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# The global leader in developing LAG-3 therapeutics

Corporate Presentation  
February 2021

*(ASX: IMM, NASDAQ: IMMP)*

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# Overview

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## Immutep

is an innovative biotechnology company developing novel immunotherapies for cancer and autoimmune diseases



## Global leadership position

in LAG-3 with four product candidates in immuno-oncology and autoimmune diseases



## Clinical Potential

Immutep's product candidates have demonstrated clinical potential in a range of indications with high unmet need



## Collaboration deals executed with industry leaders



## Corporate Strategy:

To develop product candidates to sell, licence or partner with large pharmaceutical companies at key value inflection points



# Directors & Officers



**Russell J. Howard**  
PhD  
Non-Executive  
Chairman

Scientist, executive manager and entrepreneur; previously CEO of Maxygen & Oakbio, positions at NIH, DNAX, Affymax



**Pete A Meyers**  
Non-Executive  
Director & Deputy  
Chairman

Former Chief Financial Officer of Eagle Pharmaceuticals, Inc.; previously CFO of Motif Bio; previously Co-Head of Global Health Care Investment Banking at Deutsche Bank



**Grant Chamberlain**  
Non-Executive  
Director

20+ years in investment banking; current principal of One Ventures; previously Head of Mergers and Acquisitions and Financial Sponsors Australia at Bank of America Merrill Lynch



**Marc Voigt**  
Executive Director &  
Chief Executive  
Officer

20+ years in leading positions in finance, venture capital and biotech industry, multiple financing & licensing transactions



**Prof. Frédéric Triebel**  
MD PhD,  
Chief Scientific  
Officer & Chief  
Medical Officer

Clinical haematologist, and PhD in immunology (Paris University) and successfully developed several research programs in immunogenetics and immunotherapy, leading to over 144 publications and 16 patents



**Deanne Miller**  
Chief Operating  
Officer, General  
Counsel & Company  
Secretary

Lawyer; previous positions at RBC Investor Services, Westpac, Macquarie and ASIC

# LAG-3 Overview

- The most promising immune checkpoint -

# LAG-3 Therapeutic Landscape Overview

Oncology

Autoimmune

	Company	Program	Preclinical	Phase I	Phase II	Phase III	Total Trials	Patients
Agonist	immutep <sup>+</sup>	Eftilagimod Alpha <sup>(4)</sup>		10	5		15	951
Antagonist	BMS	Relatlimab		10	26	2	38	10,528
	NOVARTIS	LAG525 (Ieramilimab)		1	4		5	1,069
	B.I.	BI754111		4	1		5	849
	Macrogenics	MGD013		3	3		5	1054
	Merck & Co. Inc.	MK4280		2	3		3	1080
	Incyte	INCAGN02385		1	1		2	92
	Regeneron <sup>(1)</sup>	REGN3767		1	1		2	769
	Symphogen A/S	SYM022		3			2	232
	Tesaro <sup>(2)</sup>	TSR-033		2			2	75
	H-L Roche	RG6139		1			1	320
	Innovent	IBI110		1			1	268
	Xencor	XmAb-22841		1			1	242
F-Star	FS-118		1			1	43	
Agonist	immutep <sup>+</sup>	IMP761					--	--
Depleting AB	gsk <sup>(3)</sup>	GSK2831781 (IMP731)		2	1		3	346

Notes:

Sources: Company websites, clinicaltrials.gov, and sec.gov, as of January 2021. The green bars above represent programs conducted by ImmuteP &/or its partners.

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

3)

Includes two completed Phase I studies and one discontinued Phase 2 study (see slide 9) Including two planned trials in MBC and HNSCC

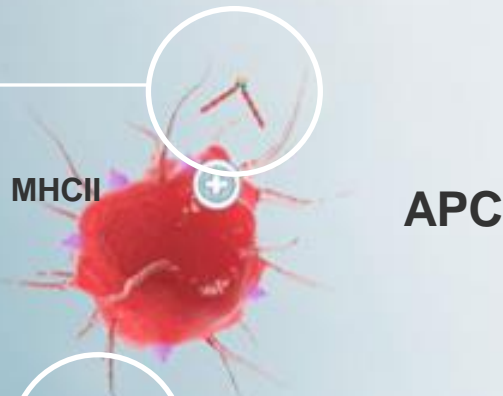
# Targeting LAG-3: Multiple Therapeutics in Numerous Diseases

LAG-3, an immune checkpoint, was discovered in 1990 by Immutep's CMO and CSO Prof Frédéric Triebel. Immutep has **four** LAG-3 product candidates:

## IMMUNOSTIMULATION

### Efti

(APC Activator)



APC

### LAG525

(Antagonistic mAb)  
Out-licensed to:



T Cell

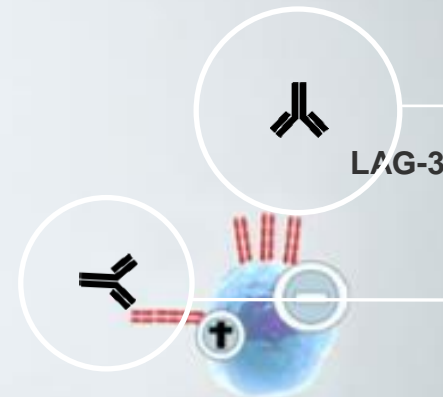
RELEVANT DISEASES

Immuno-oncology  
Combination Therapies  
Viral Infections

## IMMUNOSUPPRESSION

### IMP761

(Agonistic mAb)



T Cell

### GSK'781

(Depleting mAb)  
Outlicensed to:



RELEVANT DISEASES

Rheumatoid Arthritis  
IBD  
Other Autoimmune Diseases

# Immunotherapy Pipeline\*

Program	Preclinical	Phase I	Phase II	Late Stage <sup>(5)</sup>	Commercial Rights	Market Size <sup>(6)</sup>	
<b>Eftilagimod Alpha</b> (efti or IMP321)  APC activating soluble LAG-3 protein	Metastatic Breast Cancer (Chemo – IO) AIPAC				Global Rights 	US\$29.9 billion	
	Non-Small-Cell Lung Carcinoma (IO – IO) <sup>(1)</sup> TACTI-002			MERCK INVENTING FOR LIFE		US\$22.6 billion	
	Head and Neck Squamous Cell Carcinoma (IO – IO) <sup>(1)</sup> TACTI-002			MERCK INVENTING FOR LIFE		US\$1.9 billion	
	Head and Neck Squamous Cell Carcinoma (IO – IO) <sup>(1b)</sup>			MERCK INVENTING FOR LIFE			
	Solid Tumors (IO – IO) <sup>(2), (3)</sup> INSIGHT-004			Pfizer Merck KGaA, Darmstadt, Germany		Chinese Rights 	US\$4.5 billion
	Melanoma (IO – IO) <sup>(1)</sup> TACTI-mel						
	Solid Tumors (In situ Immunization) <sup>(2)</sup> INSIGHT						
	Solid Tumors (Cancer Vaccine) <sup>(4a)</sup> YNP01 and YCP02			CYTLIMIC Cytotoxic T Lymphocyte Immunotherapy in Cancer			
	Metastatic Breast Cancer (Chemo – IO) <sup>(4b)</sup>			EOC		US\$2.3 billion	
<b>Inf. Dis.</b> Efti	COVID-19 disease (Monotherapy) <sup>(7)</sup> EAT-COVID				Global Rights 		
<b>Autoimm.</b> IMP761 (Agonist AB)					Global Rights 	US\$149.4 billion (2025)	

Notes

- (1) Information in pipeline chart current as at January 2021
- (2) In combination with KEYTRUDA® (pembrolizumab) (1b) Planned new trial for 1<sup>st</sup> line HNSCC patients
- (3) INSIGHT Investigator Initiated Trial ("IIT") is controlled by lead investigator and therefore ImmuteP has no control over this clinical trial
- (4) In combination with BAVENCIO® (avelumab)
- (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.



# 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 ongoing for LAG525 in multiple cancer indications for over 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> GSK'781 (Depleting AB)	Ulcerative Colitis <sup>(6)</sup>				Global Rights 	Two successful Phase I studies, but the Phase II clinical study in up to 242 ulcerative colitis patients was discontinued.
	Healthy Japanese and Caucasian Subjects <sup>(2)</sup>					
	Psoriasis <sup>(3)</sup>					

Notes

- (1) Information in pipeline chart current as at January 2021
- (2) Late stage refers to Phase IIb clinical trials or more clinically advanced clinical trials
- (3) Reflects completed Phase I study in healthy volunteers
- (4) Reflects completed Phase I study in healthy volunteers and in patients with plaque psoriasis

- (5) <https://clinicaltrials.gov/ct2/results?cond=&term=LAG525&cntry=&state=&city=&dist=>
- (6) <https://clinicaltrials.gov/ct2/results?cond=&term=GSK2831781&cntry=&state=&city=&dist=> and <https://www.gsk.com/media/5957/q1-2020-results-slides.pdf>
- (7) Discontinued in Jan 2021

