

# Annual General Meeting 2025

(ASX:IMM, NASDAQ:IMMP)



Empowering the  
immune system  
to fight cancer and  
autoimmune disease

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# Forward Looking Statements

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## Agenda

- Overview of ImmuteP
- Highlights
- Efti Program
- IMP761 Program
- Summary

# Overview of Immutable

# ImmuteP Highlights

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## A leader in LAG-3 immunotherapy

Four clinical-stage assets designed to safely empower patients' immune systems to fight cancer and autoimmune diseases through the MHC Class II & LAG-3 pathways, including first-in-class immunotherapies eftilagimod alfa (efti) and IMP761.

## Phase 3 in 1L NSCLC: blockbuster potential

Registrational Phase III in collaboration with MSD (Merck & Co.) with potential to establish new standard-of-care in first line non-small cell lung cancer (1L NSCLC), one of the largest oncology markets expected to reach US\$48 billion in sales in 2031.\*

## Validation via collaborations

Multiple partnerships and collaborations with large pharma and leading institutions.



## Strong IP and balance sheet

Strong intellectual property (IP) portfolio and 12+ years of potential exclusivity for biologics like efti & IMP761. Cash & cash equivalents of ~A\$109.85 million provide runway to end of CY2026.\*










# Deep Clinical Pipeline in Oncology & Autoimmune Diseases

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## ONCOLOGY

 **Eftilagimod alfa**  
MHC Class II agonist

**Lung Cancer**  
**Lung and Head & Neck Cancers**  
**Lung Cancer<sup>1</sup>**  
**Head & Neck Cancer**  
**Metastatic Breast Cancer**  
**Early-Stage Breast Cancer<sup>1</sup>**  
**Soft Tissue Sarcoma<sup>1</sup>**  
**Urothelial Cancer<sup>1</sup>**

Preclinical	Phase I	Phase II	Phase III	Collaborations	Commercial Rights
TACTI-004: Efti + Pembrolizumab + Chemotherapy				 <b>MSD</b>	 Empowering the Immune System Global Rights ex-China
TACTI-002: Efti + Pembrolizumab				 <b>MSD</b>	
INSIGHT-003: Efti + Pembrolizumab + Chemotherapy				 <b>IKF</b>	
TACTI-003: Efti + Pembrolizumab				 <b>MSD</b>	
AIPAC-003: Efti + Paclitaxel					
Neoadjuvant Efti + Chemotherapy				 <b>GW Cancer Center</b>	
EFTISARC-NEO: Neoadjuvant Efti + Pembrolizumab + Radiotherapy				 <b>Nardowy Instytut Onkologii</b>  <b>Merck KGaA</b> Darmstadt, Germany	
INSIGHT-005: Efti + Avelumab				 <b>IKF</b>	

## AUTOIMMUNE DISEASE

 **IMP761** (LAG-3 Agonist mAb)  
 **IMP731** (Depleting LAG-3 mAb)

**Healthy Volunteers**  
**Psoriasis & Ulcerative Colitis<sup>2</sup>**

IMP761	
IMP731	

  
Empowering the Immune System

## OUTLICENSED - Oncology

 **Eftilagimod alfa**  
 **LAG525** (Anti-LAG-3 mAb)

**Metastatic Breast Cancer (China)<sup>3</sup>**  
**Solid Tumours, Blood Cancers, TNBC, Melanoma<sup>4</sup>**


 <b>EOC</b>	 <b>EOC</b> Efti China Rights
 <b>NOVARTIS</b>	 <b>NOVARTIS</b>

# Highlights



# ImmuteP's Key Value Driver

## TACTI-004 (KEYNOTE-F91) in First Line Non-Small Cell Lung Cancer (1L NSCLC)

- Lung cancer is the leading cause of cancer death and non-small cell lung cancer (NSCLC) comprises 80 to 85% of all lung cancers<sup>1,2</sup>
- ~2.0 million NSCLC diagnoses annually
- Total addressable NSCLC drug market expected to reach **US\$48 billion** in 2031 with over 50% sales from immune checkpoint inhibitors including anti-PD-1<sup>3</sup>

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# FY25 Clinical Milestones in TACTI-004 Phase III in 1L NSCLC

## Non-small cell lung cancer



### TACTI-004

TACTI-004 (KEYNOTE-F91) is a registrational Phase III trial evaluating eftri in combination with KEYTRUDA® and chemotherapy as first-line therapy for advanced/metastatic NSCLC patients regardless of PD-L1 levels

