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**The global leader in  
developing  
LAG-3 therapeutics**

*(ASX: IMM, NASDAQ: IMMP)*

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# Investment Highlights

## Addressing major markets

Immutep's clinical program is seeking to address multi-billion dollar markets with 13 clinical trials underway



## Compelling data points

Doubling the response rate of Merck blockbuster drug Keytruda to 36% in 1<sup>st</sup> line NSCLC and 2<sup>nd</sup> line HNSCC (TACTI-002 trial)



## Towards registration

New TACTI-002 data supports accelerating clinical development program into larger settings



## Partnering deals executed with industry leaders



Merck KGaA,  
Darmstadt, Germany



## Corporate Strategy

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



# Efti's Clinical Potential

## AIPAC – Efti + Chemo

### Phase IIb in MBC

- Randomized, placebo controlled.
- OS data due December 2020.

## INSIGHT-004 – Efti + Avelumab



### Phase I in Solid Tumors

Merck KGaA,  
Darmstadt, Germany

- 5/12 (41.6%) patients with partial responses in ICI insensitive indications
- Final data in 2021

## TACTI-mel – Efti + Pembro

### Phase I in Melanoma

- Deep & durable responses, outperforming pembrolizumab monotherapy

## YNP01 and YCP02

CYTLIMIC

### Phase I in Solid Tumors & Hepatocellular Carcinoma

- Cancer Vaccine with Efti as adjuvant

## TACTI-002 – Efti + Pembro



### Phase II in 1<sup>st</sup> and 2<sup>nd</sup> line NSCLC

- 1<sup>st</sup> line NSCLC: 70-90% increase in ORR compared to historical Pembrolizumab monotherapy.
- 1<sup>st</sup> line NSCLC: Responses in PD-L1 low expressing subgroups.
- 2<sup>nd</sup> line NSCLC, PD-X refractory: doubling OS compared to SOC

## EAT COVID – Efti mono

### Phase II in COVID-19

- Randomized, placebo controlled.
- Start: Q4 2020

## TACTI-002 – Efti + Pembro



### Phase II in 2<sup>nd</sup> line HNSCC

- Durable, deep responses (36% ORR, 3 CRs) in a very challenging patient population.
- Responses in PD-L1 in low expressing subgroups.



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Officer, General  
Counsel & Company  
Secretary

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

# Transactions in Oncology

Partners		Total deal value in USD	Deal focus*
Abylnx (Sanofi)	Merck & Co.	\$6,779 MM <sup>(1)</sup>	Nanobodies directed towards immune checkpoint modulators
Affimed	Genentech (Roche)	\$5,046 MM <sup>(2)</sup>	NK and T-cell therapies for solid and hematological cancers
Forty Seven, Inc.	Gilead Sciences, Inc.	\$4,900 MM <sup>(3)</sup>	Lead program, magrolimab (mAb) against the CD47 receptor
Nektar Therapeutics	BMS	\$3,630 MM <sup>(4)</sup>	NKTR214 plus Opdivio and Yervoy for various cancers
Sythorx (Sanofi)	Sanofi	\$2,500 MM <sup>(5)</sup>	THOR-707 (IL-2 candidate) for multiple solid tumors in IO combo
Argenx	J&J	\$1,600 MM <sup>(6)</sup>	Develop cusatuzumab in AML, MDS, other hematological malignancies
BeiGene	Celgene	\$1,393 MM <sup>(7)</sup>	Tislelizumab (anti-PD-1 mAb) for solid tumors
Macrogenics	Incyte	\$900 MM <sup>(8)</sup>	MGA012 (anti-PD-1 mAb)
Immunomedics	Everest Medicines	\$835 MM <sup>(9)</sup>	Sacituzumab Govitecan (antibody drug conjugate) for solid tumors
Calithera	Incyte	\$483 MM <sup>(10)</sup>	Arginase inhibitor plus anti-PD-1 combo trials for solid tumors
Viralytics (Merck & Co.)	Merck & Co.	\$394 MM <sup>(11)</sup>	Cavatac (oncolytic virus) for late stage melanoma, NSCLC etc.

Notes:

\* Information collected from Bell Potter Securities Limited, LifeSci Advisors and Informa Pharma Intelligence, excerpt

1) In 2014 with an upfront payment of US\$41m + royalties

2) In 2018 with an upfront payment of US\$96m + royalties

3) In March 2020

4) In 2018 with an upfront of US\$1.850m + royalties

5) In 2019

6) In 2018 with an upfront payment of US\$300m + royalties

7) In 2017 with an upfront payment of US\$413m + royalties

8) In 2017 with an upfront payment of US\$150 + royalties

9) In 2019 with an upfront payment of US\$60m + royalties

10) In 2017 with an upfront payment of US\$53m

11) In 2018



# LAG-3 Overview

**The most promising immune checkpoint -**



# LAG-3 Therapeutic Landscape Overview

Oncology  
Antagonist  
Agonist

Company	Program	Preclinical	Phase I	Phase II	Phase III	Total Trials	Patients
<b>Agonist</b> ImmuteP	Eftilagimod Alpha		4	2		6	455
BMS	Relatlimab		8	25	2	35	9,982
NOVARTIS	LAG525 (Ieramilimab)		1	4		5	1,069
B.I.	BI754111		4	1		5	849
Macrogenics	MGD013		2	2		4	854
Merck & Co. Inc.	MK4280		2	1		3	940
Incyte	INCAGN02385		1	1		2	92
Regeneron <sup>(1)</sup>	REGN3767		1	1		2	769
Symphogen A/S	SYM022		2			2	132
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
<b>Autoimmune</b> <b>Agonist</b> ImmuteP	IMP761					--	--
<b>Depleting AB</b> gsk <sup>(3)</sup>	GSK2831781 (IMP731)		2	1		3	346

Q1 2021:  
Phase III  
readout

Notes:

Sources: Company websites, clinicaltrials.gov, and sec.gov, as of October 2020. 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 study (see <https://clinicaltrials.gov/ct2/results?cond=&term=GSK2831781&cntry=&state=&city=&dist=>)

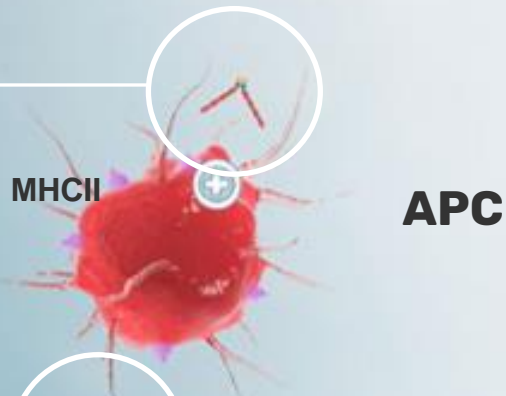
# Targeting LAG-3: Multiple Therapeutics in Numerous Diseases