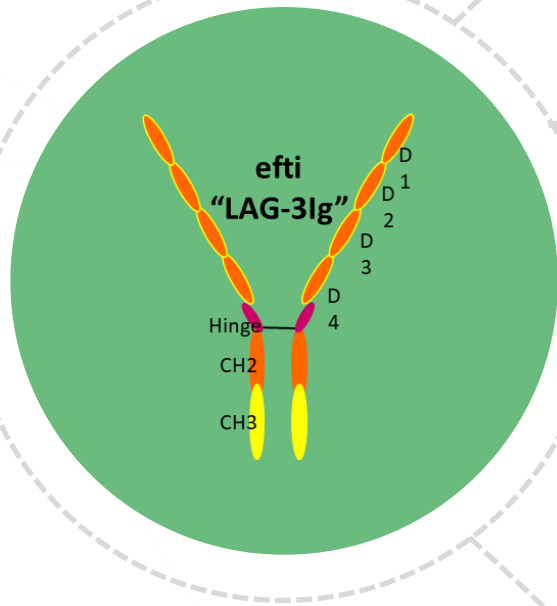
# Eftilagimod Alpha (efti or IMP321)

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# Efti: Potential Pipeline in a Product

## High intrinsic value

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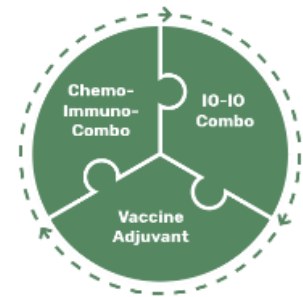
Unique APC activator (MHC II Agonist)

Effective APC activation leads to immune activation (e.g. CD8 T cells) as shown by *ex vivo* and *in vivo* experiments, and in clinical studies

*Pipeline in a product* - Not limited to a select number of oncology indications, target expressions or treatment lines

Potentially low costs of goods

Efti's safety profile enables it to be used in various combination settings



Route of admin: subcutaneously  
Dose: 30 mg every 2 weeks\*

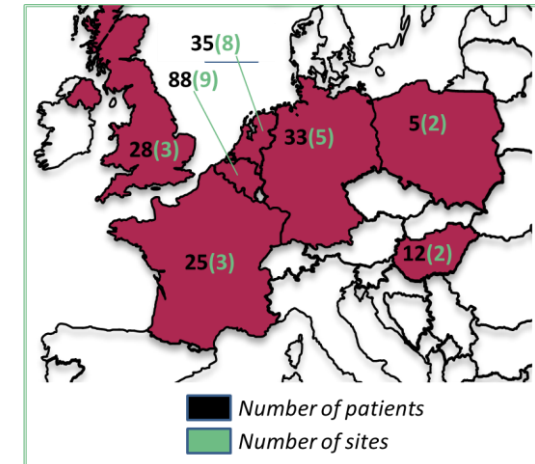
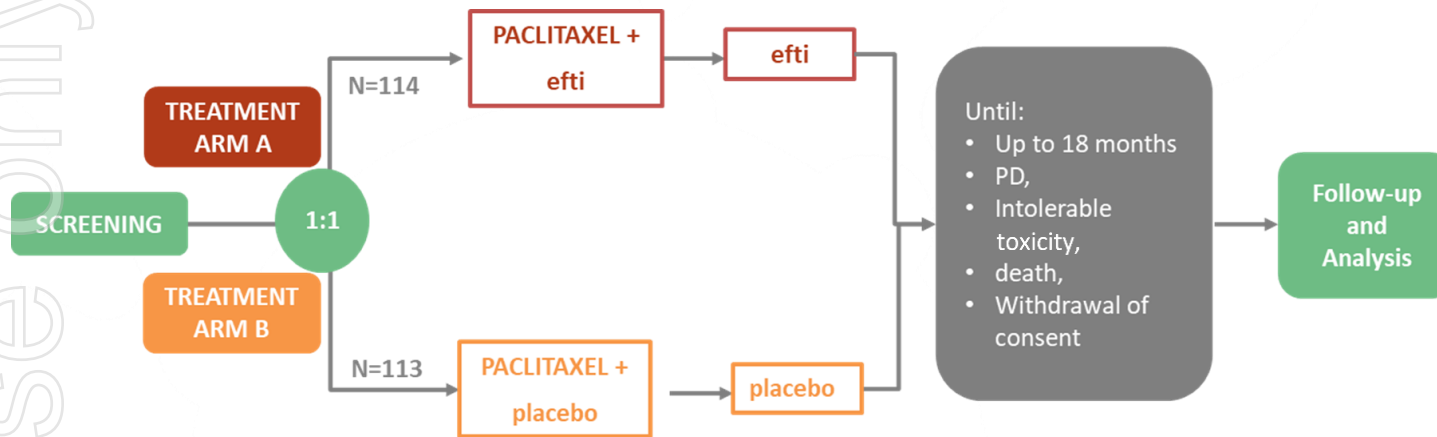
\* - can be extended to every 3 weeks after 6 months

# AIPAC Phase IIb Update:

- Exciting Interim OS Results in Dec 2020 -

# Efti: AIPAC (Phase IIb) design

## AIPAC: Active Immunotherapy PAClitaxel in HER2-/ HR+ metastatic breast cancer (MBC)



### Primary endpoint includes:

- Assessment of Progression-Free Survival (PFS) (note: no hypothesis testing) – **presented Mar 2020**

### Secondary endpoints include:

- Overall Survival (OS) – **presented Dec 2020**
- Safety and tolerability
- Overall Response Rate (ORR) and other efficacy parameters
- Biomarker and Immune Monitoring

### Fact sheet

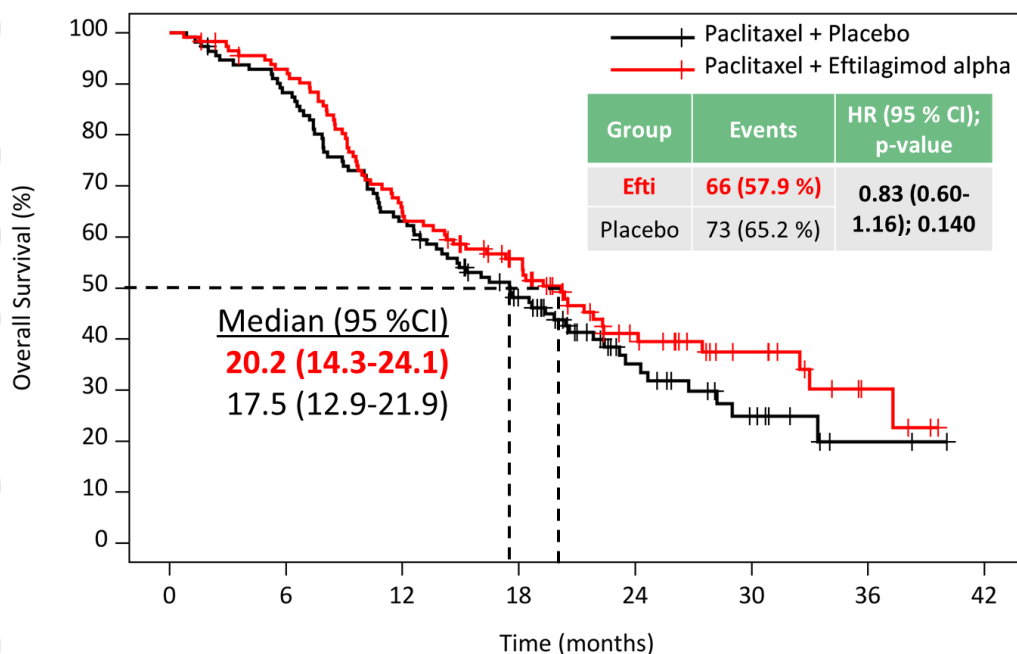
- ✓ Conducted in 7 EU countries
- ✓ Local and blinded independent central read
- ✓ LPI enrolled Jun 2019
- ✓ Primary analysis PFS (immature OS) March 2020
- ✓ Follow-up 1 analysis OS Sep 2020 (SABCS Dec 2020) – ~60% OS events
- ❖ 2<sup>nd</sup> OS follow-up analysis planned mid 2021

# AIPAC Phase IIb Clinical Results

Overall Survival – FU1 (60% events; cut-off: Sep 20)

Improving trend for the overall population (IIT) as data matures  
 Currently 2.7 months difference in median OS

Overall Survival (Follow-up<sup>‡</sup>) – Total Population



	0	6	12	18	24	30	36	42
Placebo	112 (0)	98 (1)	70 (1)	47 (8)	21 (24)	9 (31)	2 (37)	0 (39)
Efti	114 (0)	103 (3)	72 (3)	53 (12)	26 (27)	14 (37)	4 (45)	0 (48)

## Post-study treatment

was similar with 80.7% (efti) and 83.9% (placebo) receiving any post study systemic anticancer therapy. Vast majority received **chemotherapy**: 64.0% (efti) vs. 69.6% (placebo)

## Prior CDK 4/6

have negative impact on OS in placebo group (median reduced from 20.0 to 14.9 months), but **not** in the efti group (median OS 20.9 vs. 20.4 months)

CDK4/6 are now standard and most patients will have received it in future studies / real world → favorably for efti

## Quality of Life (QLQ-C30)

Significant deterioration of overall QoL in the placebo group at week 25, which was **not** observed in the efti group

Very important for reimbursement → favorably for efti

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# AIPAC Phase IIb Clinical Results

