



**2021 AGM Presentation**  
Marc Voigt, CEO

*The global leader in developing LAG-3 therapeutics*

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*This presentation was authorised for release by the CEO, Marc Voigt.*

**FY21 saw Immunetep transform into a late-stage biotech with more trials, partners and industry momentum than ever**

Global leadership position in LAG-3 with 4 LAG-3 related product candidates in immuno-oncology and autoimmune disease



Exciting potential of lead product candidate efti as a combination therapy following compelling clinical data & strong rationale to combine with multiple FDA approved treatments



Strengthened partnerships & collaborations with large pharma industry leaders



Merck KGaA,  
Darmstadt, Germany



**LAG-3 Pioneer:  
French immunologist  
Prof Frédéric Triebel,  
Immutep CMO & CSO**



# LAG-3 is a validated immune checkpoint

Existing approved immuno-oncology therapies target:

**PD-1 &  
PD-L1**

e.g.  
**OPDIVO**  
(nivolumab)

**CTLA-4**

e.g.  
**YERVOY**



LAG-3 was validated by BMS in a Phase III trial (ASCO 2021)

Immunetep is positioned to lead in LAG-3 with more LAG-3 related programs than any other pharma or biotech

# LAG-3 Therapeutic Landscape Overview

		Company	Program	Preclinical	Phase I	Phase II	Phase III	Total Trials	Patients	
Oncology	Agonist	immutep <sup>+</sup> LAG-3 IMMUNOTHERAPY	Eftilagimod Alpha <sup>(5)</sup>		10	4		14	967	
	Antagonist	BMS	Relatlimab <sup>(6)</sup>		7	32	2	PDUFA: 19 March 2022 & submitted to EMA	41	9,775
		Merck & Co. Inc.	Favezelimab		1	5			6	1066
		NOVARTIS	Ieramilimab		1	4			5	952
		Macrogenics	Tebotelimab		3	3			6	1422
		H-L Roche	RO7247669		1	2			3	538
		B.I.	BI754111		4	1			5	649
		Regeneron <sup>(1)</sup>	Fianlimab		1	1			2	836
		Innovent	IBI110		1	1			2	328
		Tesaro <sup>(3)</sup>	TSR-033		1	1			2	139
		Incyte	INCAGN02385		1	1			2	74
		Symphogen <sup>(2)</sup>	SYM022		3				3	169
		F-star	FS-118		2				2	102
Xencor	XmAb-22841		1				1	242		
Autoimmune	Agonist	immutep <sup>+</sup> LAG-3 IMMUNOTHERAPY	IMP761					--	--	
	Depleting AB	gsk <sup>(4)</sup>	GSK2831781 (IMP731)		2	1		3	207	

Sources: GlobalData, Company websites, clinicaltrials.gov, and sec.gov, as of 25th October 2021. The green bars above represent programs conducted by Immutep &/or its partners. Total trials includes all active, completed &/or inactive trials. Patient totals are based on estimated total enrolled &/or to be enrolled. Not a complete list of currently existing LAG-3 products.

1) As of January 7, 2019 Regeneron is in full control of program and continuing development ([https://www.sec.gov/Archives/edgar/data/872589/000110465919000977/a19-1325\\_18k.htm](https://www.sec.gov/Archives/edgar/data/872589/000110465919000977/a19-1325_18k.htm))

2) On 3 Apr. 2020 Les Laboratoires Servier acquired Symphogen

3) Tesaro was acquired by and is now part of GSK ([www.gsk.com/en-gb/media/press-releases/gsk-completes-acquisition-of-tesaro-an-oncology-focused-biopharmaceutical-company/](http://www.gsk.com/en-gb/media/press-releases/gsk-completes-acquisition-of-tesaro-an-oncology-focused-biopharmaceutical-company/))

4) Includes two completed Phase I studies and one discontinued Phase 2 study

5) Including IITs, one planned trials (MBC trial by EOC)