- **June 2024** - Third collaboration & supply agreement with MSD for TACTI-004 (KEYNOTE-F91) announced
- **March 2025** - Successful dosing of first patient at Calvary Mater Newcastle Hospital in Australia
- **October 2025** - +100 clinical sites across 24 countries have been activated and over 170 patients enrolled/randomized. This is an important milestone as this number of patients is above the amount needed to conduct futility analysis, which remains on track for completion in the first quarter of CY2026.<sup>2</sup>

# Efti's Key Attributes & Encouraging Key Opinion Leader Feedback



## Efti Key Attributes

- **Real innovation** – Efti is a first-in-class asset unlike any in the immunotherapy landscape
- **Pipeline in a product** – Can revolutionize treatment landscape for many solid tumours
- **Low cost of goods** – Allows for reasonable pricing with strong margins
- **Excellent safety profile** – Both as monotherapy and in multiple combination settings
- **Subcutaneous administration** – Convenient and easy to administer

## KOL Feedback on Efti & 1L NSCLC Phase III<sup>1,2,3</sup>

- **Robust fundament in NSCLC** – Positive on efti driving higher responses & survival in previous 1L NSCLC trials
- **Easy to administer and safe** – Do not see high toxicity associated with other therapies
- **Add-on strategy** – Simple add-on to standard-of-care therapy; no change to current practice
- **Easy to enrol** – All-comer PD-L1 trial design allows for easy enrolment with no PD-L1 sub-group exclusions
- **Truly first-in-class** – Efti is not a “me too product” that are often seen in combination trials

# TACTI-004/KEYNOTE-F91 Phase III Trial in 1L NSCLC

## TACTI-004 / KEYNOTE-F91 Phase III: Overview & Trial Design



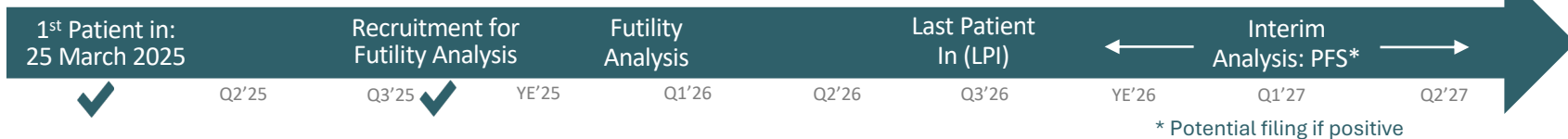
## Third collaboration & supply agreement with MSD - who jointly designed registrational TACTI-004 trial with ImmuteP - announced in June 2024:

- 1:1 randomized, double-blind trial enrolling ~756 patients in +150 sites across +25 countries with dual primary endpoints of progression-free survival (PFS) and overall survival (OS)
- ImmuteP conducting trial, MSD supplying KEYTRUDA (typical ICI supply for trial this size is ~US\$100mm), and ImmuteP retains efti's commercial rights with freedom to operate
- FDA and other regulatory agencies<sup>1</sup> provided positive feedback on study design
- +100 clinical sites across 24 countries have been activated and over 170 patients randomised as of October 2025<sup>2</sup>

# TACTI-004 Milestones and Multiple Potential Paths to Success

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## TACTI-004/KN-F91 Milestones



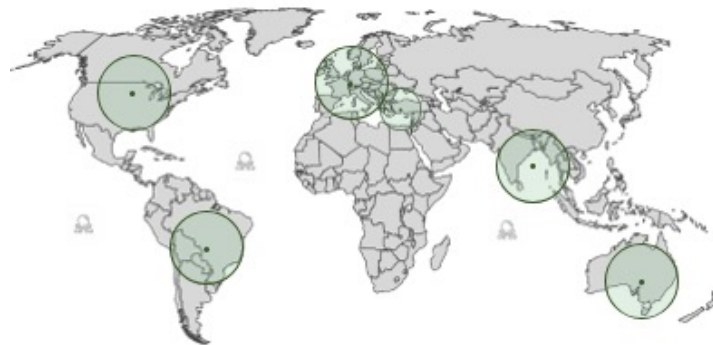
### Dual Primary Endpoints:

