



## Immutep AGM 2024 Presentation

22 November 2024

(ASX: IMM; NASDAQ: IMMP)

**Unlocking the power of the  
immune system to fight cancer  
and autoimmune disease**

# Forward-Looking Statements

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# Agenda

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→ Overview of Immutep

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→ Highlights & Outlook

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→ Efti Program & Strategy

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→ IMP761 Program

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→ Summary

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# Overview of Immunetep

# Company Overview

## Pure-play LAG-3 company with deep pipeline in oncology & autoimmune diseases:

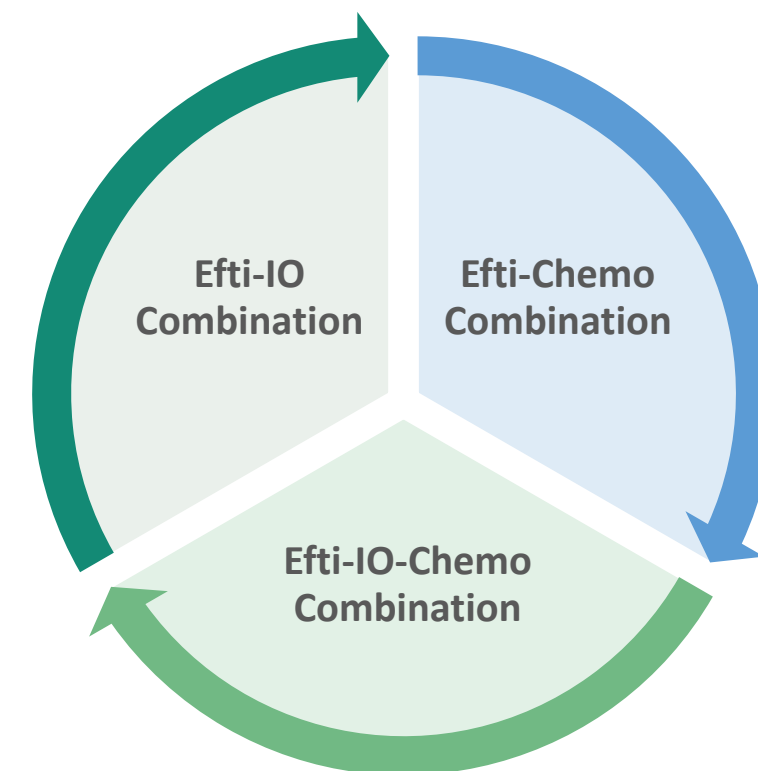
- **Multiple LAG-3 Programs** – Four clinical-stage assets and one preclinical program
- **Upcoming Milestones** – Multiple data updates from clinical programs

## Lead candidate Efti addressing therapeutic gaps across the solid tumor treatment landscape:

- **First-in-class MOA** – As unique MHC Class II agonist, efti activates innate and adaptive anti-tumor immunity
- **Activity across PD-L1 spectrum** – Activity in hot/tepid/cold tumors addressing high unmet needs
- **Consistent Outcomes** – Improved survival across multiple indications with mature data
- **Favourable Safety** – Well-tolerated profile with standard-of-care IO and/or chemotherapy
- **Manufacturing** – Achieved 2000L commercial scale production; authorization for clinical trial use granted in Sept '23

## Strong IP/Balance Sheet:

- **Intellectual Property** – Comprehensive IP portfolio; innovative biologics also potentially entitled to test data exclusivity (e.g., up to 12 years in US)
- **Well-Financed** – Cash, cash equivalent and term deposit position totalling ~A\$172.3 million<sup>1</sup> providing expected runway to end of 2026