6) RELATIVITY-047 (<https://investors.bms.com/iframes/press-releases/press-release-details/2021/Bristol-Myers-Squibb-Announces-RELATIVITY-047-a-Trial-Evaluating-Anti-LAG-3-Antibody-Relatlimab-and-Opdivo-nivolumab-in-Patients-with-Previously-Untreated-Metastatic-or-Unresectable-Melanoma-Meets-Primary-Endpoint-of-Progression-Free-Survival/default.aspx>)

# Exposure to two very large and growing pharmaceutical markets

**Autoimmune<sup>1</sup>**

US\$139.40  
billion by 2027  
growing at  
2.8% CAGR

**Oncology<sup>2</sup>**

US\$222.38  
billion by  
2027  
growing at  
7.4% CAGR

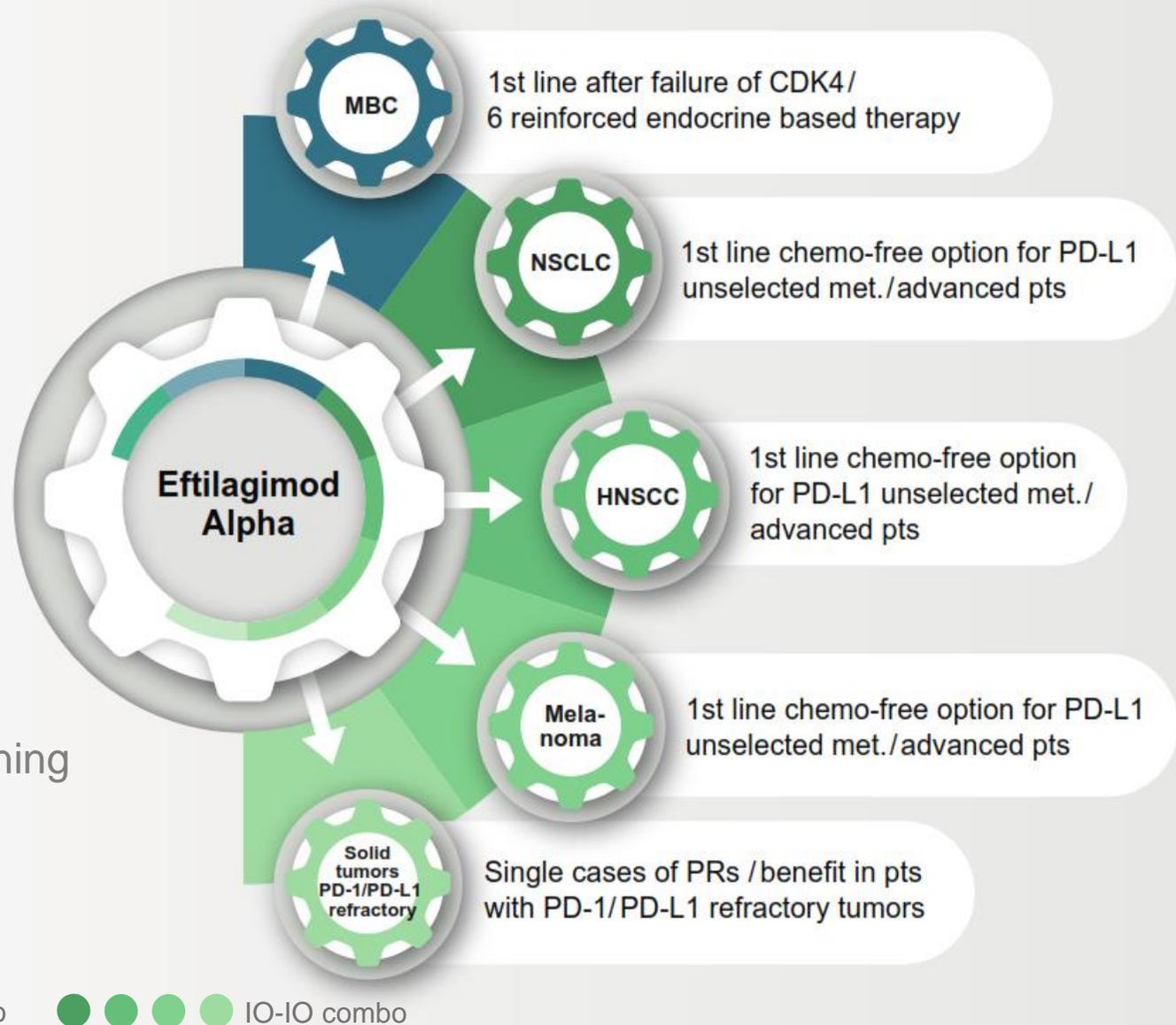
<sup>1</sup> <https://www.reportlinker.com/p06050561/Global-Autoimmune-Disease-Therapeutics-Industry.html>