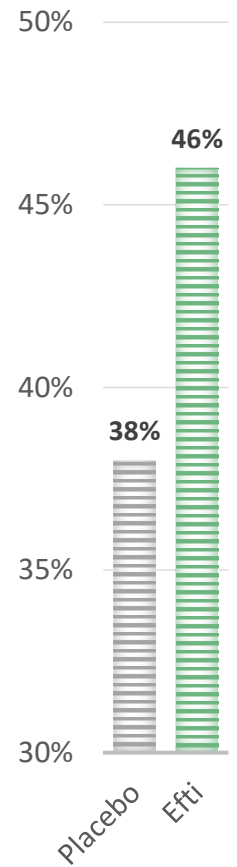
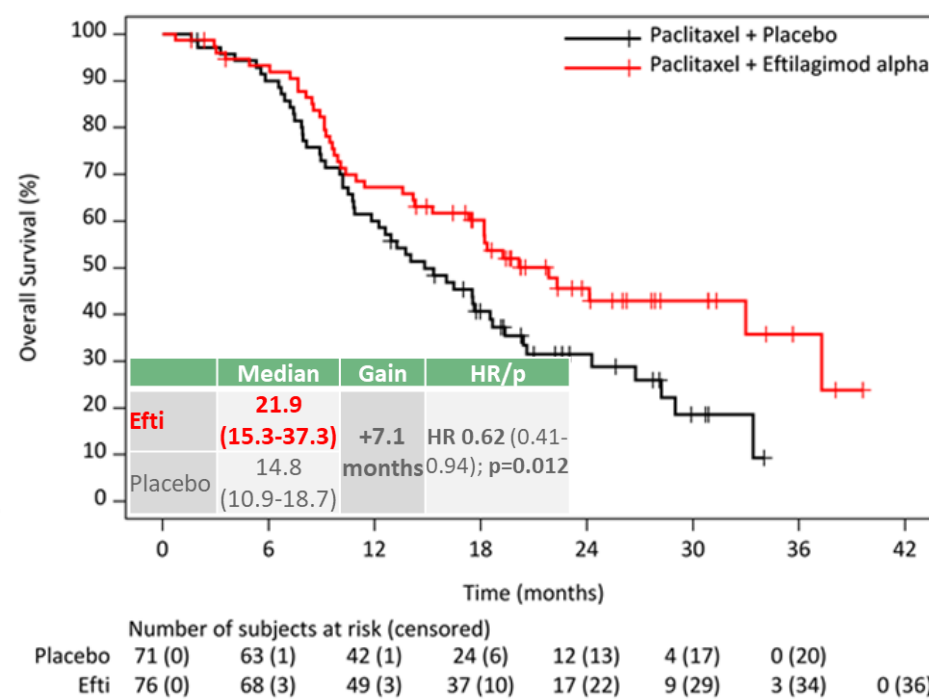
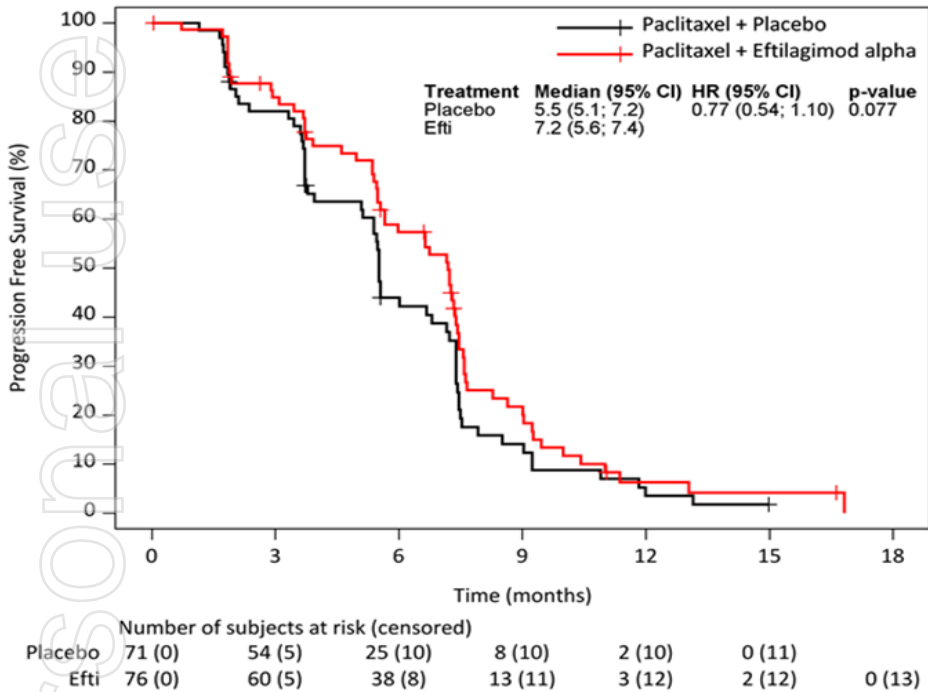
## Subgroup 1: < 65 years – PFS / OS / ORR

Clinically meaningful absolute and relative improvement for all efficacy parameters, significance for OS  
 ESMO scale of magnitude\* = level 4 (makes reimbursement very likely)

### Patients with age < 65 yrs Progression Free Survival

### Patients with age < 65 yrs Overall Survival

### ORR

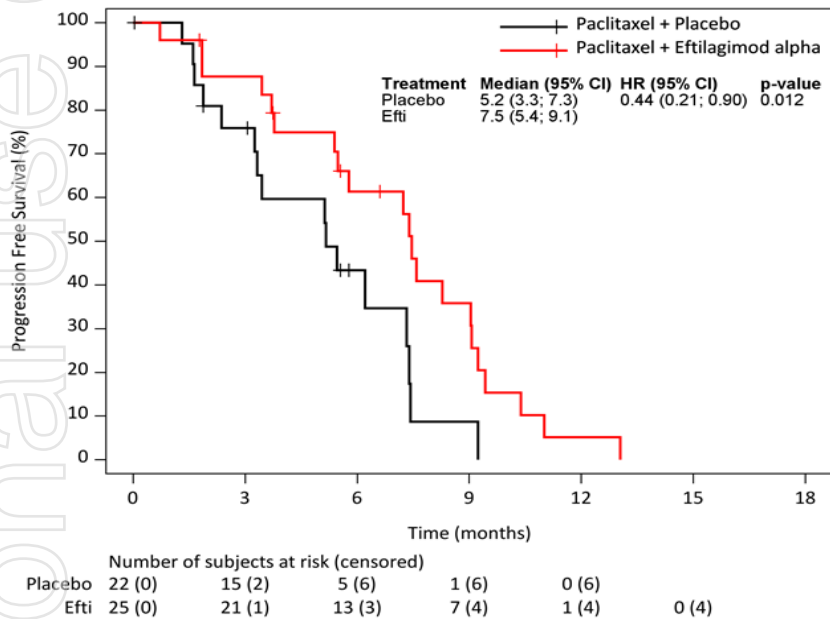


# AIPAC Phase IIb Clinical Results

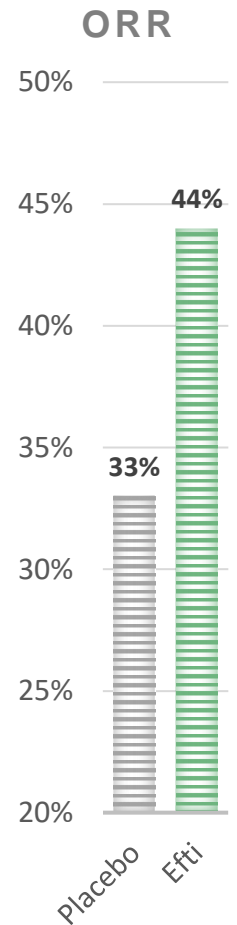
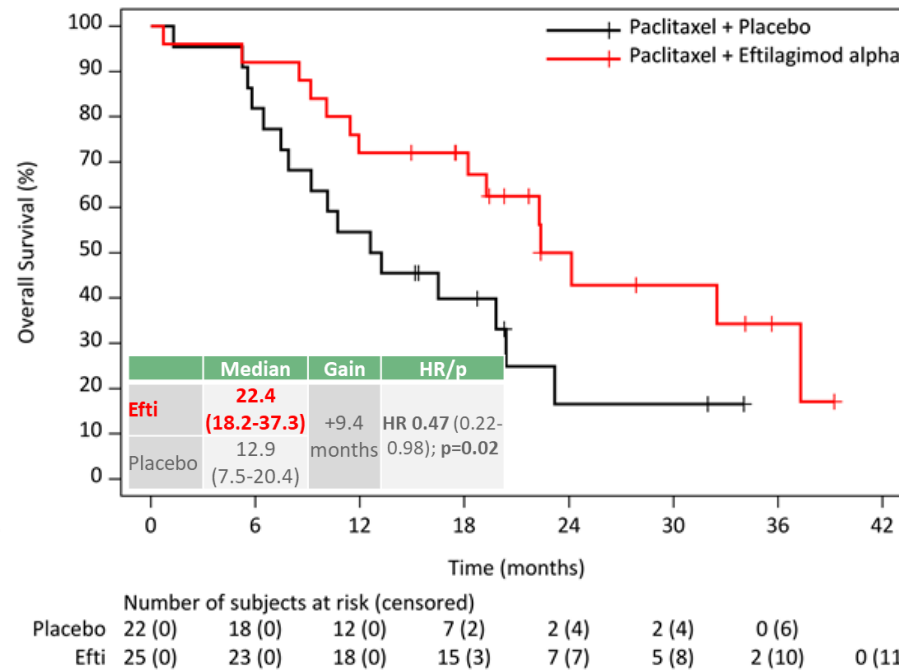
## Subgroup 2: Low Monocytes – PFS / OS / ORR

Clinically meaningful, absolute and relative improvement for all efficacy parameters, significance for PFS/OS  
 ESMO scale of magnitude\* = level 4 (makes reimbursement very likely)