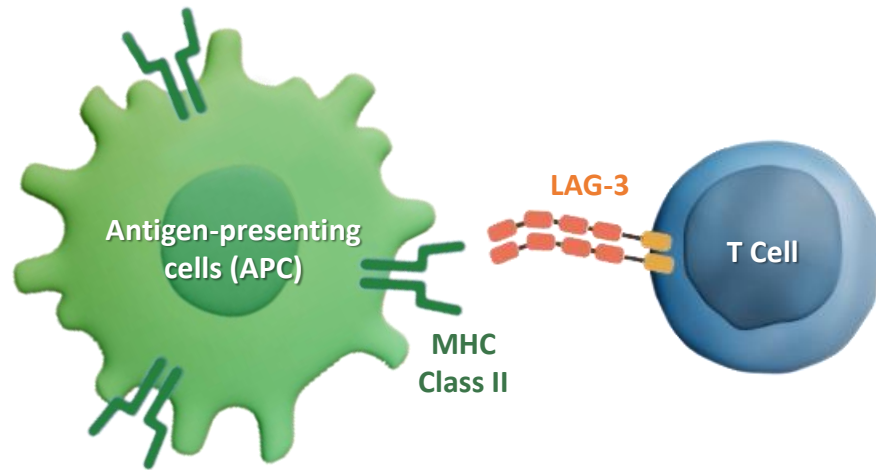


# Deep LAG-3 Pipeline in Oncology & Autoimmune Diseases

	Program	Indication	Preclinical	Phase I	Phase II	Late Stage <sup>#</sup>	Collaborations	Commercial Rights	
ONCOLOGY	<b>Eftilagimod Alfa</b> Soluble LAG-3 Protein & MHC Class II agonist	1L Non-Small Cell Lung Cancer (NSCLC)	TACTI-004   Efti + Pembrolizumab + Chemo <sup>a</sup>					MERCK MERCK MERCK IKF Merck KGaA Darmstadt, Germany  IKF Narodowy Instytut Onkologii EOC CARDIFF UNIVERSITY	LAG-3 IMMUNOTHERAPY Global Rights ex-China
		1L Head & Neck Squamous Cell Carcinoma (HNSCC)	TACTI-003   Efti + Pembrolizumab <sup>a</sup>						
		1L NSCLC, 2L HNSCC, PD-X Refractory 2L NSCLC	TACTI-002   Efti + Pembrolizumab <sup>a</sup>						
		1L Non-Squamous NSCLC	INSIGHT-003   Efti + Pembrolizumab + Chemo <sup>§</sup>						
		Urothelial Cancer	INSIGHT-005   Efti + Avelumab <sup>§, b</sup>						
		Soft Tissue Sarcoma	EFTISARC-NEO   Efti + Pembro + Radiotherapy <sup>§</sup>						
	HR+/HER2- Metastatic Breast Cancer & TNBC	AIPAC-003   Efti + Paclitaxel							
Metastatic Breast Cancer & Solid Tumors	Efti + Paclitaxel and Efti + Pembrolizumab <sup>##</sup>								
	Anti-LAG-3 Small Molecule	Undisclosed						EOC CARDIFF UNIVERSITY	EOC Efti China Rights LAG-3 IMMUNOTHERAPY Global Rights
	<b>LAG525</b> Anti-LAG-3 Antibody	Solid Tumors & Blood Cancer Triple Negative Breast Cancer Melanoma Solid Tumors Triple Negative Breast Cancer						NOVARTIS	NOVARTIS Global Rights
AUTOIMMUNE DISEASE	<b>IMP731*</b> Depleting LAG-3 Antibody	Ulcerative Colitis Psoriasis Healthy Subjects						LAG-3 IMMUNOTHERAPY Global Rights	
	<b>IMP761**</b> Agonist LAG-3 Antibody	Undisclosed							