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

## IMMUNOSTIMULATION

### Efti

(APC Activator)



APC

### LAG525

(Antagonistic mAb)  
Out-licensed to:



T Cell

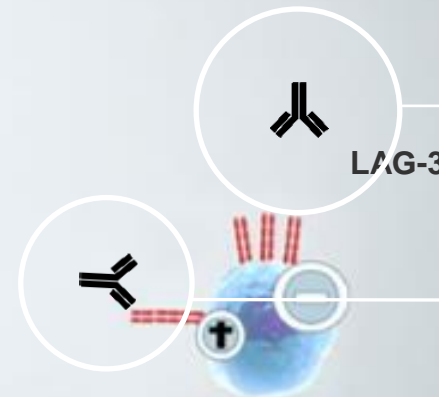
RELEVANT DISEASES

Immuno-oncology  
Combination Therapies  
Viral Infections

## IMMUNOSUPPRESSION

### IMP761

(Agonistic mAb)



T Cell

### GSK'781

(Depleting mAb)  
Outlicensed to:



RELEVANT DISEASES

Rheumatoid Arthritis  
IBD  
Multiple Sclerosis

# Immutep Controlled Immunotherapy Pipeline\*

Program	Preclinical	Phase I	Phase II	Late Stage <sup>(5)</sup>	Commercial Rights	Market Size <sup>(6)</sup> (by)
<b>Eftilagimod Alpha</b> (efti or IMP321)  APC activating soluble LAG-3 protein	Metastatic Breast Cancer (Chemo – IO) AIPAC				Global Rights 	US\$12.7 billion (2024) <sup>(6.1)</sup>
	Non-Small-Cell Lung Carcinoma (IO – IO) <sup>(1)</sup> TACTI-002			MERCK INVENTING FOR LIFE		US\$33.9 billion (2026) <sup>(6.2)</sup>
	Head and Neck Squamous Cell Carcinoma (IO – IO) <sup>(1)</sup> TACTI-002			MERCK INVENTING FOR LIFE		US\$2.8 billion (2026) <sup>(6.3)</sup>
	Solid Tumors (IO – IO) <sup>(2), (3)</sup> INSIGHT-004			Pfizer Merck KGaA, Darmstadt, Germany		US\$7.8 billion (2026) <sup>(6.4)</sup>
	Melanoma (IO – IO) TACTI-mel					
	Solid Tumors (In situ Immunization) <sup>(2)</sup> INSIGHT					
	Solid Tumors (Cancer Vaccine) <sup>(4)</sup> YNP01 and YCP02			CYTLIMIC Cytotoxic T Lymphocyte Immunotherapy in Cancer		
Metastatic Breast Cancer (Chemo – IO)			EOC	Chinese Rights 		
<b>IMP761</b> (Agonist AB)					Global Rights 	US\$149.4 billion (2025) <sup>(6.5)</sup>

Notes

- (1) Information in pipeline chart current as at October 2020
- (2) In combination with KEYTRUDA® (pembrolizumab) in non-small cell lung carcinoma ("NSCLC") or head and neck carcinoma ("HNSCC")
- (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) Conducted in Japan. Immutep has no control over this trial.
- (6) Late stage refers to Phase IIb clinical trials or more clinically advanced clinical trials
- (6) Estimation of Datamonitor Healthcare, Informa Pharma Intelligence for US, JP, EU (5) and KBV Research (6.1: Breast cancer: HR+/HER2- Forecast, January 2017; 6.2: Non-small cell lung cancer (NSCLC) Forecast, August 2018; 6.3: Head and neck cancer Forecast, December 2017; 6.4: Melanoma Forecast, May 2018; July 2019; 6.5: <https://www.kbvresearch.com/autoimmune-disease-therapeutics-market/>)

# 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				Global Rights 	GSK's ongoing Phase II clinical study is evaluating GSK'781 in 242 ulcerative colitis patients with clinical Proof-of-Concept expected H1 2021.
	Healthy Japanese and Caucasian Subjects <sup>(2)</sup>					
	Psoriasis <sup>(3)</sup>					

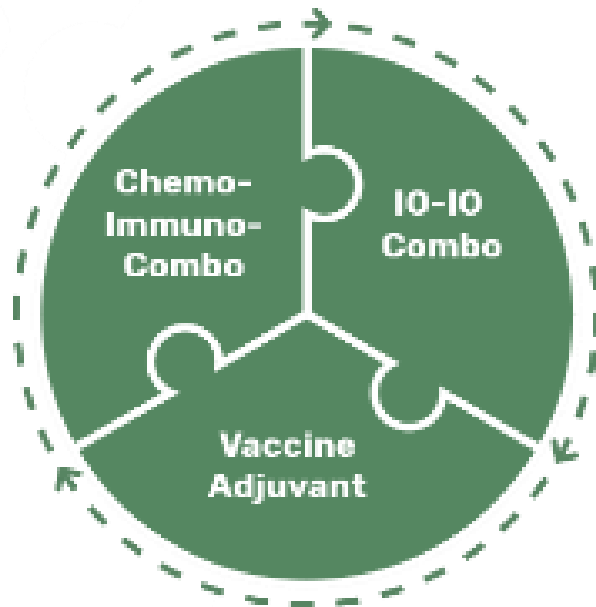
Notes

- (1) Information in pipeline chart current as at October 2020
- (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