### Patients with low monocytes Progression Free Survival



### Patients with low monocytes Overall Survival



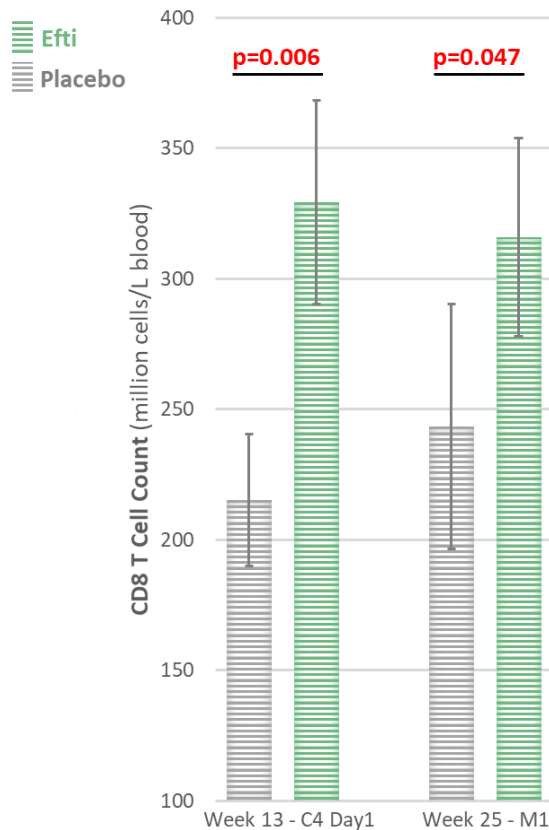


# AIPAC Phase IIb Clinical Results

Immune Monitoring on Fresh Blood (up to 70 patients)

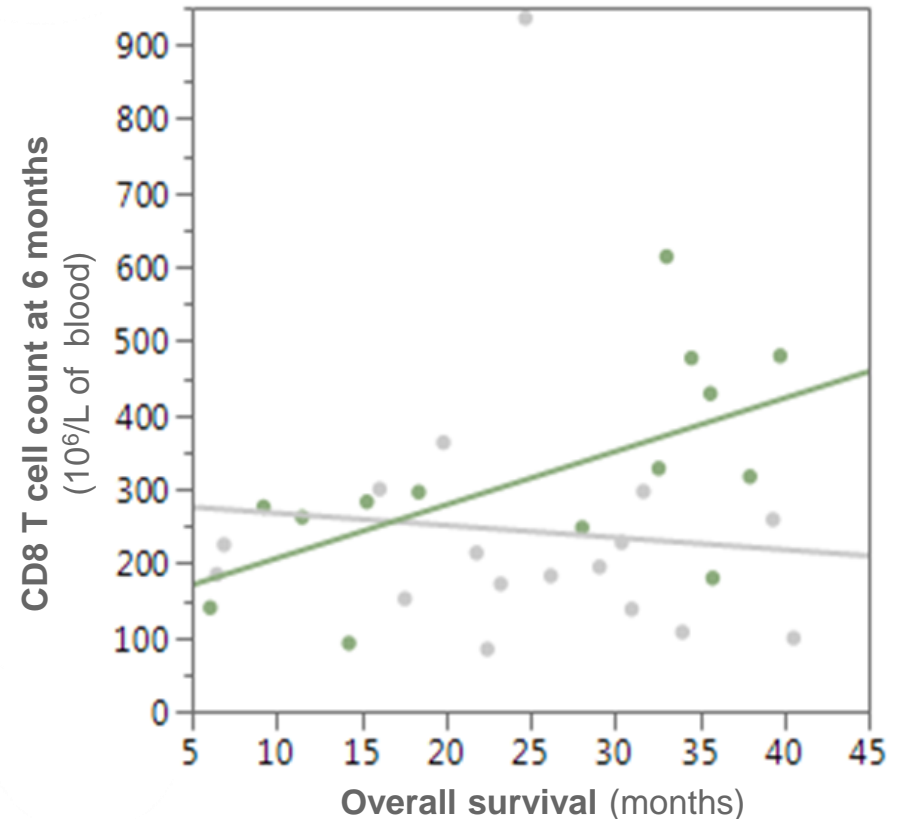
## Cytotoxic CD8<sup>+</sup> T Cell count over time

(Mean  $\pm$  SEM million cells/L of blood;  
p-value Wilcoxon)



Number of T cells increased in efti group, especially cytotoxic CD8<sup>+</sup> → Proof of Principle.

Stat. significant (**p=0.020**)  
Correlation: OS and cytotoxic CD8<sup>+</sup> T cell count



Increased number of cytotoxic CD8<sup>+</sup> T Cells correlated with improved OS in the efti arm → Proof of Concept.

# AIPAC Phase IIb Clinical Results

## Summary and Conclusions

### First time



*an APC activator has shown meaningful increase in Overall Survival (OS) in a randomised setting*

### Proof of Principle



*Significant increase in cytotoxic T cell numbers compared to placebo*

### Proof of Concept



*Prolonged OS in the overall population and clearly linked to pharmacodynamic effect (increase in CD8 T cells)*

### Path Forward



*Regulatory (FDA and EMA) discussions are prioritised now*

# Updates on Anti-PD-1 Combinations

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# Efti: TACTI-002 Trial in Different Cancers

TACTI-002 evaluates the combination of efti with KEYTRUDA® (pembrolizumab) in a PD-L1 all comer study. In collaboration with



## Key Results from 1<sup>st</sup> line non-small-cell lung carcinoma (NSCLC) (as at 8<sup>th</sup> October 2020):

- 36.1% Objective Response Rate (iORR)
- 61% patients had tumour shrinkage
- 2 Complete Responses (complete disappearance of all lesions)

## Key Results from 2<sup>nd</sup> line head and neck squamous cell carcinoma (HNSCC) (as at 8<sup>th</sup> October 2020):

- 35.7% Objective Response Rate (iORR)
- 3 (10.7%) Complete Responses (complete disappearance of all lesions)

## Key Results from 2<sup>nd</sup> line non-small-cell lung carcinoma (NSCLC) (as at 8<sup>th</sup> October 2020):

- 72% alive at 6.3 months → **OS: 6+ months**
- 50+% alive at 12 months

**Next:** More data throughout 2021 is expected to be released.

*ORR combination results are higher than pembrolizumab alone (ORR of ~20%)(1) without additional toxicity*

*Higher ORR compared to pembrolizumab alone (ORR of 14.6%)(2) without additional toxicity*

*OS already higher than SOC (Docetaxel mOS: 6 months; ~24% alive at 12 months)(3)*



## Phase II

Open label trial, Simon's 2 stage design; PD-L1 all comer



## Up to 183

Patients with with 2<sup>nd</sup> HNSCC or NSCLC in 1<sup>st</sup> and 2<sup>nd</sup> line