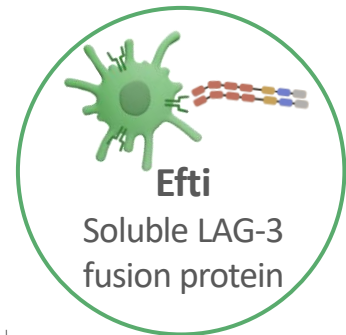
Information current as of September 2024. For EOC's China rights, ImmuteP may receive undisclosed milestones plus royalties; LAG525 (ieramilimab)- ClinicalTrials.gov (for Novartis' global rights, ImmuteP may receive milestones plus royalties); ImmuteP has no control over the trials. § Investigator Initiated Trials controlled by lead investigator & therefore ImmuteP has no control over these clinical trials. <sup>a</sup> In combination with KEYTRUDA<sup>®</sup>. <sup>b</sup> In combination with BAVENCIO<sup>®</sup>. # Late stage refers to active Phase IIb clinical trials or more clinically advanced clinical trials. ## Conducted by EOC in China. \* IMP731 - The clinical-stage asset GSK'781 is being transitioned back to ImmuteP as the licensing agreement has been terminated with an effective date of 30 May 2024. \*\* IMP761 – Phase I study to launch mid-CY2024.

# Pioneering LAG-3 Immunotherapy Portfolio



ImmuteP has designed multiple first-in-class therapeutics targeting either **MHC Class II molecules** on antigen-presenting cells (APC) or **LAG-3** on T-cells to fight cancer & autoimmune disease

## Targeting MHC Class II on APCs<sup>#</sup>

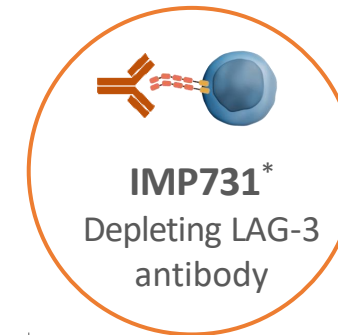
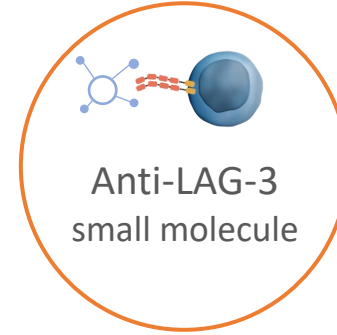


**Oncology**  
Immune Stimulation

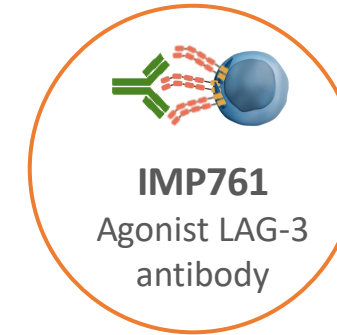
## Targeting LAG-3 on T cells



**Oncology**  
Immune Stimulation



**Autoimmune Disease**  
Immune Suppression



# Highlights & Outlook



## Non-small cell lung cancer



TACTI-004

**Phase III TACTI-004 trial (KEYNOTE-PNC-91) tests efti in combination with KEYTRUDA® and chemotherapy in ~750 first-line metastatic NSCLC patients regardless of PD-L1 expression**

- Advanced preparations for the trial, including productive interactions with regulatory agencies and other stakeholders
- Signed third clinical trial collaboration with MSD, receiving its key drug KEYTRUDA at no cost, while retaining commercial rights to efti
- Study start in late CY2024 or Q1 CY2025

INSIGHT-003

- Very encouraging mOS data (32.8 m) released from first 21 patients
- 55% ORR from 40 patients
- Recruitment ongoing

## Head and neck squamous cell carcinoma



TACTI-003

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

- Achieved a 34.5% ORR across all patients, with PD-L1 and strong DOR and DCR, and a 35.5% ORR in PD-L1-negative patients—outperforming anti-PD-1 monotherapy
- Data presented at ESMO Virtual Plenary session and ESMO annual conference
- FDA Fast Track designation in 1L HNSCC

## Metastatic breast cancer



AIPAC-003

**AIPAC-003 is an integrated Phase II/III trial evaluating efti in combination with chemotherapy (paclitaxel) for metastatic HER2-neg/low breast cancer and triple-negative breast cancer, which account for ~78% of breast cancer cases**