- (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>

# Efti: Potential Pipeline in a Product

Potential for use in various combination settings



Efti is the ideal candidate to combine with available cancer treatments



First-in-Class MHCII agonist



Good safety profile



Encouraging efficacy data



Low cost of goods

# 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%)(<sup>1</sup>) without additional toxicity*

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

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



## Phase II

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



## Up to 109

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



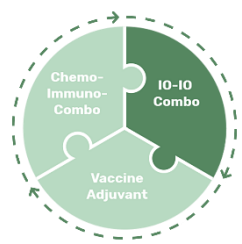
## 12

Clinical trial sites



## Multi-centre

Australia, Europe and US



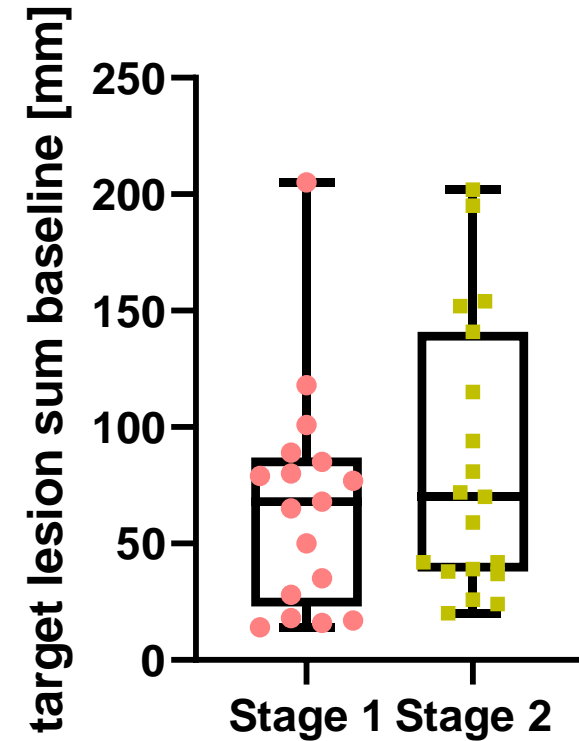
# Efti: TACTI-002

## Results<sup>(1)</sup> - 1<sup>st</sup> line NSCLC (Part A, Stage 1+2)



### Comparison Baseline Disease Characteristic Stages 1 and 2<sup>(1)</sup>

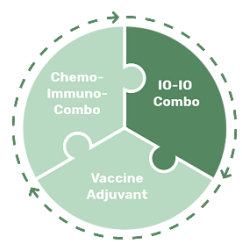
Baseline Characteristics <sup>(1)</sup>	Stage 1 (N=17) N (%)	Stage 2 (N=19) N (%)	Stage 1+2 (N=36) N (%)
Median age, years (range)	65 (53-76)	74 (60-84)	68.5 (53-84)
Female	6 (35.3)	5 (26)	11 (30.6)
Male	11 (64.7)	14 (74)	25 (69.4)
ECOG 0	12 (70.6)	3 (16)	15 (41.7)
ECOG 1	5 (29.4)	16 (84)	21 (58.3)
Never a smoker	1 (5.9)	1 (5.3)	2 (6)
Current or former smoker	16 (94.1)	18 (94.7)	34 (94)
Squamous (SQ)	10 (58.8)	5 (26)	15 (41.7)
Non-squamous (NSQ)	7 (41.2)	14 (73)	21 (58.3)



- 25% and 75% percentile clearly lower in Stage 1<sup>(1)</sup>

→ different patient population in Stage 2 with some poor prognostic markers





# eftilagimod alpha - TACTI-002

## Results<sup>(1)</sup> - 1<sup>st</sup> line NSCLC (part A, stage 1+2)



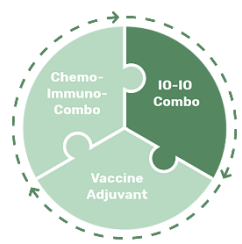
### Summary stage 1 and 2 and benchmarking<sup>(1)</sup>

→ Encouraging efficacy across endpoints especially in pts with <50% PD-L1 expression

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- RECIST and iRECIST show comparable results
- PFS / OS / DoR look favorable, but immature for stage 2

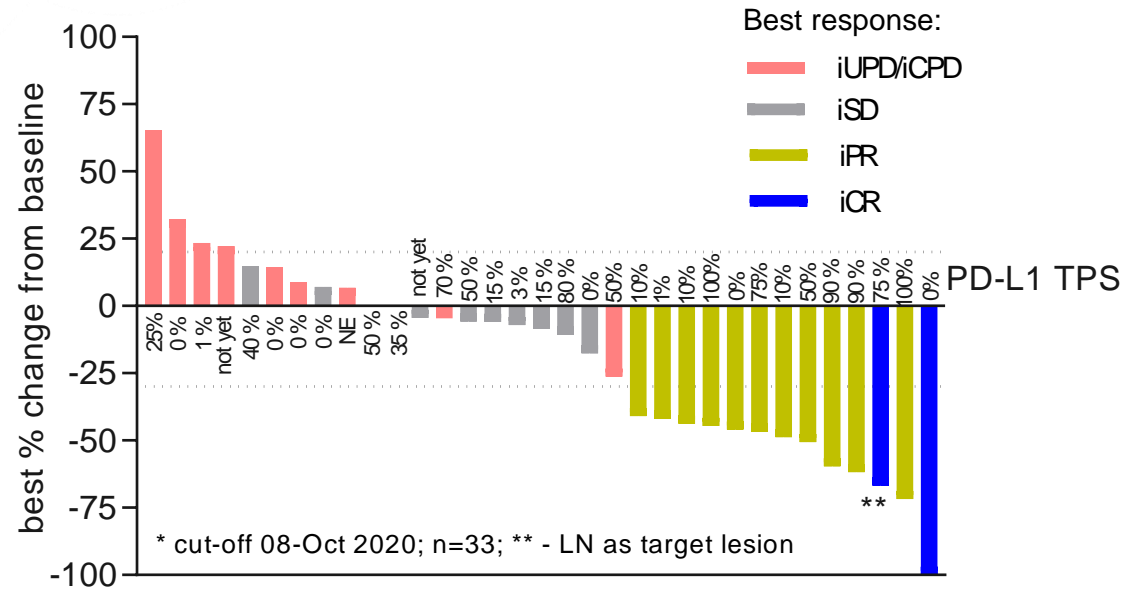
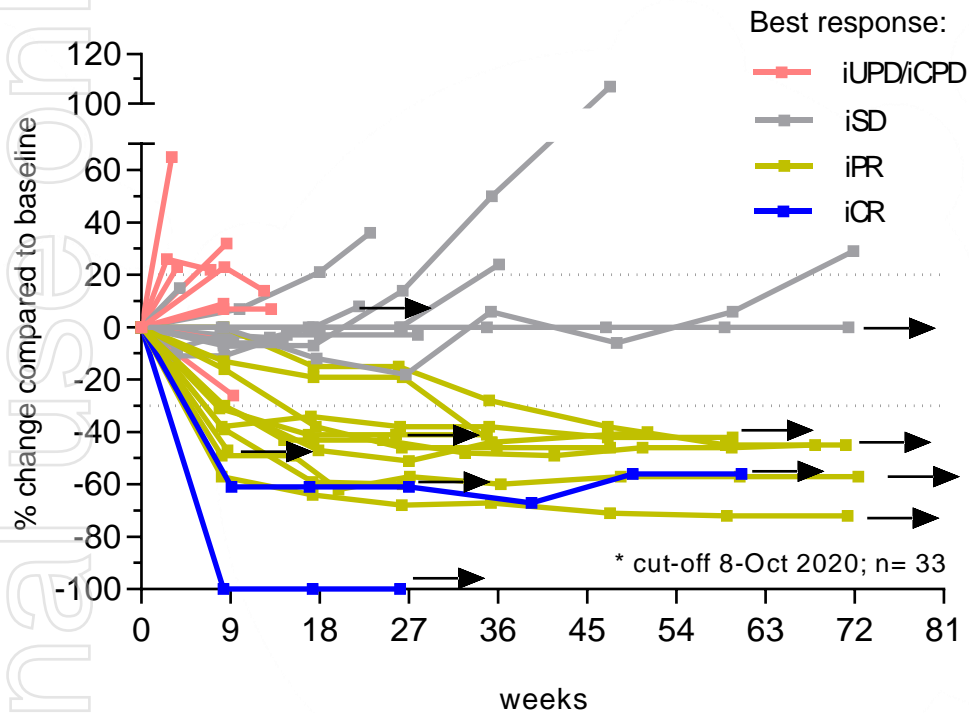
Tumor response (iRECIST)	Stage 1 (N=17) N (%)	Stage 2 (N=19) N (%)	Stage 1+2 (N=36) N (%)
Complete Response	1 (5.9)	1 (5.3)	2 (5.6)
Partial Response	8 (47.1)	3 (15.8)	11 (30.6)
Stable Disease	4 (23.5)	7 (36.8)	11 (30.6)
Progression	4 (23.5)	5 (26.3)	9 (25.0)
Not evaluable**	0 (0)	3 (15.8)	3 (8.3)
		Disease Control Rate	24 (66.7)
		Overall Response Rate [95 % CI interval]	13 (36.1) [20.8-53.8]
		Response rate – evaluable pts only	13 / 33 (39.4)



