real option valuation framework for HNSCC commercialisation. Base case scenario**

HNSCC TACTI-003 (Efti)

| | TACTI-003 2b topline success | Accelerated FDA approval | Phase III confirmatory & full approval/s | Market access |
|---|---|---|---|---|
| Estimated probabilities (p) | 100% | 52% | 70% | 90% |
| Estimated timing | 15/12/2024 | 30/06/2026 | 30/09/2028 | 31/12/2029 |
| R&D costs (A$m) | - | - | 35.0 | - |
| S+ (upside values, A$m) | 156.8 | 355.6 | 638.8 | 806.1 |
| S- (salvage values) | - | - | - | - |
| S (start of phase value) | 156.7 | 156.8 | 355.6 | 638.8 |
| q (risk-free probabilities) | 1.0 | 0.5 | 0.6 | 0.8 |
| **Real option values (A$m)** | **141.2** | **141.3** | **320.6** | **638.8** |

Source: Wilsons Advisory.

In **Figure 3** below we modify the model by bringing the launch forward by two years and moving p(success) for accelerated approval to 100%. Notice that in addition to the $35M Phase III expense, we add a further $25M opex investment supporting market development and other launch activities. In that we'd also include further exploration in other HNSCC settings. Our reading in the space has led us to see the Efti+KEYTRUDA combination as potentially developable in locally advanced and even neoadjuvant HNSCC. A leading hypothesis as to why so many immune checkpoint inhibitors have failed in these settings is that the concomitant high dose radiation inhibits T cell priming. Here Efti's mechanism as a MCH Class II agonist is possibly quite useful.

Program valuation thus increases 2.4x to $336.7M or $0.21 per share with AA. Early commercialisation in HNSCC would likely also obviate the need for capital during the forecast period. There is no change to funding adequacy or our capital requirements in our modelling. Post the June equity raise, Immutep is fully funded through to end CY26 (~$195M) – at which time we anticipate having passed the TACTI-004 futility analysis (end CY25) and have completed recruitment of that n=750 patient pivotal trial, with an interim (efficacy) analysis also achievable by CY26 end. If we backed out future equity requirements from our model, the AA option would support an overall PT upgrade to $1.25/share (+19%).

**Figure 3: Real option valuation framework for HNSCC commercialisation. AA success scenario**

HNSCC TACTI-003 (Efti)

| | TACTI-003 2b topline success | Accelerated FDA approval | Phase III confirmatory & full approval/s | Market access |
|---|---|---|---|---|
| Estimated probabilities (p) | 100% | 100% | 70% | 90% |
| Estimated timing | 15/12/2024 | 30/06/2026 | 30/06/2026 | 2/07/2027 |
| R&D costs (A$m) | - | 25.0 | 35.0 | - |
| S+ (upside values, A$m) | 392.0 | 458.4 | 654.9 | 806.1 |
| S- (salvage values) | - | - | - | - |
| S (start of phase value) | 391.8 | 392.0 | 458.4 | 654.9 |
| q (risk-free probabilities) | 1.0 | 0.9 | 0.7 | 0.8 |
| **Real option values (A$m)** | **336.7** | **337.1** | **423.4** | **654.9** |

Source: Wilsons Advisory.

**Figure 4: Sum of parts valuation for Immutep (PT $1.05)**

| Valuation (SOTP) | | Risked valuation (A$m) | Comments / methodology | Un-risked valuation (A$m) |
|---|---|---|---|---|
| Efti mBC | | 330 | Real options valuation for EU and US market | 1,193 |
| Efti HNSCC | | 141 | Real options valuation for EU and US market | 427 |
| Efti NSCLC | | 1,177 | Real options valuation for EU and US market | 8,683 |
| IMP761 | | - | Phase I data 2H CY25 to determine addition to valuation | - |
| LAG525 | | - | Licensed to Novartis (milestones/royalty optionality) | - |
| Enterprise value ($M) | | 1,648 | | 10,304 |
| **EV per share (A$) - PT** | **$** | **1.05** | **Unrisked price per share (A$)** | **6.57** |
| SOI used for PT (M) | | 1,569 | | |
| End-FY25e cash (A$M) | | 132 | Current probability of success within risked valuation | 16% |
| **Equity value per share (A$)** | **$** | **1.13** | | |

Source: Wilsons Advisory.

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## Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/disclosures.

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## Wilsons Advisory contact

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