- Encouraging efficacy, safety, and pharmacodynamic data reported from the six patients in the safety lead-in phase
- Patient recruitment finished in the randomised Phase II part
- Data collection and cleaning ongoing with the main task to identify the OBD

## Soft tissue sarcoma

EFTISARC-NEO

**Phase II, open-label trial, examining the combination of efti, radiotherapy and KEYTRUDA in up to 40 patients with soft tissue sarcoma (STS) in the neoadjuvant setting (before surgery)**

- Initial efficacy data very encouraging and presented at a conference (first 21 patients)
- Recruitment ongoing

## Autoimmune disease

IMP761

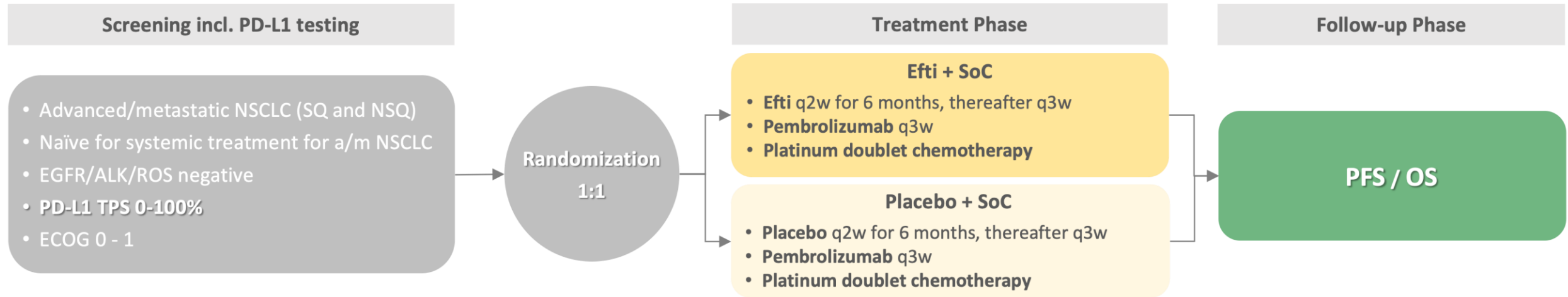
**First-in-human Phase I clinical trial of IMP761 in healthy volunteers**

- Toxicology trial completed
- Dosed first patient, recruitment ongoing

# TACTI-004 Trial: Immutep & MSD Phase III Trial in NSCLC

Opportunity to set a new standard of care across entire NSCLC population regardless of PD-L1 expression

## TACTI-004 / KEYNOTE-PNC-91 Trial Design



### Trial Overview:

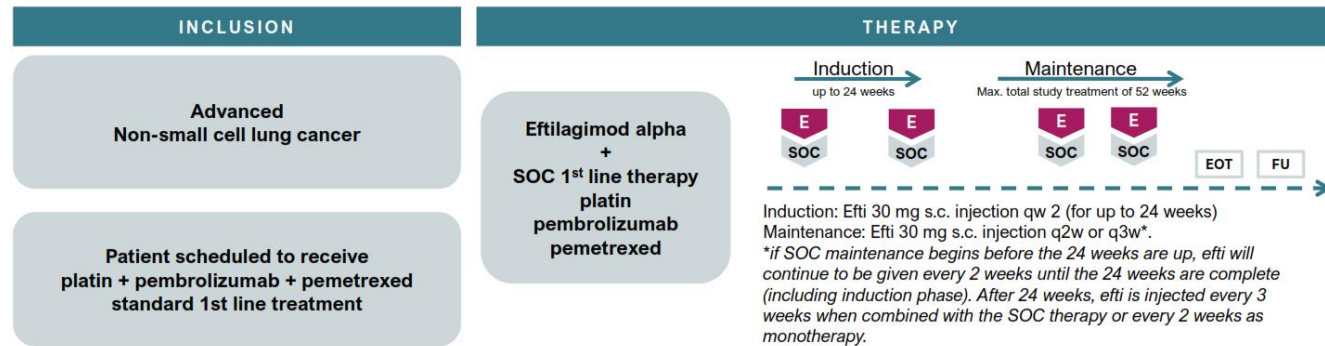
- TACTI-004 will be a 1:1 randomized, double-blind, multinational, controlled clinical study with ~750 patients
- Trial will enroll first line squamous and non-squamous NSCLC patients who are unselected for PD-L1 expression
- Dual primary endpoints will be Progression-Free and Overall Survival with both being adequately powered