## Up to 12 months

Combination treatment, then pembrolizumab alone for another 12 months



## 12

Clinical trial sites



## Multi-centre

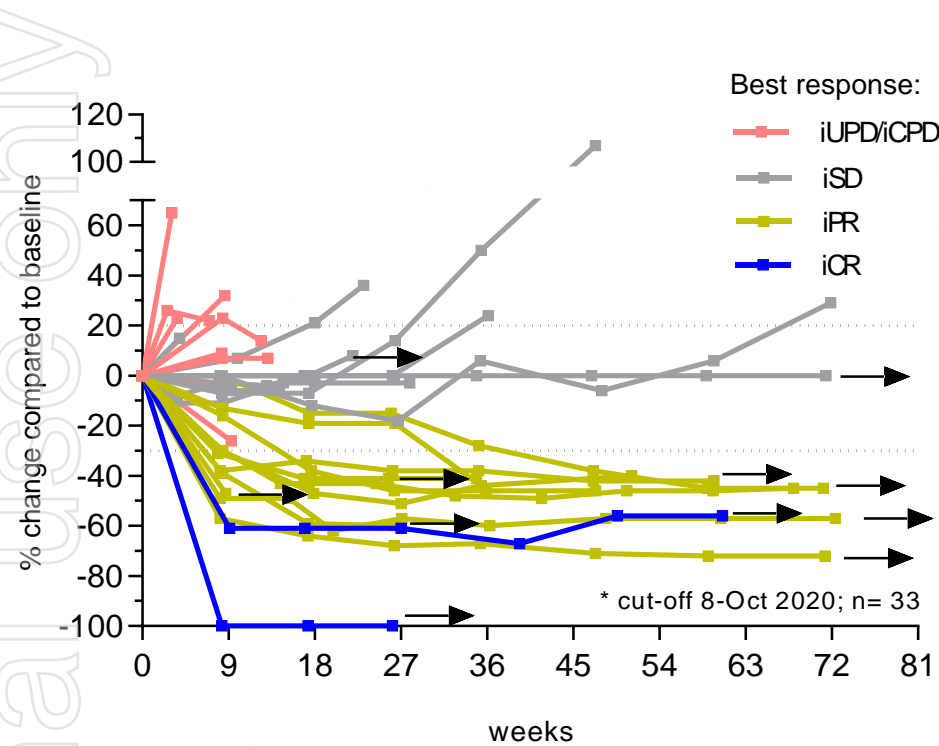
Australia, Europe and US

### Notes:

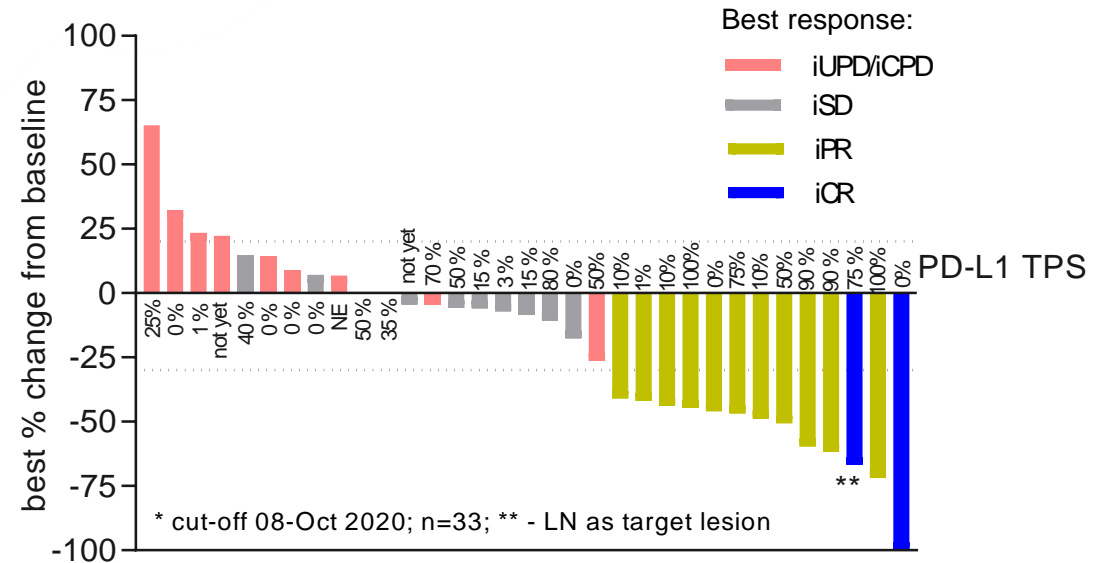
- (1) Internal calculation based on published data: Garon et al, N Engl J Med 2015; 372:2018-2028 available from: <https://www.nejm.org/doi/full/10.1056/NEJMoa1501824>
- (2) Keynote-040 results: EEW Cohen et al. [http://dx.doi.org/10.1016/S0140-6736\(18\)31999-8](http://dx.doi.org/10.1016/S0140-6736(18)31999-8)
- (3) CheckMate-017: DOI: 10.1056/NEJMoa1504627; N Engl J Med 2015; 373:123-135

# TACTI-002 Results<sup>(1)</sup>

## 1<sup>st</sup> line NSCLC (Part A)



- iORR of 36.1% [95% CI 20.8-53.8]
- 2 complete responses
- 22/36 (61%) with target lesion decrease



- Responses in all PD-L1 subgroups:
- ORR in < 50%: 31.6% (6/19)
- ORR in ≥ 1%: 44% (11/25)
- At data cut-off, 11 pts still under therapy

# TACTI-002 Results<sup>(1)</sup>

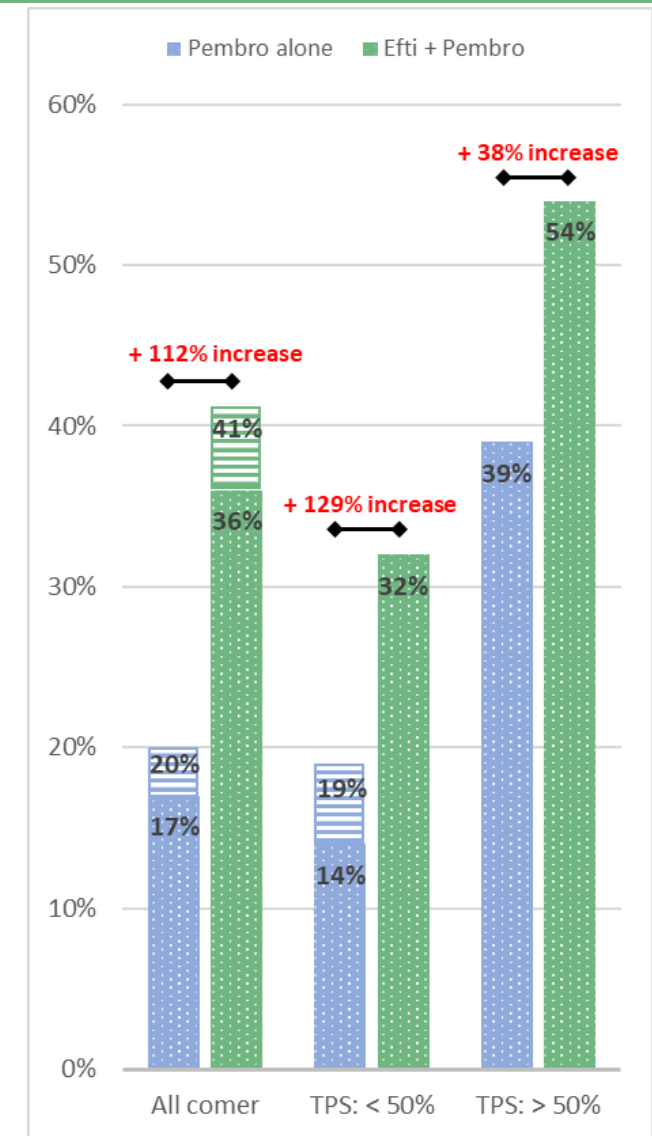
## Benchmarking - 1<sup>st</sup> line NSCLC

	PD-L1 (TPS)	Pembro alone** (KN042/ KN001)	TACTI-002
ORR	All comer (with PD-L1 results)	17-20%	41%* (36%, regardless of available PD-L1 test results)
	≥ 50%	39.5%	54%*
	≥ 1%	27.3%	44%*
	1-49%	~17%	33%*
	< 50%	14-19%	32%*

\* only patients evaluated where PD-L1 test results available (32 out of 36 patients); \*\* Data for pembro derived from KN042 and KN001<sup>(2)(3)</sup>

- Most of pembro responses come from 50%+ and especially 90%+ TPS<sup>(4)</sup>
- Highest unmet medical need in < 50% TPS group → ehti addresses these needs.
- TIGIT does not → effects predominantly in ≥ 50% groups.

**Ehti plus pembro warrants further clinical development in 1<sup>st</sup> line NSCLC especially considering the excellent safety profile**



Data for pembro derived from KN042 and KN001<sup>(2)(3)</sup> and ORR in PD-L1 TPS <1% was taken from doi:10.1093/annonc/mdx076 and used to calculate ORR for TPS <50 for pembro mono. TACTI-002 data cut off 08. Oct. 2020.

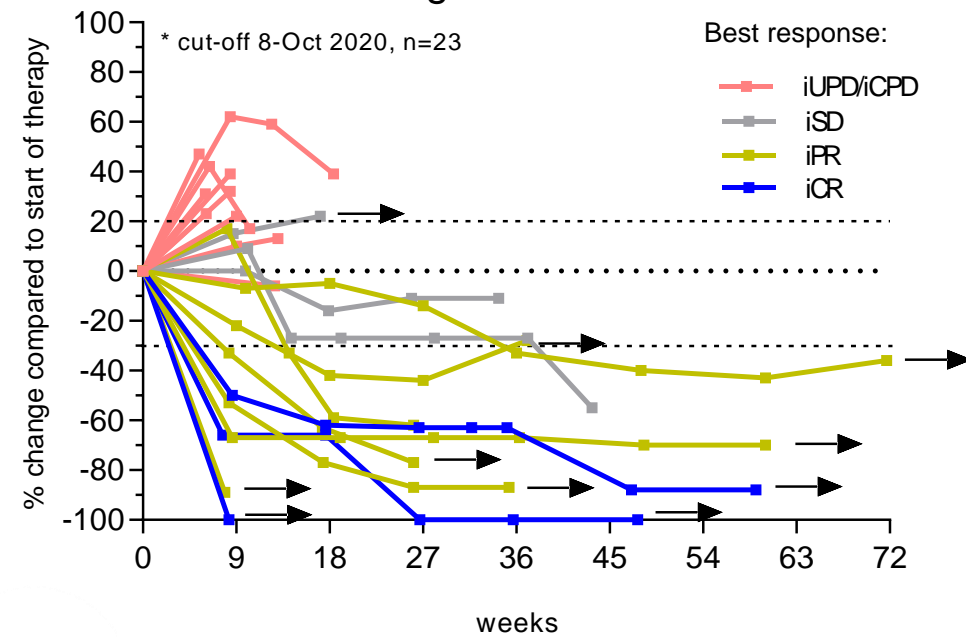
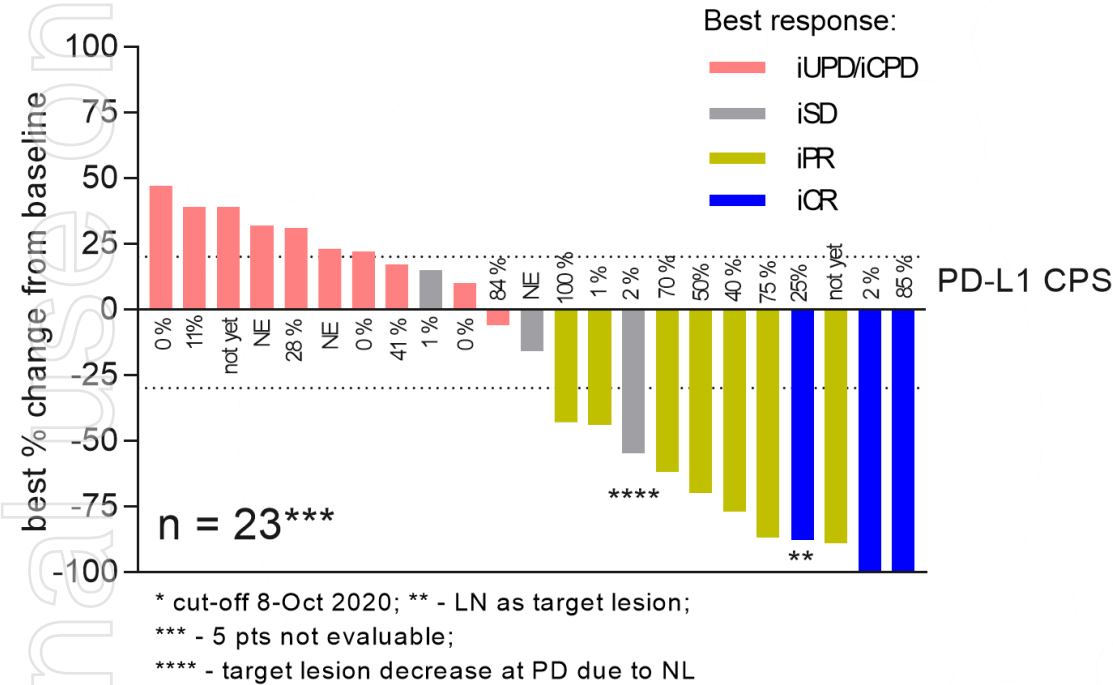
Notes:

- (1) Preliminary data, cut-off 08 Oct 2020 for TACTI-002
- (2) KEYNOTE-042: TSK Mok et al, The Lancet 2019, [http://dx.doi.org/10.1016/S0140-6736\(18\)32409-7](http://dx.doi.org/10.1016/S0140-6736(18)32409-7)
- (3) KEYNOTE-001: NB Leighl et al, The Lancet 2019, [http://dx.doi.org/10.1016/S2213-2600\(18\)30500-9](http://dx.doi.org/10.1016/S2213-2600(18)30500-9)
- (4) EJ Aguilar et al; Annals of Oncology 30: 1653–1659, 2019, doi:10.1093/annonc/mdz288

# TACTI-002 Results<sup>(1)</sup>

## 2nd line HNSCC (Part C)

personally



- All (except one) pts with response ongoing
- PD-L1 all comer trial → responses in PD-L1 low expressors

# TACTI-002 Results<sup>(1)</sup>

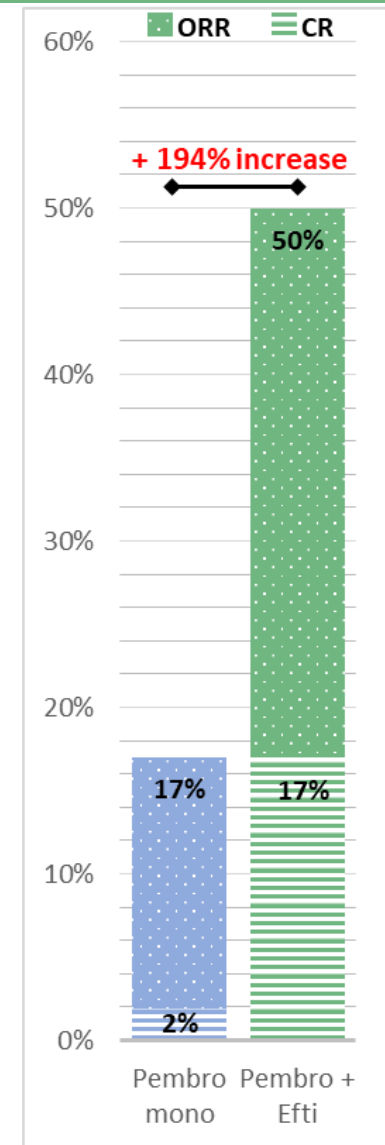
## Benchmarking – 2<sup>nd</sup> line HNSCC

	PD-L1 (CPS)	Pembro alone**	TACTI-002*
ORR	≥1	17.3% 2% CR	50%* 16.7% CR*
	(with PD-L1 results)	14.6%	42.9%* (35.7% regardless of available PD-L1 test results)

\* only patients evaluated where PD-L1 test results available (21 out of 28 patients); \*\* Data for pembro derived from KN040<sup>(2)</sup>

- ORR of pembro mono generally low → increase to 22% (≥ 20 CPS) and 28% (≥ 50 CPS) <sup>(4)</sup>
- Duration of response drops dramatically if you add chemo<sup>(5)</sup> – not the case with efti
- ORR is clearly higher with high rates of CRs; duration of response very promising (only 1 pt with PR discontinued in TACTI-002 so far)

**Efti plus pembro warrants late stage clinical development in HNSCC especially considering the excellent safety profile**



Trial P015 Part C - Historical comparison of ORRs and CRs in metastatic HNSCC for patients who has a PD-L1 CPS of ≥1. ORR for Pembrolizumab monotherapy was taken from KEYNOTE-040.

Notes:

(1) Preliminary data, cut-off 08 Oct 2020  
 (2) Keynote-040 results: available from <https://www.esmo.org/newsroom/press-office/KEYNOTE-040-Evaluates-Pembrolizumab-in-Head-and-Neck-Cancer>

(3) RL Ferris et al.: Nivolumab for Recurrent Squamous-Cell Carcinoma of the Head and Neck. *N Engl J Med* 2016;375:1856-67.  
 (4) E Cohen et al; *Annals of Oncology* 2019; doi:10.1093/annonc/mdz252  
 (5) KN-048: *The Lancet*, 2019; [https://doi.org/10.1016/S0140-6736\(19\)32591-7](https://doi.org/10.1016/S0140-6736(19)32591-7)

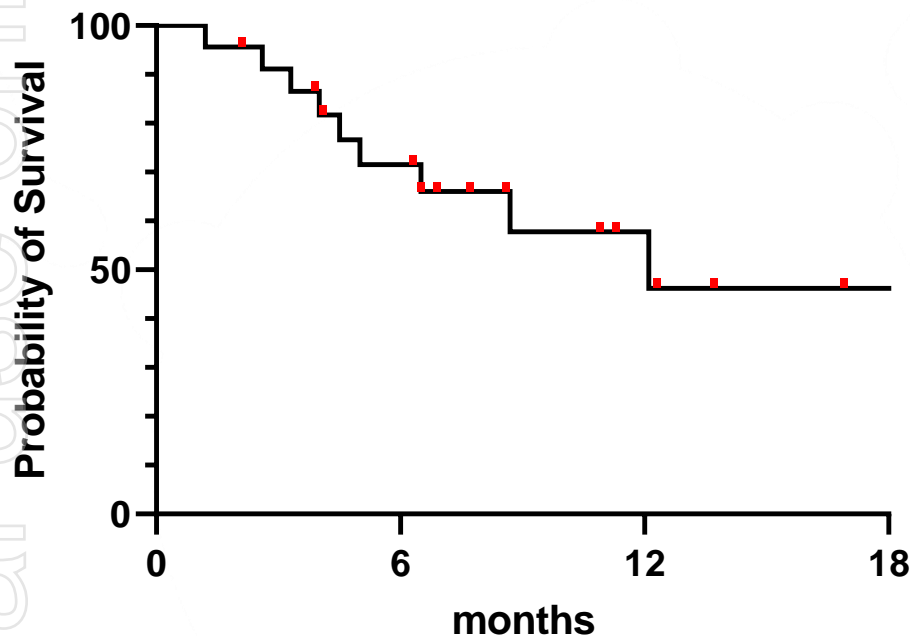
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# Efti: TACTI-002 Results<sup>(1)</sup>

## 2<sup>nd</sup> line NSCLC (Part B) - Benchmarking

### OS - Stage 1 - Part B - NSCLC



- 1 confirmed PR and DCR of 35%
- 72% alive at 6.3 months → encouraging although data immature beyond 6 months
- 50+% alive at 12 months
- At data cut-off, 3 patients still under therapy

- All patients included in this trial had progressed on 1<sup>st</sup> line therapy containing PD-1/PD-L1, confirmed by 2 consecutive scans.
- 85% of patients have PD-L1 expression level < 50%

### Encouraging OS with 12 months Comparison<sup>(2)</sup>:

- Docetaxel mOS: 6 months
- ~24% alive at 12 months

Notes:

(1) Preliminary data, cut-off 8<sup>th</sup> Oct 2020

(2) CheckMate-017: DOI: 10.1056/NEJMoa1504627; N Engl J Med 2015; 373:123-135

# Efti: INSIGHT-004 Trial in Solid Tumours

INSIGHT-004 is a dose escalation study evaluating efti in combination with Bavencio® (avelumab). Conducted as the 4<sup>th</sup> arm of the INSIGHT trial.