# Efti: TACTI-002 Results<sup>(1)</sup> - 1<sup>st</sup> line NSCLC (Part A, Stage 1+2)

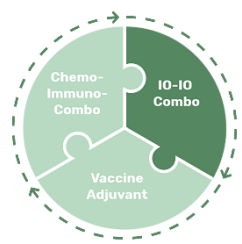


## Results Stages 1 and 2 <sup>(1)</sup>



- 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



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

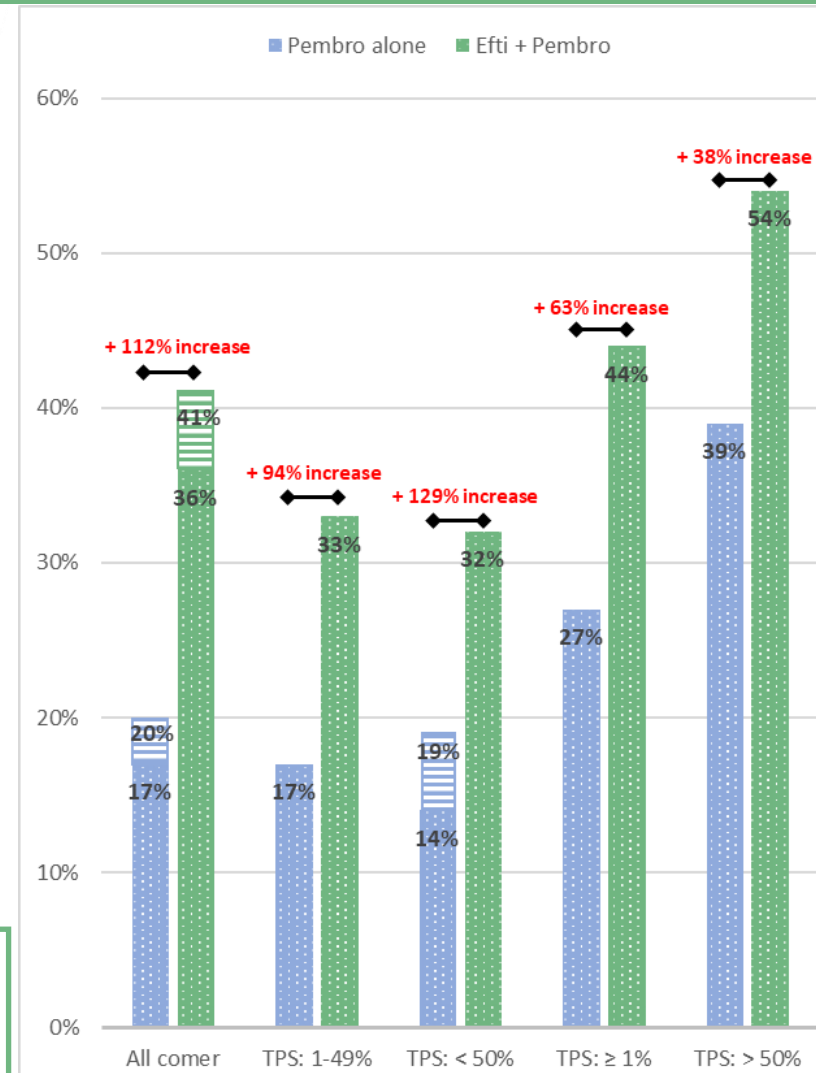


## Benchmarking against Pembrolizumab 1st line NSCLC

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

\* - only patients evaluated where PD-L1 results available (32 out of 36); \*\* 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 → efi addresses these needs
- TIGIT does not → effects predominantly in ≥ 50 % groups

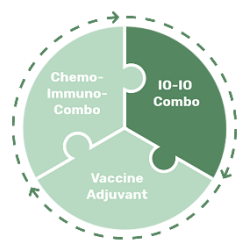


Data for pembro derived from KN042 and KN001<sup>(2)(3)</sup> and ORR in PD-L1 TPS <1% was taken from doi:10.1093/annonc/mdx076 and used to calculate ORR for TPS <50 for pembro mono. TACTI-002 data cut off 15. Oct. 2020.

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

Notes:

- (1) Preliminary data, cut-off 8 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 Aquilar et al; Annals of Oncology 30: 1653–1659, 2019, doi:10.1093/annonc/mdz288



# Efti: TACTI-002

## Results<sup>(1)</sup> - 2nd line HNSCC (Part C, Stage 1+2)



### Baseline Disease Characteristic + ORR Stage 1 and 2

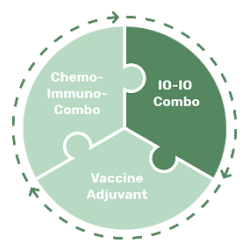
Baseline Characteristics	N (%); N=28
Median age, years (range)	65.5 (48-84)
Female	2 (7.1)
Male	26 (92.9)
ECOG 0	11 (39.3)
ECOG 1	17 (60.7)
Current or Former smoker	25 (89.3)
Previous chemotherapy	28 (100)
Previous cetuximab	13 (46.4)