### Key Milestones:

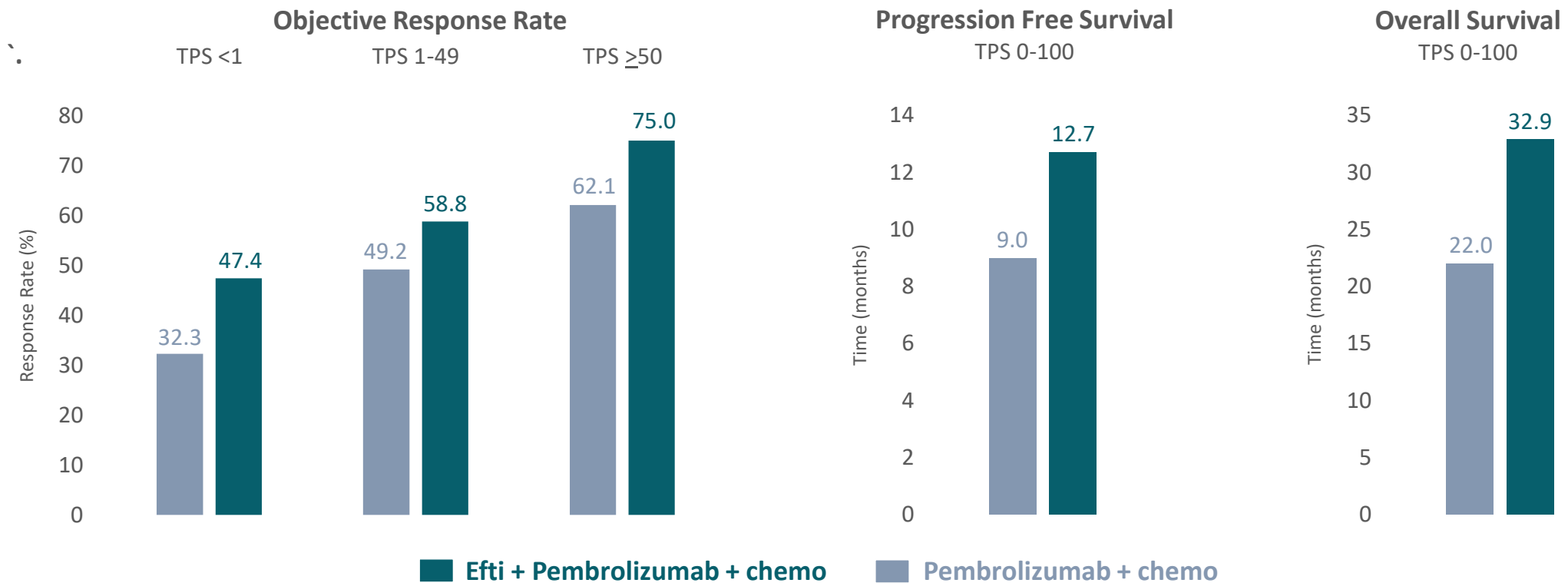
- Study start expected in Q4 2024 / Q1 2025
- Futility analysis expected in late 2025 / early 2026 and interim analysis in late 2026 till mid-2027 (event driven)

# INSIGHT-003: Excellent Mature Survival Data

Promising efficacy & safety from first-in-human study evaluating Efti + KEYTRUDA + doublet chemo