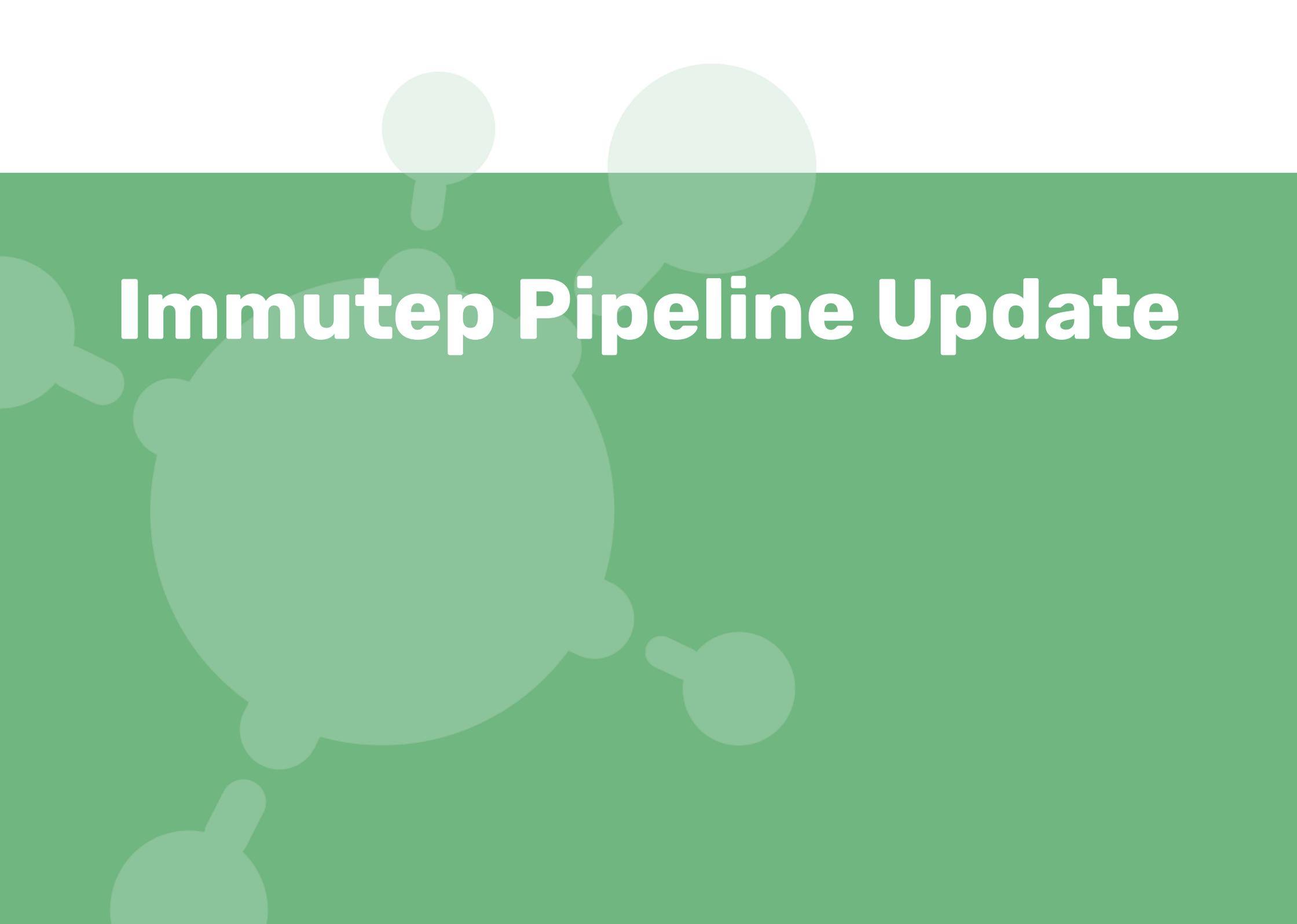
<sup>2</sup> <https://www.alliedmarketresearch.com/oncology-cancer-drugs-market>