Tumor response (iRECIST)	Stage 1 +2 N (%); (N=28)
<b>Complete Response</b>	<b>3 (10.7)</b>
Partial Response	7 (25.0)
Stable Disease	3 (10.7)
Progression	10 (35.7)
Not evaluable**	5 (17.9)
<b>Overall Response Rate [95 % CI interval]</b>	<b>10 (35.7) [18.6 – 55.9]</b>
Response rate – evaluable pts only	10 / 23 (43.5)

34/37 pts enrolled; 28 evaluated (≥ 1 post-baseline staging); 10/28 pts still on therapy at cut-off

Patients with oropharynx (n=7; 25%), hypopharynx (n=6; 21%); oral cavity (n=10; 36%) and larynx (N=5; 18%) enrolled.  
iORR of 35.7% [95% CI 18.6%, 55.9%] incl. 3 complete responses

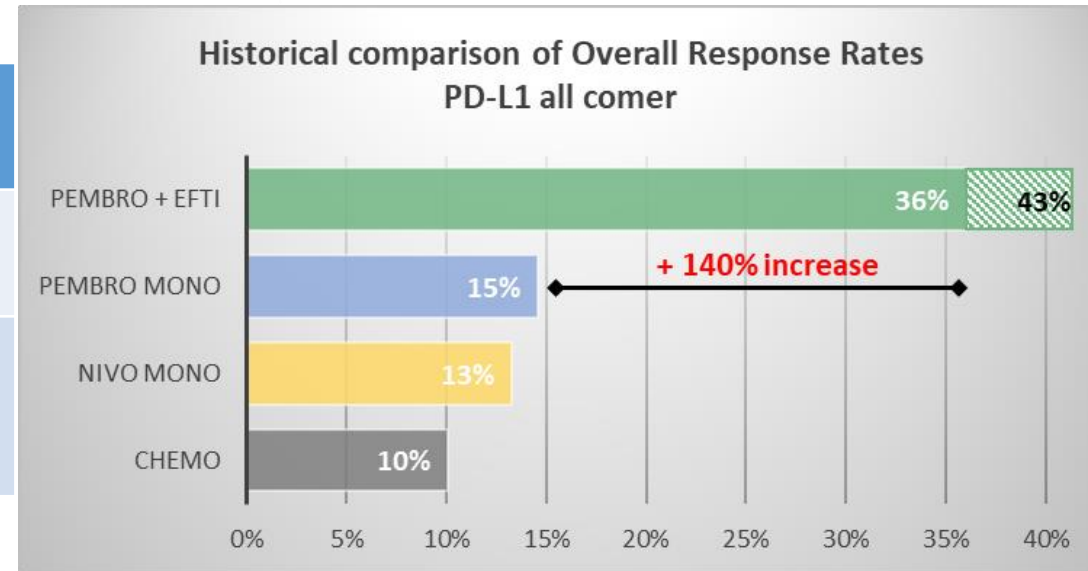




# eftilagimod alpha - TACTI-002 Results<sup>1</sup> - Benchmarking

## Benchmarking against Pembrolizumab in 2nd line HNSCC

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



Data for pembro derived from KN040<sup>(2)</sup> and for Nivo from CheckMate-141<sup>(3)</sup> Data cut off for TACTI-002, Oct. 2020.

\* - only patients evaluated where PD-L1 results available (21 out of 28); \*\* 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>
- ORR is clearly higher with high rates of CRs; duration of response very promising (only 1 pt with PR discontinued in TACTI-002)

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

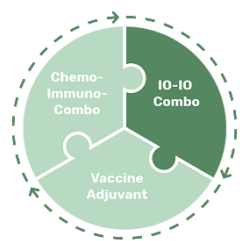
Notes:

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



# Efti: TACTI-002

## Results<sup>1</sup> - 2<sup>nd</sup> line NSCLC (Part B, Stage 1)



### Baseline Disease Characteristic + ORR Stage 1

Baseline Characteristics	N (%); N=23
Median age, years (range)	67.0 (46-84)
Female	10 (43.5)
Male	13 (56.5)
ECOG 0	7 (30.4)
ECOG 1	16 (69.6)
Current or Former smoker	21 (91.3)
Squamous	5 (21.7)
Non-squamous	18 (78.3)
Prior PD-1/PD-L1	100 %

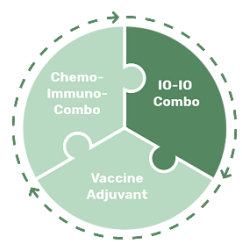
Tumor response (iRECIST)	Stage 1 N (%); (N=23)
<b>Partial Response</b>	<b>1 (4.4)</b>
Stable Disease	7 (30.4)
Progression	14 (60.9)
Not evaluable**	1 (4.4)
Overall Response Rate [95 % CI interval]	1 (4.4) [0.11 – 21.95]
<b>Disease control rate (DCR)</b>	<b>8 (34.8)</b>

- All pts progressed on 1<sup>st</sup> line therapy containing PD-1/PD-L1, which was confirmed by 2 consecutive scans
- Majority (61%) received combination of PD-1/PD-L1 plus chemo as 1st line (100% PD-X resistant)

- 85% of pts have PD-L1 of < 50%
- BOR of 1<sup>st</sup> line therapy was SD/PD in 61% of pts
- 1 confirmed PR and DCR of 35%
- 50+ % alive at 12 months
- At data cut-off, 3 pts still on therapy

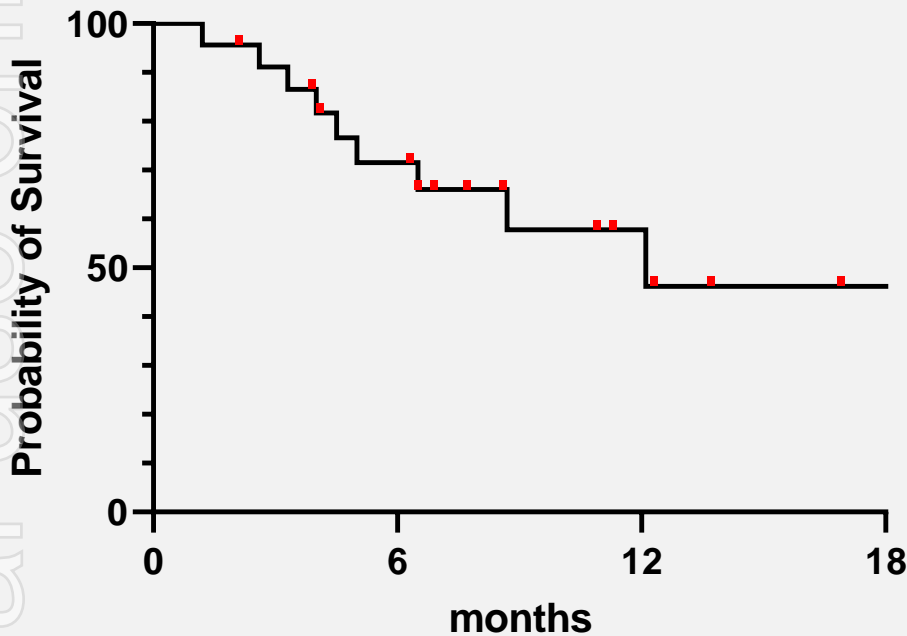
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# Efti: TACTI-002 Results<sup>(1)</sup> 2<sup>nd</sup> line NSCLC (part B) - Benchmarking

## 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 pts still under therapy

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

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

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

# Efti: TACTI-mel trial in melanoma

TACTI-mel evaluated efti in combination with MSD's KEYTRUDA® (pembrolizumab) in a dose escalation trial.