- Progression-free Survival
- Overall Survival
  - ✓ Multiple pre-specified analyses are planned for these dual endpoints, each of which could potentially lead to a BLA and/or MMA filing opportunity

### Patient Stratification:

- Important prognostics and predictive markers are used for stratification (e.g. PD-L1 levels and tumour subtypes)

TACTI-004 is global trial with sites in North & South America, Europe, and APAC



# Global Phase III Landscape for Advanced/Metastatic 1L NSCLC

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Companies that have a CTCSA with MSD for Phase III trials in advanced/metastatic 1L NSCLC <sup>1</sup>	No PD-L1 TPS <1%	Low PD-L1 TPS 1-49%	High PD-L1 TPS ≥50%	Non-Squamous	Squamous	% of 1L NSCLC Population
% of 1L NSCLC patient population by segment <sup>2</sup> →	~35%	~35%	~30%	~70%	~30%	→ Up to 100%
<b>ImmuteP</b> TACTI-004/KEYNOTE-F91 (Efti + KEYTRUDA + chemo)	✓	✓	✓	✓	✓	100%
<b>Daiichi Sankyo</b> TROPION-Lung07 (DatoDXd + KEYTRUDA)	✓	✓	✗	✓	✗	49%
<b>Gilead</b> EVOKE-03 (Sacituzumab Govitecan + KEYTRUDA)	✗	✗	✓	✓	✓	30%
<b>Daiichi Sankyo</b> TROPION-Lung08 (DatoDXd + KEYTRUDA)	✗	✗	✓	✓	✗	21%

## Key aspects of TACTI-004/KEYNOTE-F91:

- Efti a simple add-on to KEYTRUDA & chemo, the dominant standard-of-care most often chosen in 1L NSCLC
- Addressing entire PD-L1 population (TPS 0-100%) and both non-squamous/squamous patient populations
- Initial primary read-out in late 2026 thru mid-2027 followed by additional pre-specified analyses<sup>3</sup>
- Strong ORR & PFS in efti's prior 1L NSCLC trials translate to compelling Overall Survival

## Other approaches in Phase III trials:

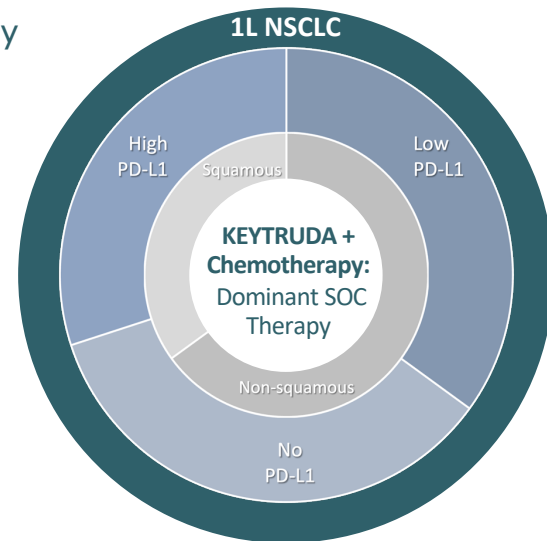
- **ADCs:** Often have high toxicity profiles, particularly when used in combination, that may limit broad usage in 1L NSCLC
- **PD-1/VEGF:** Strong ORR & PFS; unknowns to date include durability of effect and translation to Overall Survival
- **TIGIT:** Trial failures (e.g. SKYSCRAPER-01/06, ARC-10) & program terminations (e.g. MSD) suggest limited impact<sup>4</sup>
- **Anti-LAG-3:** Program terminations (e.g. MSD) and a Phase III for TPS ≥1/NSQ suggest limited impact<sup>4,5</sup>

# Potential Blockbuster Commercial Opportunity

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If TACTI-004 is successful it presents a potential multi-billion US\$ opportunity for efti as it will be a safe add-on to KEYTRUDA & chemo in 1L NSCLC:

- KEYTRUDA has revolutionized treatment landscape and MSD captures 7 to 8 of every 10 metastatic lung cancer patients.<sup>1</sup> Estimates are ~27% of KEYTRUDA's \$29.5 billion in 2024 sales are from lung cancer.<sup>2</sup>
- Potential peak sales for efti can be reached faster vs. a typical drug launch given KEYTRUDA + chemo is the standard-of-care therapy most often used in 1L NSCLC.
- 1L NSCLC may be first of many indications that efti can improve efficacy when combined with KEYTRUDA (over 40 approvals in 18 cancer types).