# Efti: Potential Pipeline in a Product

Potential for use in various combination settings

- Unique MHC II agonist
- Excellent safety profile
- Encouraging efficacy data
- Low cost of goods
- Unique protective IP positioning (unlike ICI mAbs)





# Immutable Pipeline Update

# Clinical data building efti's intrinsic value in FY21

## AIPAC phase IIb trial in breast cancer



- Final Overall Survival (OS) data supports Phase III clinical development
- OS benefit trend in total population, with median survival benefit of +2.9 months from efti plus chemotherapy, compared to chemotherapy plus placebo
- Statistically significant and clinically meaningful OS benefit pre-specified patient subgroups of:
  - +7.5 months in patients under 65 years
  - +19.6 months in patients with low monocytes
  - +4.2 months in patients with luminal B

## TACTI-002 phase II trial in lung cancer (Part A)



- Very favourable overall response rate (ORR) of 41.7% with favourable duration and depth of responses in 1st line NSCLC
- 2 patients with Complete Responses (complete disappearance of all lesions)
- Tumor responses seen in all PD-L1 subgroups, including patients typically less responsive to anti-PD-1 therapy

## TACTI-002 phase II trial in head and neck cancer (Part C)

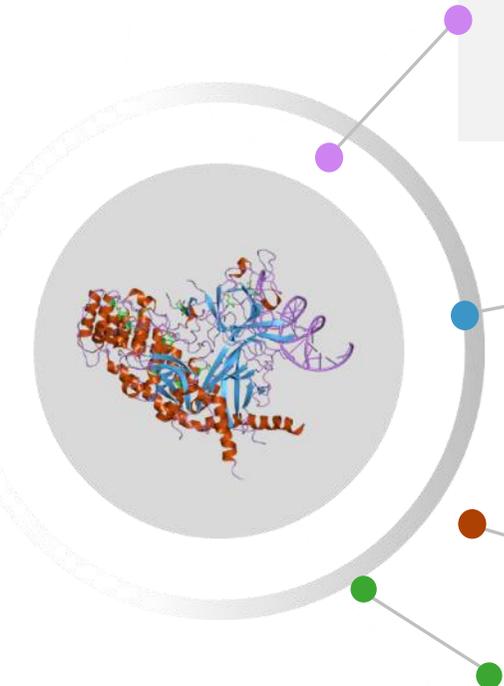


- Encouraging ORR of 29.7% in 2nd line HNSCC patients
- Very favourable duration and depth of responses, with 5 Complete Responses and a minimum duration of response extended to > 9 months across all responding patients
- Responses continue to be seen across all PD-L1 subgroups

## INSIGHT-004 trial in solid cancers



- 41.7% of patients showed a Partial Response
- Encouraging anti-tumour activity signals in difficult to treat cancers



# Expanded Trial Pipeline

## Registrational Phase III Trial

Planning commenced for a new Phase III trial evaluating efti in metastatic breast cancer. Positive EMA scientific advice received post FY21.



## TACTI-003 Phase IIb

New study evaluating efti in the commercially more relevant 1<sup>st</sup> line recurrent or metastatic HNSCC in a randomized setting



## INSIGHT-003 (Stratum C)

First triple combination therapy study of efti in various solid tumours



## INSIGHT-005 (Stratum E)

New study of efti in combination with bintrafusp alfa in patients with various solid tumours in collaboration with\*