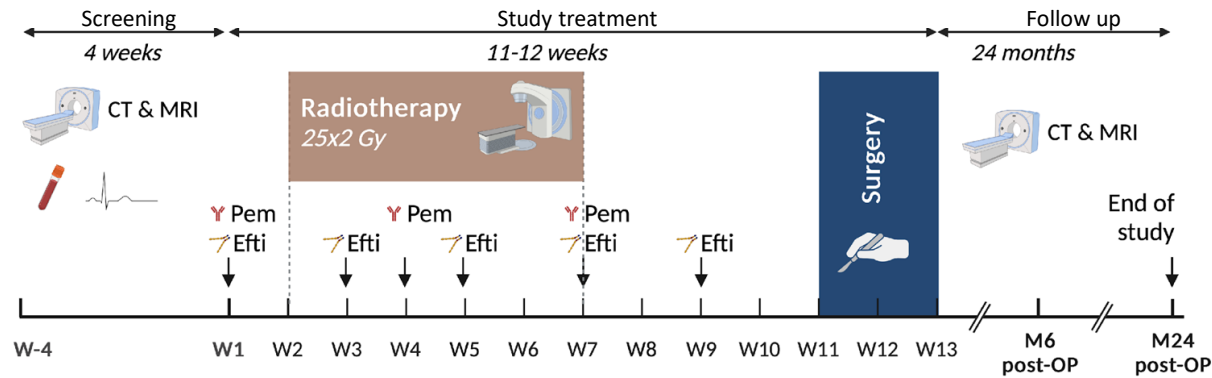
- Investigator-initiated Phase I study in first line metastatic non-squamous NSCLC regardless of PD-L1 (TPS 0-100)
- Multi-centre trial led by the Frankfurt Institute of Clinical Cancer Research (IKF)
- Completion of patient enrollment expected in Q1'2025



# Soft Tissue Sarcoma: Orphan Disease with High Unmet Need

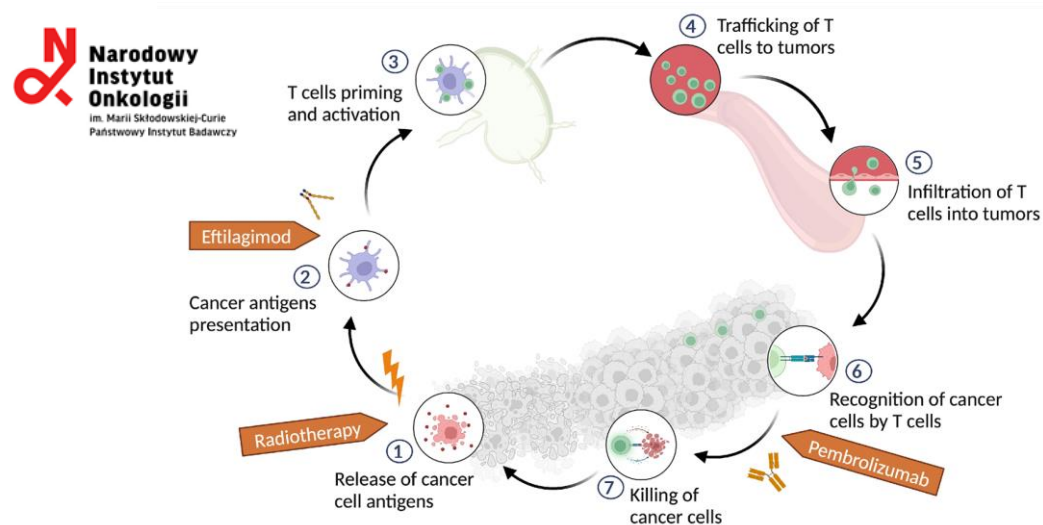
Investigator-initiated trial studying novel triple combination of Efti + Radiotherapy + KEYTRUDA

## EFTISARC-NEO Phase II Trial Design\*



- First trial studying efti in neoadjuvant setting and with radiotherapy
- Importantly, study will provide access to tumor tissue prior to and after treatment, so tumor microenvironment can be assessed\*\*
- Cost-efficient Phase II study funded by grant from Polish government
- Completion of patient enrollment expected in Q1'2025