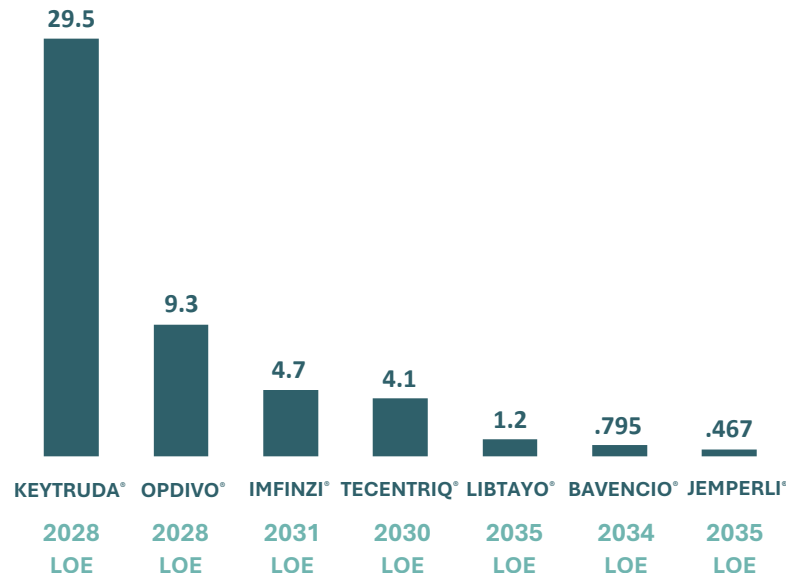


# Efti's Potential to Extend IP for PD-1 Inhibitors

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- Efti's comprehensive patent portfolio provides an opportunity to enhance and substantially extend established or new PD-(L)1 franchises
- Two leading PD-1 inhibitors, KEYTRUDA & OPDIVO (over \$38 billion in 2024 sales), face key patent expirations and loss of exclusivity (LOE) in 2028

2024 Sales of Anti-PD-(L)1 Therapies (\$ Billions)





# FY25 Clinical Milestones in Additional Efti Clinical Trials

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## Non-small cell lung cancer



### INSIGHT-003

**INSIGHT-003 is evaluating efti in combination with KEYTRUDA® and chemotherapy in ~50 first-line patients with advanced/metastatic non-squamous NSCLC**

A high 62.7% objective response rate and 90.2% disease control rate were observed across all PD-L1 expression levels

The results were most impressive in patients of high unmet need with PD-L1 expression below 50%.

Importantly, these results provide strong validation for the rationale underpinning our Phase III TACTI-004 trial design using the same combination therapy

## Soft tissue sarcoma



### EFTISARC-NEO

**EFTISARC-NEO is evaluating neoadjuvant efti in combination with KEYTRUDA® and radiotherapy in ~40 patients with resectable soft tissue sarcoma (STS)**

- Novel combination including neoadjuvant efti met primary endpoint of study, driving a 51.5% tumour hyalinization/fibrosis rate in patients with STS, over 3-fold greater than historical results from standard-of-care radiotherapy alone
- Results presented in Proffered Paper oral presentation at ESMO Congress 2025 & CTOS 2025
- Awarded the Golden Scalpel Award in Poland reserved for projects that demonstrate exceptional innovation and impact in medical research and clinical practice

## Head & neck squamous cell carcinoma



### TACTI-003

**TACTI-003 is evaluating efti in combination with KEYTRUDA® in first-line recurrent/metastatic HNSCC, with 171 patients enrolled across 30 countries**

- Reported median overall survival (OS) of 17.6 months in patients with PD-L1 expression below 1 (CPS<1) from the chemotherapy-free combination of efti with KEYTRUDA
- Received positive feedback from FDA on late-stage clinical development on eftilagimod alfa in head and neck cancer with CPS <1.

## Metastatic breast cancer



### AIPAC-003

**AIPAC-003 is evaluating efti in combination with chemotherapy for metastatic HER2-neg/low breast cancer and triple-negative breast cancer**

- Completed enrolment in randomised Phase II evaluating efti in combination with chemotherapy and continued patient follow-up throughout the year.
- This study helped determine the optimal biological dose of 30mg for efti while addressing an underserved patient population that has exhausted endocrine therapy options. We look forward to sharing further data by the end of CY2025.