**Merck KGaA**  
Darmstadt, Germany



# Immutep's LAG-3 Trial Pipeline\*

	Program	Preclinical	Phase I	Phase II	Late Stage <sup>(5)</sup>	Commercial Rights	Market Size <sup>(6)</sup>				
Oncology	Eftilagimod Alpha (efti or IMP321) APC activating soluble LAG-3 protein	Metastatic Breast Cancer (Chemo – IO) AIPAC					Global Rights 	US\$29.9 billion			
		Head and Neck Squamous Cell Carcinoma (IO – IO) <sup>(1b)</sup> TACTI-003						Global Rights 	US\$1.9 billion		
		Head and Neck Squamous Cell Carcinoma (IO – IO) <sup>(1)</sup> TACTI-002							Global Rights 	US\$22.6 billion	
		Non-Small-Cell Lung Carcinoma (IO – IO) <sup>(1)</sup> TACTI-002					Global Rights 				
		Solid Tumors (IO – IO) <sup>(2), (3a)</sup> INSIGHT-004				Merck KGaA, Darmstadt, Germany		Chinese Rights 			
		Solid Tumors (IO – IO) <sup>(2), (3b)</sup> INSIGHT-005				Merck KGaA, Darmstadt, Germany			Global Rights 		
		Solid Tumors (IO – IO – chemo) <sup>(2)</sup> INSIGHT-003								Chinese Rights 	
		Solid Tumors (Cancer Vaccine) <sup>(4a)</sup> YNP01 / YCP02 / CRESCENT 1				CYTOLIMIC Cytotoxic T Lymphocyte Immunotherapy in Cancer					Global Rights 
		Metastatic Breast Cancer (Chemo – IO) <sup>(4b)</sup>					Chinese Rights 		US\$2.3 billion		
Inf. Dis.	Efti	COVID-19 disease (Monotherapy) <sup>(7)</sup> EAT-COVID				Global Rights <sup>(8)</sup> 					
Autoimm.	IMP761 (Agonist AB)					Global Rights 	US\$149.4 billion (2025)				

Notes

\* Information in pipeline chart current as at November 2021

(1) In combination with KEYTRUDA® (pembrolizumab) (1b) Planned new trial for 1<sup>st</sup> line HNSCC patients

(2) INSIGHT Investigator Initiated Trial ("IIT") is controlled by lead investigator and therefore Immutep has no control over this clinical trial

(3) a) In combination with BAVENCIO® (avelumab); b) in combination with Bintrafusp alfa

(4) a) Conducted by CYTLIMIC in Japan; b) Conducted by EOC in China. Immutep has no control over either of these trials.

(5) Late stage refers to Phase IIb clinical trials or more clinically advanced clinical trials

(6) GlobalData Market Size forecast for US, JP, EU5, Urban China and Australia; [KBV Research: https://www.kbvresearch.com/autoimmune-disease-therapeutics-market/](https://www.kbvresearch.com/autoimmune-disease-therapeutics-market/)

(7) IIT conducted by University Hospital Pilsen. Immutep has no control over this trial.

(8) Ex China

# Immutep Out-Licensed Immunotherapy Pipeline\*

Program	Preclinical	Phase I	Phase II	Late Stage <sup>(1)</sup>	Commercial Rights/Partners	Updates
<b>Oncology</b>  LAG525 (Antagonist AB)	Solid Tumors + Blood Cancer (IO-IO Combo)				Global Rights 	Novartis currently has five clinical trials for LAG525 in multiple cancer indications for approx. 1,000 patients. <sup>(4)</sup>
	Triple Negative Breast Cancer (Chemo-IO Combo)					
	Melanoma (IO-IO-Small Molecule Combo)					
	Solid Tumors (IO-IO Combo)					
	Triple Negative Breast Cancer (Chemo-IO-Small Molecule Combo)					
<b>Autoimmune</b>  GSK781 (Depleting AB)	Ulcerative Colitis <sup>(6)</sup>				Global Rights 	Two successful Phase I studies. Phase II clinical study in up to 242 ulcerative colitis patients was discontinued. <sup>(5)</sup>
	Healthy Japanese and Caucasian Subjects <sup>(2)</sup>					
	Psoriasis <sup>(3)</sup>					

Notes

\* Information in pipeline chart current as at November 2021

13 (1) Late stage refers to Phase IIb clinical trials or more clinically advanced clinical trials

(2) Reflects completed Phase I study in healthy volunteers

(3) Reflects completed Phase I study in healthy volunteers and in patients with plaque psoriasis