## Key Results <sup>(1)</sup>

- Deep & durable responses
- 66% of patients were progression free at 6 months
- Safe and well tolerated

## Primary endpoint conclusion:

30 mg of efti recommended dosage for a Phase II trial



## Phase I

Open label clinical trial in metastatic melanoma



**24**

Patients with unresectable or metastatic melanoma



**6 or 12 months**

Combination treatment



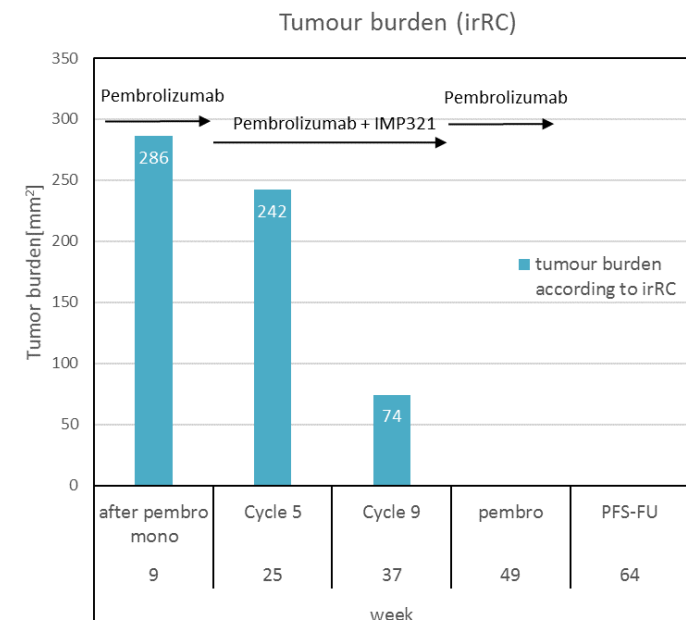
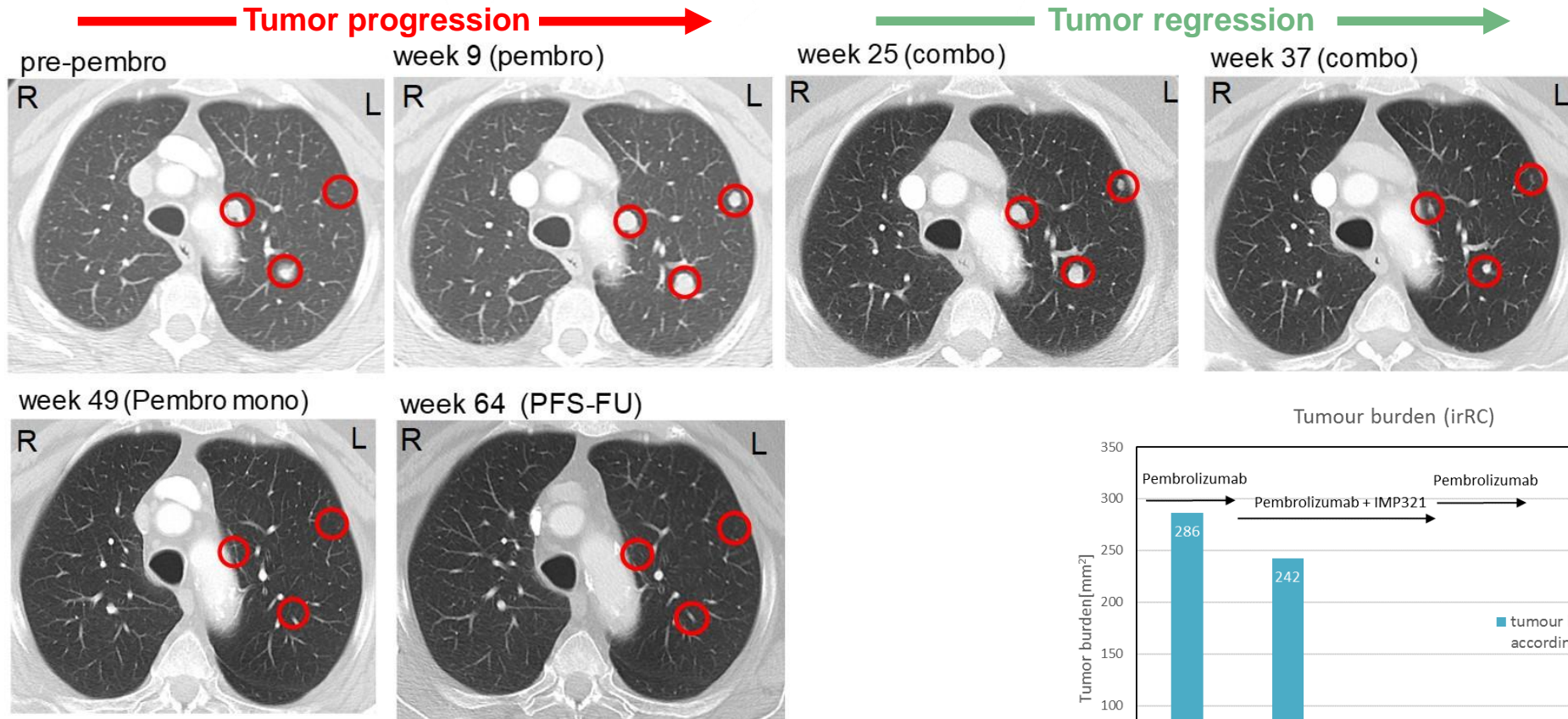
**7**

Clinical trial sites in Australia

# Efti: TACTI-mel trial in melanoma

## Results (Part A, Single Case)

### Efficacy: Metastatic Melanoma



- Patient progressing on pembrolizumab monotherapy
- At 1 yr all lesions disappeared → CR (confirmed)
- Patient without treatment and disease free → now lost to FU

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# Efti: INSIGHT-004 Trial in Solid Tumours

INSIGHT-004 is a dose escalation study evaluating efti in combination with Bavenico<sup>®</sup> (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>*

## 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

# Efti: AIPAC Trial in Breast Cancer

AIPAC is evaluating efti in combination with a taxane-based standard of care chemotherapy, paclitaxel.