# INSIGHT-003: Strong Efficacy Across All PD-L1 Levels

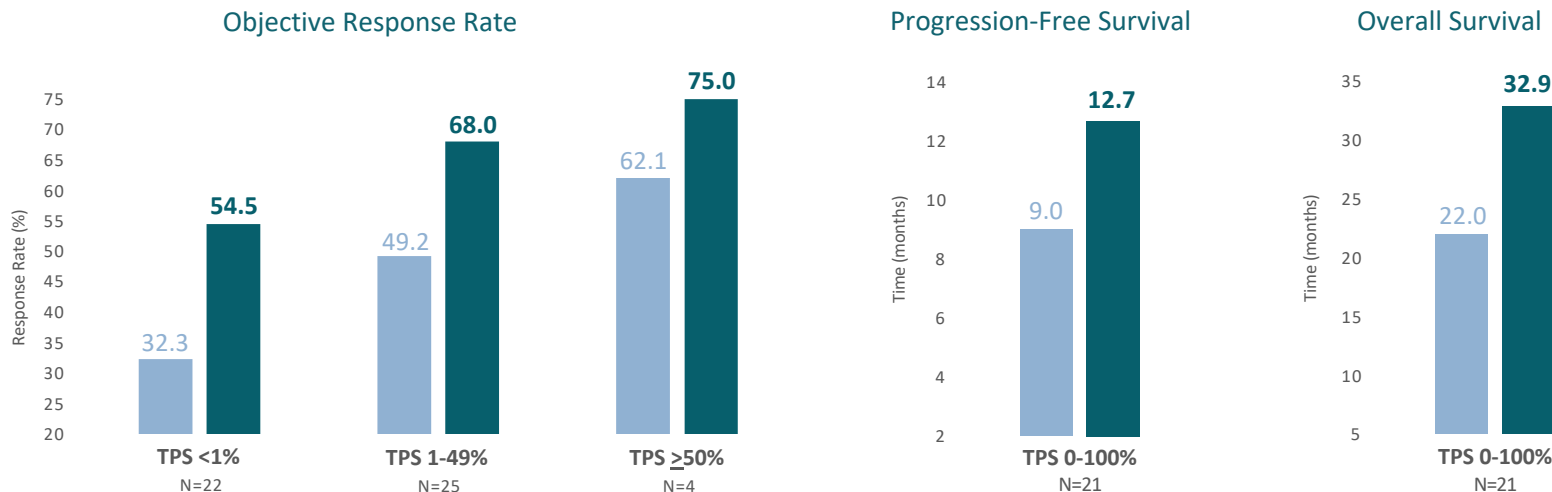
## INSIGHT-003 (Stratum C) Phase I: Overview & Trial Design

Overview	Screening	Treatment Phase		Follow Up
<ul style="list-style-type: none"> <li>Indication: 1L NSCLC</li> <li>Status: Ongoing</li> <li>Recruitment: Completed</li> <li>Enrolled: ~50 pts</li> <li>Locations: Multi-center study in Germany</li> </ul>	<ul style="list-style-type: none"> <li>Advanced/metastatic</li> <li>Non-squamous</li> <li>0-100% PD-L1 expression</li> <li>EGFR/ALK negative</li> </ul>	<b>Induction</b> 30mg efti Q2W + 200 mg pembrolizumab + platinum doublet chemo Up to 24 weeks	<b>Maintenance</b> 30mg efti Q2W/Q3W* + 200 mg pembrolizumab + platinum doublet chemo Max. total study treatment: 52 weeks	ORR, PFS, DOR, OS, and Safety



INSIGHT-003 is an investigator-initiated, multi-centre Phase I trial led by Frankfurt Institute of Clinical Cancer Research (IKF)

Benchmarking **Efti + KEYTRUDA + Chemo**<sup>1</sup> in non-squamous 1L NSCLC to **KEYTRUDA + Chemo**<sup>2</sup>



# INSIGHT-003 Case Study: Patient with PD-L1 TPS 0%

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## Case study of a 75-year-old male with partial response (PR):

PD-L1 TPS 0%, no actionable genetic alterations

TTF1 pos. Adeno-Carcinoma, G3

ECOG PS 1

cT1c pN2 cM1c, Stage IVb

Partial Response achieved after treatment cycle 3; maintained until planned end of treatment (week 52)