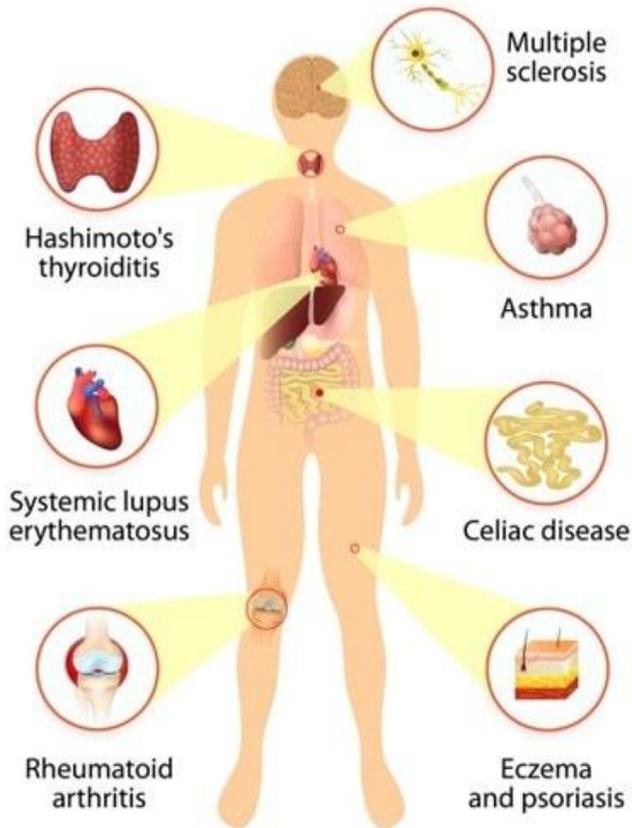
(4) <https://clinicaltrials.gov/ct2/results?cond=&term=LAG525&cntry=&state=&city=&dist=>

(5) <https://clinicaltrials.gov/ct2/results?cond=&term=GSK2831781&cntry=&state=&city=&dist=> and <https://www.gsk.com/media/5957/q1-2020-results-slides.pdf>

(6) Discontinued in Jan 2021

# Broad potential in targeting auto-reactive memory T cells with IMP761

## AUTOIMMUNE DISEASES

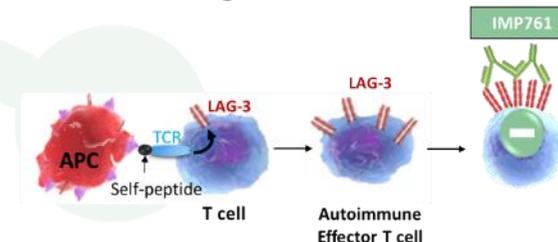


## THE PRESENT: FIGHTING THE SYMPTOMS

Treating general inflammation:  
corticoids, methotrexate,  
anti-TNF- $\alpha$ , -IL-6, -IL-17, -IL-23 mAbs

## THE FUTURE: FIGHTING THE CAUSE

Treating the disease process:  
silencing the few autoimmune memory T cells  
accumulating at the disease site with IMP761



**POTENTIAL GAME CHANGER IN AUTOIMMUNE DISEASES (US\$139.40 billion by 2027)<sup>1</sup>**

<sup>1</sup> <https://www.reportlinker.com/p06050561/Global-Autoimmune-Disease-Therapeutics-Industry.html>

# Other Highlights of FY 21

-  TACTI-002 Part A expansion - 1st line non-small cell lung cancer (NSCLC)
-  TACTI-002 whole trial recruitment advanced
-  Efti GMP manufacturing scale up progress to increase manufacturing to 2,000L capacity bioreactors
-  IMP761 cell line development completed and preparations for GMP manufacturing commenced
-  Intellectual property position strengthened with 9 new patents in FY21 for efti, IMP761 and IMP701 (leramilimab)



## Post FY21

Final AIPAC and interim TACTI-002 data presented at SITC 2021

Two further Chinese patents granted

TACTI-002 1<sup>st</sup> line and 2<sup>nd</sup> line NSCLC fully recruited

French R&D tax incentive received (A\$3.4m)

# Partner & Collaborator Progress



## IMP701 (LAG525)

5 clinical trials in multiple cancer indications - more than 1,000 patients. Data presented at ESMO Congress in 2021.