## Key Results <sup>(1)</sup>

- Efficacy improvement observed from efti/chemo compared to placebo in terms of Overall Response Rate
- Effect on Progression Free Survival when paclitaxel is given together with efti
- Compelling results observed in patient subgroup populations
- Safe and well tolerated

## Next milestone:

First Overall Survival data will be presented at a Spotlight Presentation at San Antonio Breast Conference Dec 2020



## Phase IIb

Clinical trial in breast cancer



**227**

Randomised patients with HER2-negative / Hormone Receptor positive (HR+) metastatic breast cancer



**6 months**

Combination treatment, then maintenance phase



**>30**

Clinical trial sites



**7 countries**

Germany, the UK, France, Hungary, Belgium, Poland and the Netherlands

# Efti Partnerships



- EOC, an Eddingpharm spin-off holding the Chinese rights for efti, Phase I study in MBC ongoing
- 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 Immunep); Phase I completed

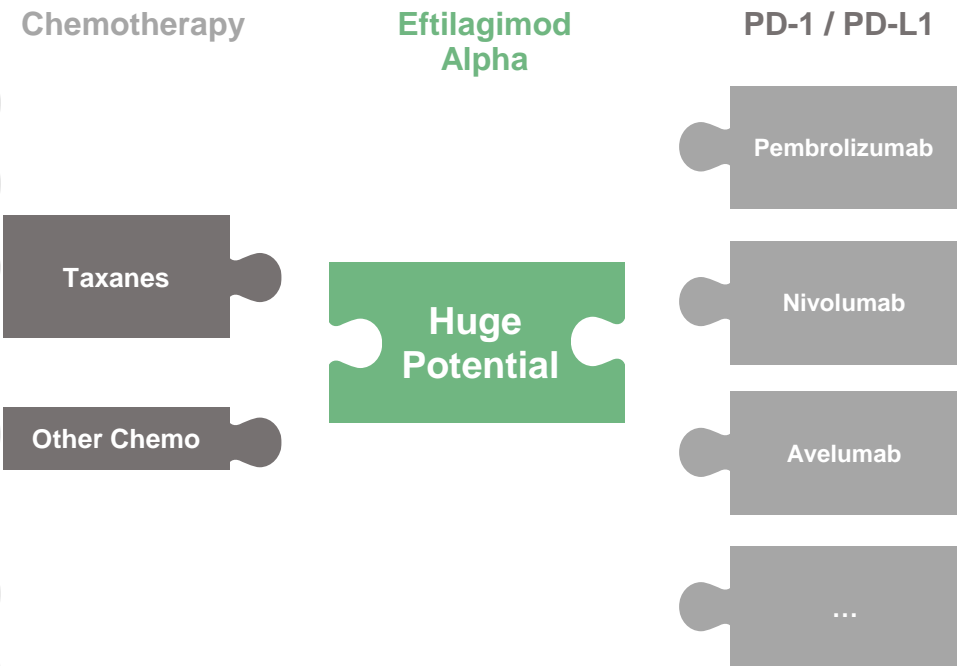


- Strategic supply partnership for the manufacture of efti
- Through WuXi, Immunep was the first company to use a Chinese manufactured biologic in a European clinical trial



# Efti: Current Strategic Potential & Plans

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



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



**Up to 145 patients**

in anti-PD-(L)1 combinations



**272 patients**

in chemo-immune combination



**Safety & efficacy**

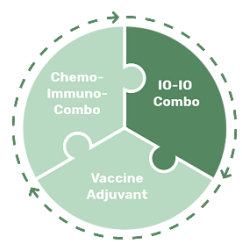
Good safety & encouraging efficacy data in NSCLC, HNSCC, met. Melanoma and MBC



**Big pharma**

A variety of development options with big pharma support





# 1st line NSCLC Design + Status extension Part A



## 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)**

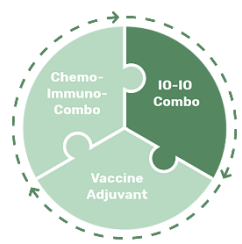
**Secondary: PFS, OS, PK,  
biomarker, PD, safety and  
tolerability**

## Design:

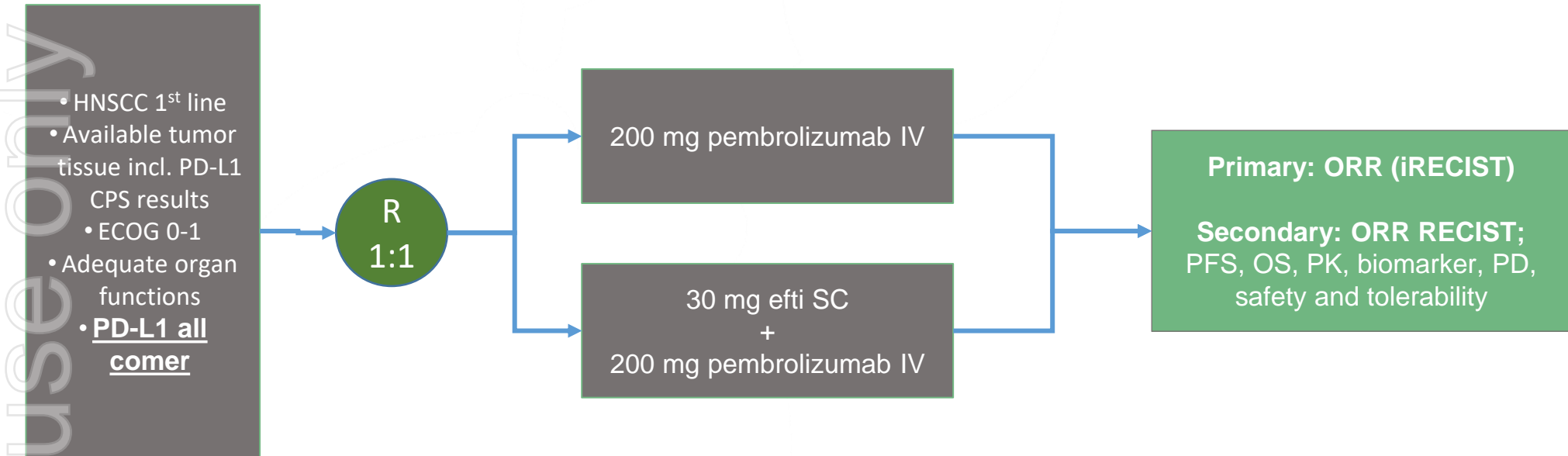
- Expansion of TACTI-002 part A: 74 pts in addition in order to prepare for registration trials (specific patient population analysis)