**Baseline**  
September 2024

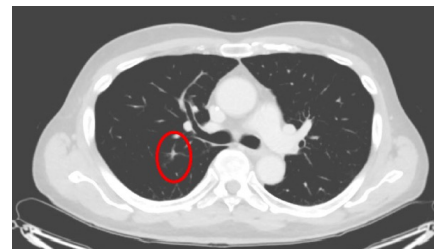


TL1  
Lung:  
27 mm



TL2  
Pleura:  
24 mm

**After 1 Year of Therapy**  
September 2025



TL1  
Lung:  
7 mm



TL2  
Pleura:  
0 mm

# Primary Endpoint Met in Phase II Trial in Soft Tissue Sarcoma

## EFTISARC-NEO Phase II: Overview & Trial Design

Overview	Screening	Treatment Phase	Surgery	Follow Up
<ul style="list-style-type: none"> <li>Indication: Soft Tissue Sarcoma</li> <li>Status: Ongoing</li> <li>Recruitment: Completed</li> <li>Enrolled: 40 pts</li> <li>Location: Poland's national reference centre</li> </ul>	<ul style="list-style-type: none"> <li>Primary or locally recurrent STS</li> <li>Grade 2 or 3; primary tumour size 5cm or locally recurrent of any size</li> <li>Measurable disease (RECIST1.1)</li> </ul>	<u>Efti + Pembrolizumab + Radiotherapy</u> <ul style="list-style-type: none"> <li>30mg efti Q2W (W1, W3, W5, W7, W9)</li> <li>200 mg pembrolizumab Q3W (W1, W4, W7)</li> <li>Radiotherapy (50 Gy) for 5 weeks between W2 &amp; W7</li> </ul>		<ul style="list-style-type: none"> <li>Primary Endpoint: tumour hyalinization</li> <li>Secondary Endpoints: DFS, LRFS, DMFS, OS &amp; Safety*</li> </ul>

EFTISARC-NEO is an investigator-initiated Phase II trial conducted at Poland's national reference centre for sarcoma, the Maria Skłodowska-Curie National Research Institute of Oncology (MSCNRO)

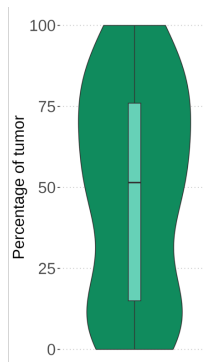
## ESMO Congress 2025 – Proffered Paper Oral Presentation

Neoadjuvant efti + KEYTRUDA + radiotherapy met primary endpoint with median 51.5% tumour hyalinization/fibrosis ( $p < 0.001$ )<sup>1</sup> in patients with soft tissue sarcoma (STS)

Results over 3-fold higher than median 15% from standard-of-care radiotherapy based on historical data<sup>2</sup>

Tumour hyalinization/fibrosis may serve as early surrogate endpoint correlated with enhanced overall and recurrence-free survival in STS<sup>3</sup>

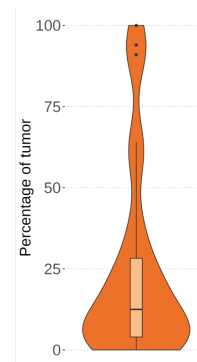
### Hyalinization/Fibrosis



**Median 51.5%**  
IQR 15.0-76.0

$p < 0.001^*$

### Viable Tumour Cells



**Median 12.5%**  
IQR 4.5-30.0

# First-in-Human Phase I Trial of IMP761

World-class research institute, CHDR, appointed to conduct first-in-human study

## Overview / Key Milestones:

- Placebo-controlled, double-blind Phase I
- Centre for Human Drug Research (CHDR) in Leiden, the Netherlands, conducting study in healthy volunteers
- Initial pharmacological data shows significant T cell suppression and favourable safety profile at 0.9 mg/kg dosing level<sup>1</sup>
- Single ascending dose levels continuing with 2.5, 7, 14 mg/kg
- Additional data expected in CY2025