## Rationale for triple combination based on cancer-immune cycle\*



## Positive data from EFTISARC-NEO presented at CTOS 2024:

- ✓ Based on preliminary analysis among 21 patients available for primary endpoint assessment, triple combination with efti demonstrates significant efficacy
- ✓ Median 50% tumour hyalinization (primary endpoint and important predictor of overall survival) is greater than 3-fold increase versus historical median 15% from radiotherapy alone
- ✓ 71.4% of patients achieved pathologic response defined as  $\geq 35\%$  of hyalinization/fibrosis
- ✓ 9.5% of patients achieved a complete pathologic response
- ✓ Therapy well tolerated

## Manufacturing at Commercial Scale

- Comparability of Drug Substance and Drug Product manufactured at 2,000L scale achieved
- Regulatory authorisation for ehti manufactured at commercial 2,000L scale
- Enables use in clinical trials across multiple European countries and the United States
- Follows successful scale up of the manufacturing process from the 200L process to 2,000L at WuXi Biologics



## Robust Intellectual Property Protection

### Ehti

- Eight new patents granted in FY24:
  - Protects combinations with chemotherapy or anti-PD-1 therapy in Europe, Korea and Brazil
  - Patent for Immunetep's binding assay for determining MHC Class II binding activity in Brazil, Canada, India, Macao, and Russia
- Broad protection for ehti across a total of 9 patent families

### IMP761

- Two new patents granted in FY24 in Australia and Mexico



# FY24 Financial Summary

- Strong cash position of approx. A\$172.3 million including investment in term deposit as of 30 Sept 2024 following A\$100.2 million equity raise in June 2024
- Disciplined cash management strategy with focus on the development strategy for efti and IMP761
- Total revenue and other income were A\$7.8 million in FY24 compared to A\$5.2 million in FY23
- Research and development and intellectual property expenses increased to A\$41.5 million in FY24 due to clinical trial activity and associated expenses
- Increases in clinical trial costs drove the increase in R&D expenses and the net loss

	FY24	FY23
Revenue and other income	A\$7.8M	A\$5.2M
G&A Expenses	A\$8.9M	A\$8.7M
R&D and IP expenses	A\$41.5M	A\$36.3M
Net loss	A\$42.7M	A\$39.9M
Net operating cash outflow	A\$34.8M	A\$35.4M
Cash and cash equivalents at the end of the financial year	A\$181.8 M	A\$123.4M
Cash and cash equivalents at 30 September	A\$172.3M	A\$110.1M

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

## 2024

- **Non-Small Cell Lung Cancer** – TACTI-004 preparations for study start in late 2024 / early 2025
- **Head and Neck Squamous Cell Carcinoma** – Update from Cohort B of TACTI-003 trial at the ESMO Immuno-Oncology Congress
- **Autoimmune Diseases** – Safety data from IMP761 first-in-human Phase I trial anticipated by year-end

## 2025

- **Non-Small Cell Lung Cancer** – Potential futility analysis in TACTI-004 Phase III trial by year end 2025; update from INSIGHT-003 trial
- **Metastatic Breast Cancer** – Update from AIPAC-003 trial
- **Head and Neck Squamous Cell Carcinoma** – Update from TACTI-003 trial
- **Soft Tissue Sarcoma** – Update from investigator-initiated EFTISARC-NEO trial
- **Metastatic Urothelial Carcinoma** – Update from investigator-initiated INSIGHT-005 trial
- **Autoimmune Diseases** – Update from IMP761 first-in-human Phase I trial
- **Additional Updates** – From ongoing clinical trials, partnered programs, and potential expansion of clinical trial pipeline
- **Well-Funded** – Cash, cash equivalent and term deposit totalling ~A\$172.3 million (~US\$119.1 million)<sup>1</sup>; runway expected to end of CY2026



Thank You