In collaboration with  **Merck KGaA,**  
Darmstadt, Germany **I.K.F.**

**Key Results** in patients with mostly cancers of the **gastrointestinal tract**:

- No dose limiting toxicity
- 5/12 (41.6%) patients with partial responses

*Encouraging single patient cases in cancers that don't usually benefit from immunotherapy.*

*Only 5% of patients usually benefit.<sup>(1)</sup>*

**Data presented at:**

ESMO 2020

**Next:**

Final data expected in 2021



## Phase I

Open label trial



## 12

Patients: 2 cohorts of 6 patients each



## 6 months

Combination treatment , then 6 months avelumab monotherapy



## One site

Germany

Notes:

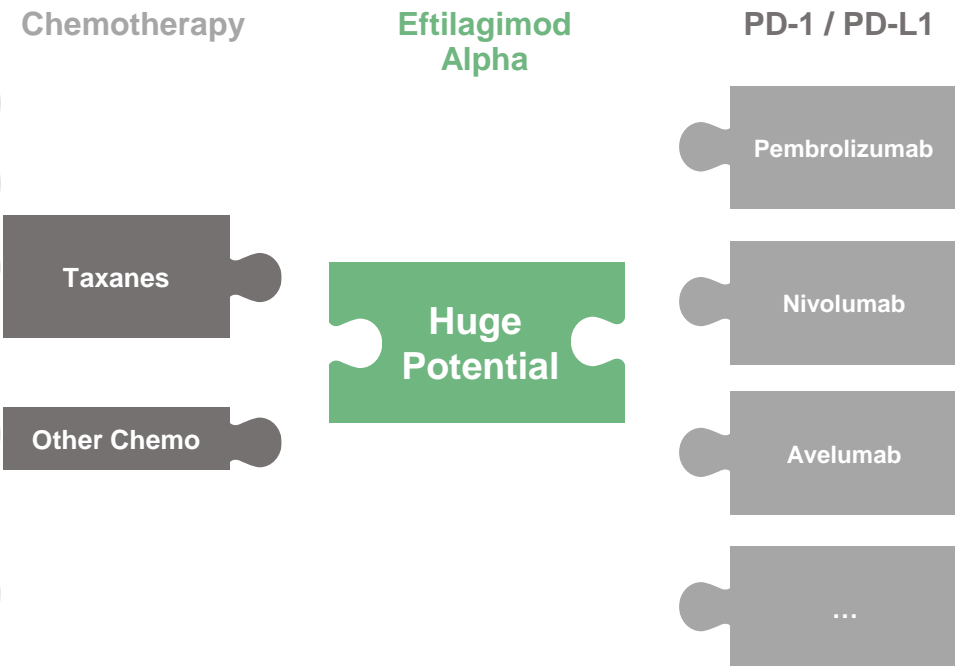
Data cut-off: 12 June 2020.

(1) J Tintelnot, A Stein: Immunotherapy in colorectal cancer: Available clinical evidence, challenges and novel approaches.

World J Gastroenterol. 2019 August 7; 25(29): 3920-3928

# Efti: Current Strategic Potential & Plans

Efti is the ideal candidate to combine with  
✓ chemo and ✓ PD-1/PD-L1 antagonists



Efti's current data base includes<sup>(1)</sup>:



**Up to 219 patients**  
in anti-PD-(L)1 combinations



**272 patients**  
in chemo-immuno combination



**Safety & efficacy**  
Good safety & encouraging efficacy data in NSCLC, HNSCC, melanoma and MBC



**Big pharma**  
A variety of development options with big pharma support

# TACTI-002 Extension in 1<sup>st</sup> line NSCLC Results<sup>(1)</sup>

## Design + Status

### Eligibility

- Available tumor tissue
- ECOG 0-1
- Adequate organ functions
- **PD-L1 all comer**

**Part A:**  
1<sup>st</sup> line met. NSCLC  
+ 74 pts according to protocol

30 mg efti SC  
+  
200 mg pembrolizumab IV

Up to 12 months then pembrolizumab alone for another 12 months


**Primary: ORR (iRECIST)**

**Secondary: PFS, OS, PK, biomarker, PD, safety and tolerability**

### Design:

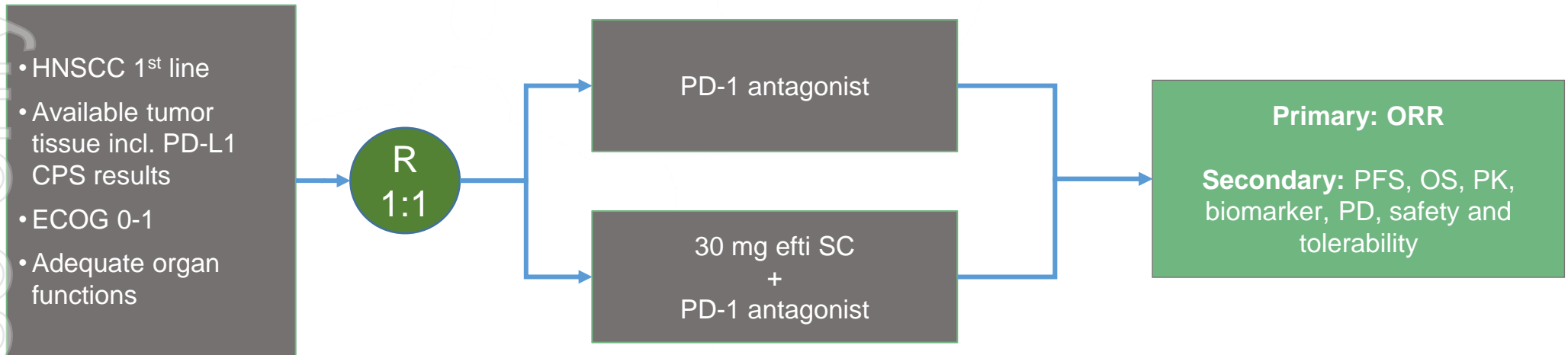
- Expansion of TACTI-002 Part A: 74 additional pts in order to prepare for registration trials (specific patient population analysis)

### Status:

- Approved by all competent authorities (incl. FDA);
- Recruitment commenced with results throughout 2021/2022
- Keytruda supply ensured
- In collaboration with  **MERCK**  
INVENTING FOR LIFE

# Trial in 1<sup>st</sup> line HNSCC

## Potential Design + Status



### Design:

- Randomised study with ORR as primary endpoint
- Sites worldwide (AU, US, Europe)
- Approx. 160 pts to be randomized to have sufficient pts in each group

### Status:

- Advanced planning & collaboration discussions

# Efti Partnerships



- EOC, an Eddingpharm spin-off holding the Chinese rights for efti, Phase I study in MBC ongoing with a Phase II trial in preparation (152 patients)
- Milestone and royalty bearing partnership



- Spin off from NEC, Japan: aims to develop cancer drugs discovered by artificial intelligence → mainly cancer vaccines
- Clinical Trial Collaboration (up to US\$5 million for Immunetep); Phase I completed



- Strategic supply partnership for the manufacture of efti
- Through WuXi, Immunetep was the first company to use a Chinese manufactured biologic in a European clinical trial



# Efti in COVID-19 Patients

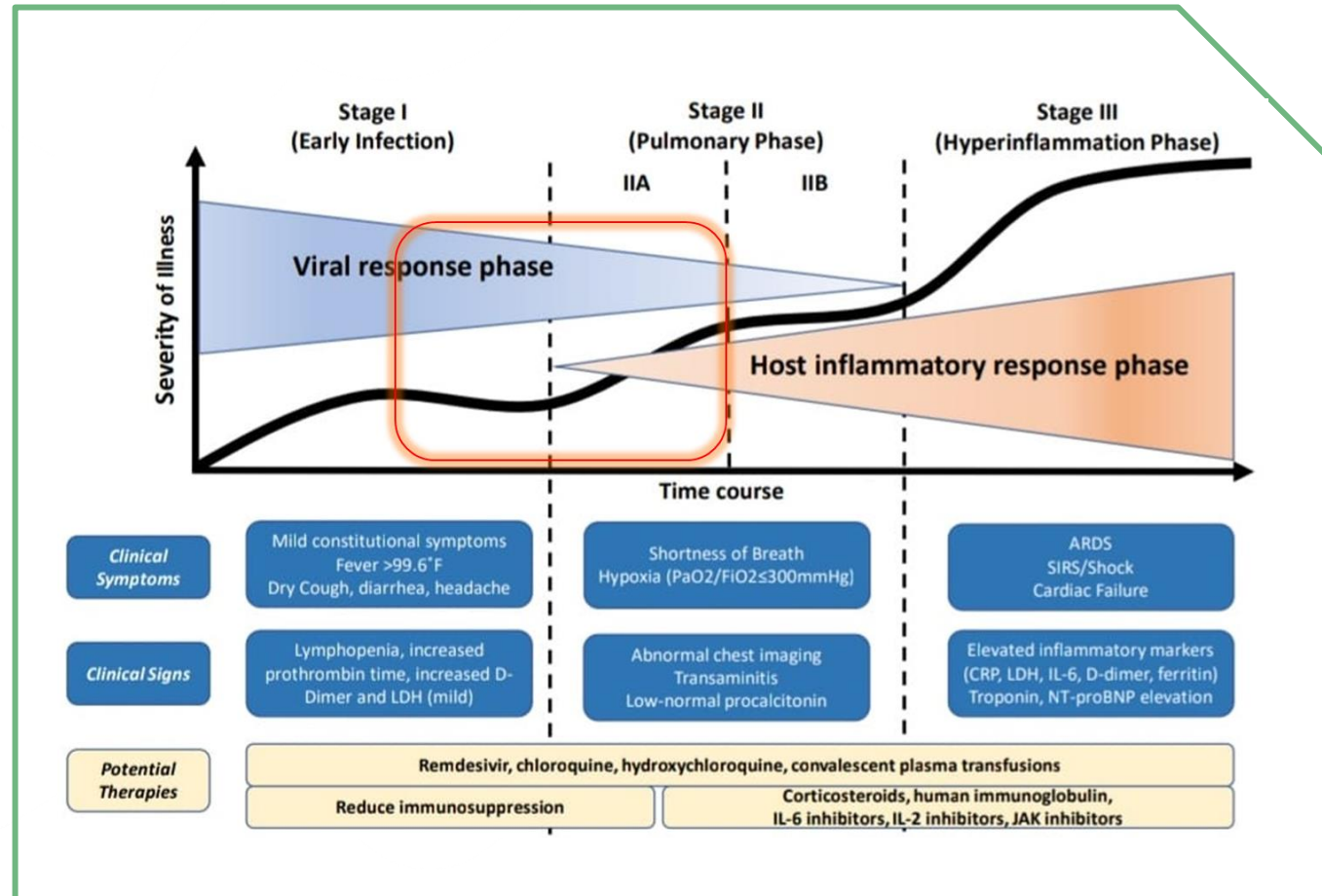
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# EAT COVID trial

**Window of opportunity** to boost the immune response prior to deterioration requiring intensive care unit (ICU) admission and mechanical ventilation

**Goal is to:**

- prevent T cell exhaustion and profound lymphopenia
- eradicate the COVID-19 virus
- avoid any extensive organ tissue damage



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# EAT COVID trial

EAT COVID is an investigator-initiated trial evaluating efti in hospitalised COVID-19 patients

Aims to “push the gas” on a patient’s immune response to prevent severe COVID-19 symptoms requiring intensive care and leading to respiratory failure and death.