### Single Ascending Dose (SAD): Healthy volunteers

#### Part A:

Cohort 1-SAD-A : 3 Subjects 0.0075 mg/kg + 2 placebo

COMPLETED

FIH  
Microdosing

Single IV

#### Part B:

Cohort 2-SAD-B : 4 Subjects 0.03 mg/kg + 1 placebo  
Cohort 3-SAD-B : 4 Subjects 0.1 mg/kg + 1 placebo  
Cohort 4-SAD-B : 8 Subjects 0.3 mg/kg + 2 placebo  
Cohort 5-SAD-B : 8 Subjects 0.9 mg/kg + 2 placebo  
Cohort 6-SAD-B : 8 Subjects 2.5 mg/kg + 2 placebo  
Cohort 7-SAD-B : 8 Subjects 7.0 mg/kg + 2 placebo  
Cohort 8-SAD-B : 8 Subjects 14.0 mg/kg + 2 placebo

COMPLETED  
ONGOING

3x KLH  
immunization,  
Delayed Type  
Hypersensitivity  
(DTH)

PK/PD

Single IV

### Multiple Ascending Dose (MAD): Healthy volunteers

#### Part C:

Cohort 9-MAD-C : 5 Subjects X mg/kg + 2 placebo  
Cohort 10-MAD-C : 5 Subjects Y mg/kg + 2 placebo

PK

Multiple (Q4W)  
IV



CHDR offers a unique Keyhole Limpet Hemocyanin (KLH) challenge model allowing for evaluation of IMP761's pharmacological activity at early stages of development



# FY25 Financial Summary

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Strong cash position of approx. A\$109.9 million as of 30 Sept 2025 (includes short term deposits)

Total revenue and other income were A\$10.3 million in FY25 compared to A\$7.8 million in FY24

Research and development and intellectual property expenses increased to A\$61.4 million in FY25 due to clinical trial activity and associated expenses

Increases in clinical trial costs drove the increase in R&D expenses and the net loss

Disciplined cash management strategy with focus on the development strategy for efti and IMP761

Expanded team with additional experienced staff

**Strong cash runway to end of CY2026\***

	FY25	FY24
Revenue and other income	A\$10.3M	A\$7.8M
G&A Expenses	A\$8.6M	A\$8.9M
R&D and IP expenses	A\$61.4M	A\$41.6M
Net loss	A\$61.4M	A\$42.7M
Net operating cash outflow	A\$62.0M	A\$34.8M
Cash and cash equivalents including term deposits at the end of the financial year as at 30 June	A\$129.7M	A\$181.8M
Cash and cash equivalents including term deposits as at 30 September	A\$109.9M	A\$172.3M

\*As reported in Immutep Quarterly Activities Report on 29 October 2025.

# ImmuteP Enters the S&P/ASX 300 & Patent Protection

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## S&P/ASX300

- Recognising ImmuteP's considerable growth over the years as a listed company, the Company was added to the S&P/ASX 300 index following the September 2024 quarterly review of the S&P Dow Jones Indices.
- Joining the S&P/ASX 300 enhances ImmuteP's market visibility and supports investor confidence.



## Robust Intellectual Property Protection

### Efti

- Seven patents were granted in FY24:
  - This included six patents for efti in combination with a PD-1 pathway inhibitor, as follows: three in New Zealand, two in Brazil, and one in each of South Korea Japan and Israel.
  - Additionally, a patent was granted in Mexico directed to a binding assay for determining MHC Class II binding activity of LAG-3 protein used in characterisation of efti in GMP-grade manufacturing.

### IMP761

- Seven patents were granted for IMP761:
  - This included five patents for IMP761 in India, Israel, Malaysia, Philippines, New Zealand and South Korea. Additionally, a patent was granted in Russia directed to an assay for use in measuring the potency of IMP761.

### LAG525

- Five patents were granted for LAG525, namely in Australia, Taiwan, Philippines and the United States.



# Upcoming Milestones

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- **Non-Small Cell Lung Cancer** – TACTI-004 futility analysis in Q1 2026
- **Head and Neck Squamous Cell Carcinoma** – Ongoing evaluation of potential options for collaborative clinical development & paths for accelerated approval in 1L HNSCC CPS <1
- **Metastatic Breast Cancer** – Update from AIPAC-003 trial at San Antonio Breast Cancer Symposium in December 2025
- **Early-Stage Breast Cancer** – Initiation of the new IIT Phase II evaluating neoadjuvant efti
- **Autoimmune Diseases** – Update from IMP761 first-in-human Phase I trial in Q4 CY2025 and beyond
- **Additional Updates** – From ongoing clinical trials (e.g. INSIGHT-003, EFTISARC-NEO), partnered programs, and potential expansion of clinical trial pipeline

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# Thank You