## IMP731 (GSK2831781)

Ulcerative colitis trial stopped; further assessment ongoing to determine next steps. Partnership remains in place.



## Efti as vaccine adjuvant

Studies of peptide vaccine, CYT001 in advanced or metastatic solid cancer.



## Efti

New study of efti in combination with chemotherapy in metastatic breast cancer patients in China.



## Diagnostic

Collaboration with LabCorp (NYSE: LH) to support the development of immuno-oncology products or services.



# Key Financials

- 

Licensing revenue decreased in FY21 mainly due to a GSK milestone payment of A\$7.49M in FY20. No such milestones were recognised in FY21
- 

Research material sales increased from A\$280K for FY20 to A\$313K for FY21
- 

A\$3.4m R&D tax rebate from Australian and French government were recognised in FY21
- 

R&D and IP expenses decreased as expected due to the decreased clinical trial activity for AIPAC & TACTI-mel
- 

Strengthened cash balance with A\$29.6 million placement in November 2020 and A\$67.2 million two-tranche placement and share purchase plan (tranche two completed in July 2021)
- 

Loss after tax for FY21 was higher compared to FY20 mainly due to the decrease in licencing income

	FY21	FY20
Revenue and other income	A\$4.0M	A\$16.5M
G&A Expenses	A\$6.3M	A\$6.3M
R&D and IP expenses	A\$17.2M	A\$22.5M
Net loss	A\$29.9M	A\$13.5M
Net operating cash outflow	A\$17.6M	A\$10.8M
Cash and cash equivalents at the end of the financial year	A\$60.6M	A\$26.3M
Cash and cash equivalents at 30 September 2021	A\$106.4M	



# Outlook

# 2022 News Flow\*

## H1 2022

- TACTI-003 start & ongoing recruitment of **new randomised trial in 1st line HNSCC** in 2021/2022
- Further data from **TACTI-002**
- Planning for **AIPAC-003** trial in MBC
- Further intellectual property protection via new patents
- Further updates from partnered programs (e.g. EOC Pharma, GSK, Novartis, EAT COVID, CYTLIMIC)

## H2 2022

- Manufacturing scale up to 2,000L
- Ongoing **regulatory** engagement, including US FDA
- Further data from **TACTI-002**
- Further updates from **TACTI-003**
- **INSIGHT-003** first interim results in 2022
- Updates from **IMP761**
- Further updates from partnered programs

Notes:

\*The actual timing of future data readouts may differ from expected timing shown above. These dates are provided on a calendar year basis.

Global leadership position in LAG-3 with 4 LAG-3 product candidates in immuno-oncology and autoimmune disease, all with different mechanisms of action

Multiple active clinical trials (including partnered candidates), with further significant data read-outs expected in 2022

Compelling clinical data from efiti & strong rationale to combine with multiple FDA approved treatments

Established collaborations with e.g. Merck (MSD), Pfizer, Merck KGaA, Novartis and GSK

# Corporate Snapshot

Ticker symbols	IMM (ASX) IMMP (NASDAQ)
Securities on issue <sup>(1)</sup> as at 23 November 2021	~ 853.9 million ordinary shares
Cash balance as at 30 September 2021	~ A\$106.4 million (US\$76.7 million)
Market Cap <sup>(2)</sup> as at 23 November 2021	~ A\$435.5 million (US\$314.5 million)

(1) Currently ~30.28% of the ordinary shares are represented by ADSs listed on NASDAQ where 1 ADS represents 10 ordinary shares. Please refer to latest Appendix 2A released on ASX for a detailed summary of all securities on issue.

(2) Market capitalisation based on ASX share price of A\$0.51 on 23 November 2021.

USD equivalent of cash balance was calculated with FX rate of 0.7206 and USD equivalent of market cap was calculated with FX rate of 0.7221.



**immutep**<sup>®</sup>  
LAG-3 IMMUNOTHERAPY

**Thank you**