- Fully funded by University Hospital Pilsen, Czech Republic
- Efti supplied under a Material Transfer Agreement

Initial safety run-in data from reviewed by independent Data and Safety Monitoring Board:

- 6 patients - age range, 50-83 years; 2 women, 4 men
- All received full treatment and discharged from hospital
- No adverse events reported

Recommendation to advance to randomised portion of study.

**Next:**

Opening of recruitment for first cohort of 26 randomised patients  
Further results expected in 2021



## Phase II

Placebo controlled, double blinded and 1:1 randomised study



## Up to 110

Adult patients hospitalised with COVID-19



## 15 day

Primary endpoint is patient’s clinical status at day 15 (WHO recommended)



## Single site

Czech Republic

**Efti is currently the only APC activator of its kind being evaluated against COVID-19 in a randomised Phase II trial**

# Out-Licensed Immunotherapy Pipeline

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# LAG525 (IMP701) for Cancer

- Novartis holds an exclusive WW licence to develop and commercialise LAG525 (which is derived from Immunetep's antagonist antibody known as IMP701)
- 1st and 2nd milestone payments received by Immunetep in August 2015 (undisclosed) and August 2017 (US\$1 million)
- In 2018 Novartis cancelled 90 other R&D programs but continued to invest heavily in progressing the development of LAG525<sup>(1)</sup>
- Novartis currently has five clinical trials ongoing for LAG525 in multiple cancer indications for over 1,000 patients<sup>(2)</sup>



- **IMP701 is an anti-LAG-3 mAb that blocks LAG-3-mediated immune down-regulation**
- **LAG-3 is a prime target for immune checkpoint blockade as it is readily expressed at a high level in many human tumors**

# GSK'781 (IMP731) for Autoimmune Diseases

- GSK holds an exclusive WW licence to develop and commercialise GSK'781 (which is derived from Immunep's depleting antibody known as IMP731)
- Up to £64 million in upfront payments and milestones, plus royalties
- GSK portfolio review in 2017 -> GSK'781 continued despite cancellation of 13 clinical and 20 preclinical programs<sup>(1)</sup>
- March 2018: Phase I trial in psoriasis completed in 67 subjects/patients<sup>(2)</sup>
- September 2019: 1<sup>st</sup> patient dosed in Phase II trial in ulcerative colitis in 242 patients triggered a £4 million (~US\$5.0 million) milestone payment to Immunep<sup>(2)</sup>
- Phase I clinical study completed, evaluating GSK'781 in 36 healthy Japanese and Caucasian subjects, PK/PD study<sup>(2)</sup>
- Phase II in Ulcerative Colitis discontinued in January 2021

**GSK's investigational product, GSK2831781, which is derived from IMP731 antibody, aims to kill the few activated LAG-3<sup>+</sup> T cells that are auto-reactive in autoimmune disease leading to long term disease control without generalized immune suppression**



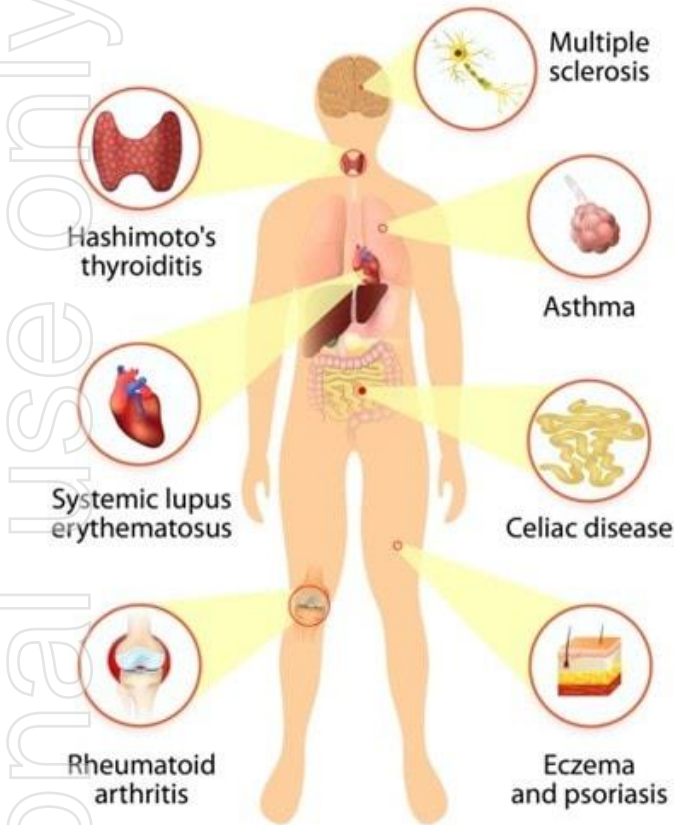
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**IMP761**

**- Autoimmune Diseases -**

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

## AUTOIMMUNE DISEASES

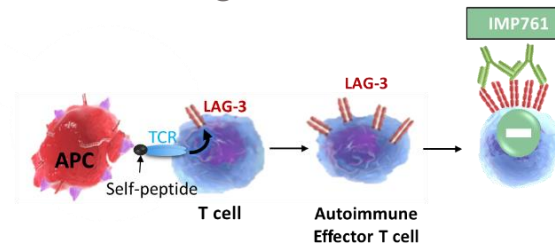


## THE PRESENT: FIGHTING THE SYMPTOMS

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 (\$149.4 billion market size by 2025)<sup>1</sup>**

# Other Partnerships

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# New collaboration with LabCorp



- Licence and Collaboration Agreement for immuno-oncology products or services
- Development of lab tests that may help oncologists select the right therapeutic options for their patients
- Upfront and potential commercial milestone and service related payments to Immunetep
- Immunetep selected for its LAG-3 expertise

*Laboratory Corporation of America Holdings (LabCorp) is a leading global life sciences company focused on guiding patient care that provides diagnostic, drug development and technology-enabled solutions for more than 160 million patient encounters per year.*

**Enables Immunetep to enter the immuno-oncology diagnostics market through its technology and LAG-3 expertise**



# Corporate Snapshot & Outlook

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# Corporate Snapshot

<b>Ticker symbols</b>	IMM (ASX) IMMP (NASDAQ)
<b>Securities on issue<sup>(1)</sup></b> (as at 1 February 2021)	648.7 million ordinary shares
<b>Cash &amp; Term Deposits</b> (as at 31 December 2020)	~A\$54.9 million (US\$42.3 million)
<b>Market Cap<sup>(2)</sup></b> (as at 1 February 2021)	A\$256.2 million (US\$196.3 million)

**Notes:**

- (1) Currently ~33% of the ordinary shares listed on ASX are represented by ADSs listed on NASDAQ where 1 ADS represents 10 ordinary shares. For a detailed summary of securities on issue refer to latest Appendix 2A released on ASX.
- (2) Market capitalization based on ASX share price and basic ordinary shares outstanding.

# 2020 & 2021 News Flow\*

2020

- ✓ **AIPAC** – PFS, ORR, Overall Survival delivered
- ✓ US **IND** for MBC
- ✓ **TACTI-002** – recruitment & data delivered e.g. at ASCO, EMSO & SITC for
  - ✓ 1<sup>st</sup> line NSCLC
  - ✓ 2<sup>nd</sup> line NSCLC
  - ✓ 2<sup>nd</sup> line HNSCC
- ✓ Support of global **COVID** efforts (Phase II)
- ✓ New **partnerships**: LabCorp
- ✓ Progress from **IMP761**
- ✓ Expansion of **IP portfolio**
- ✓ Strong **financial position**

2021

- ❑ Final data from **AIPAC**: 2<sup>nd</sup> OS follow up
- ❑ Data from **TACTI-002** Parts A, B and C
- ❑ Recruitment & first data from **TACTI-002** Part A extension
- ❑ Start & ongoing recruitment of **new trial in 1st line HNSCC**
- ❑ Final data from **INSIGHT-004**
- ❑ Ongoing **regulatory** engagement
- ❑ Updates from **IMP761**
- ❑ Updates from partnered programs (e.g. GSK, Novartis, EAT COVID, CYTLIMIC and EOC Pharma)
- ❑ Potential new partnerships and expansion of existing programs

Plus, the potential validation of LAG-3 through readout of BMS's Phase III data for relatlimab

# Summary

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

Multiple active clinical trials (including partnered candidates), with further significant data read-outs in 2021

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

Established commercial partnerships with Merck (MSD), Pfizer / Merck KGaA, Novartis and GSK

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



**Thank You**