## Status

- Approved by all competent authorities (incl. FDA); Keytruda supply ensured; could start immediately with results in Q1 2022
- Regulatory submissions planned
- In collaboration with  **MERCK**  
INVENTING FOR LIFE



# 1st line HNSCC Potential Design + Status TACTI-003



## Design:

- Randomized study with ORR as primary endpoint
- Especially US and EU to be included
- Appr. 160 pts to be randomized to have sufficient pts in each group and potentially use the data for registrational purposes

## Status:

- Advanced planning & collaboration discussions
- First results could be expected by end of 2021

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# **Out-Licensed Immunotherapy Pipeline**

# 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 Immunetep'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 Immunetep<sup>(2)</sup>
- Phase I clinical study completed, evaluating GSK'781 in 36 healthy Japanese and Caucasian subjects, PK/PD study<sup>(2)</sup>
- Clinical Proof of Concept expected H1 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**

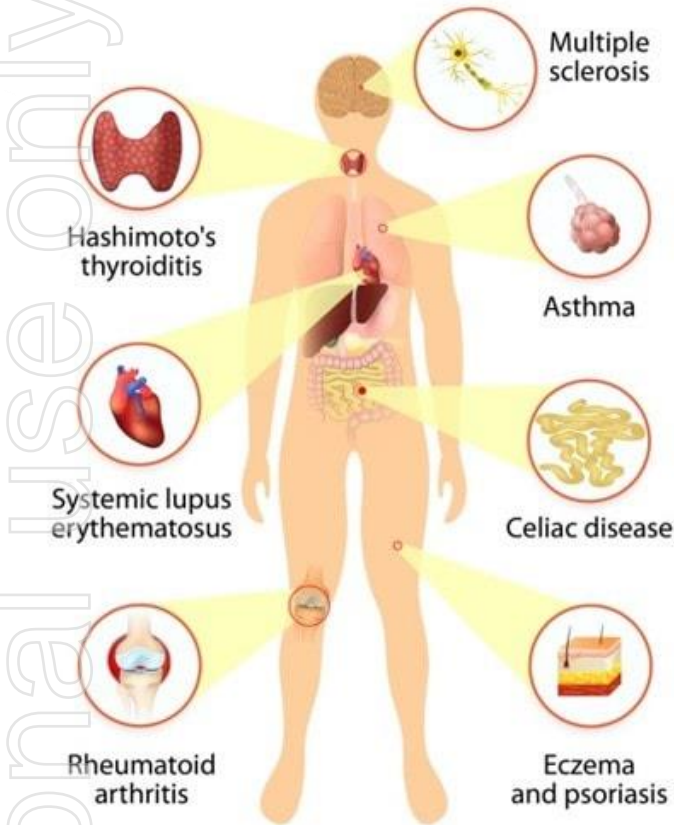


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# **IMP761** **(Autoimmune Diseases)**

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

## AUTOIMMUNE DISEASES

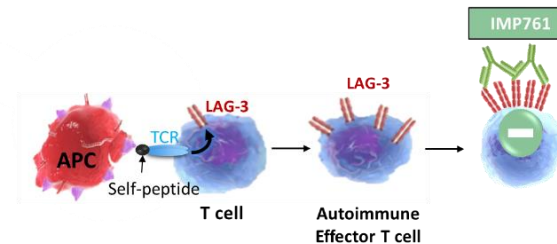


## THE PRESENT: FIGHTING THE SYMPTOMS

**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 bn \$ market size by 2025)<sup>1</sup>**



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# Offer Details

# Capital Raising Overview

Immunetep is conducting a capital raising of approximately A\$29.6 million to fund clinical development of its product candidates

## Capital Raising Structure:

- Placement of approximately A\$29.6 million to institutional investors in Australia and eligible offshore institutional investors under the Company's existing 25% Placement capacity under ASX Listing Rule 7.1 & 7.1A
- The offer price of A\$0.24 per Share under the Placement represents a 15.7% discount to the 5 day VWAP over the 5 days up to and including 17 November 2020 as traded on ASX.
- Costs of the offering is approximately A\$1.5 million.

## Use of Proceeds:

Description	A\$m
Clinical Development	18.0
Manufacturing	5.4
Working Capital and Offer Costs	4.4
Other R&D	1.8
<b>Total</b>	<b>29.6</b>

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# Immutep Financials & Outlook

# Key Financials

## Corporate Snapshot

<b>Ticker symbols</b>	IMM (ASX) IMMP (NASDAQ)
<b>Securities on issue<sup>(1)</sup></b> (as at 2 November 2020)	492.9 million ordinary shares
<b>Cash &amp; Term Deposits</b> (as at 30 September 2020)	~A\$22.7 million (US\$16.1 million)
<b>Market Cap<sup>(2)</sup></b> (as at 13 November 2020)	A\$142.9 million (US\$103.3 million)

## FY results for year ended 30 June 2020

<b>Revenue and other income</b>	A\$16.5 million (US\$11.3 million)
<b>R&amp;D and IP expenses</b>	A\$20.4 million (US\$14.0 million)
<b>G&amp;A expenses</b>	A\$6.3 million (US\$4.3 million)
<b>Net operating cash outflow</b>	A\$10.8 million (US\$7.4 million)

**Notes:**

(1) Currently ~25% of the ordinary shares are represented by ADSs listed on NASDAQ where 1 ADS represents 10 ordinary shares.

(2) Market capitalization based on ASX share price.

NB: US equivalent of amounts above are based on foreign exchange rate for AUD/USD of 0.6863 as at 30 June, except a) cash balance which is calculated using FX rate of 0.7108 as at 30 September and b) market capitalization which is calculated using FX rate of 0.7230 as at 13 November 2020.

# 2020 & 2021 News Flow\*

2020

- **AIPAC** - Overall Survival data from breast cancer: end of 2020
- **TACTI-002** - more data from NSCLC 1st line: throughout 2020
- **TACTI-002** - more data from HNSCC 2nd line: throughout 2020
- **TACTI-002** - initial data from NSCLC 2nd line: 2020
- Regulatory progress
- Progress from partnered programs

2021

- Final data from **TACTI-002** Parts A and C
- Final data from **INSIGHT-004**
- Ongoing regulatory engagement
- Updates from **IMP761**
- Progress from partnered programs
- Final Overall Survival data from **AIPAC**

# Summary

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

**10 active clinical trials (including partnered products) with further significant data read-outs throughout 2020 and 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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**immunetep**<sup>®</sup>  
LAG-3 IMMUNOTHERAPY



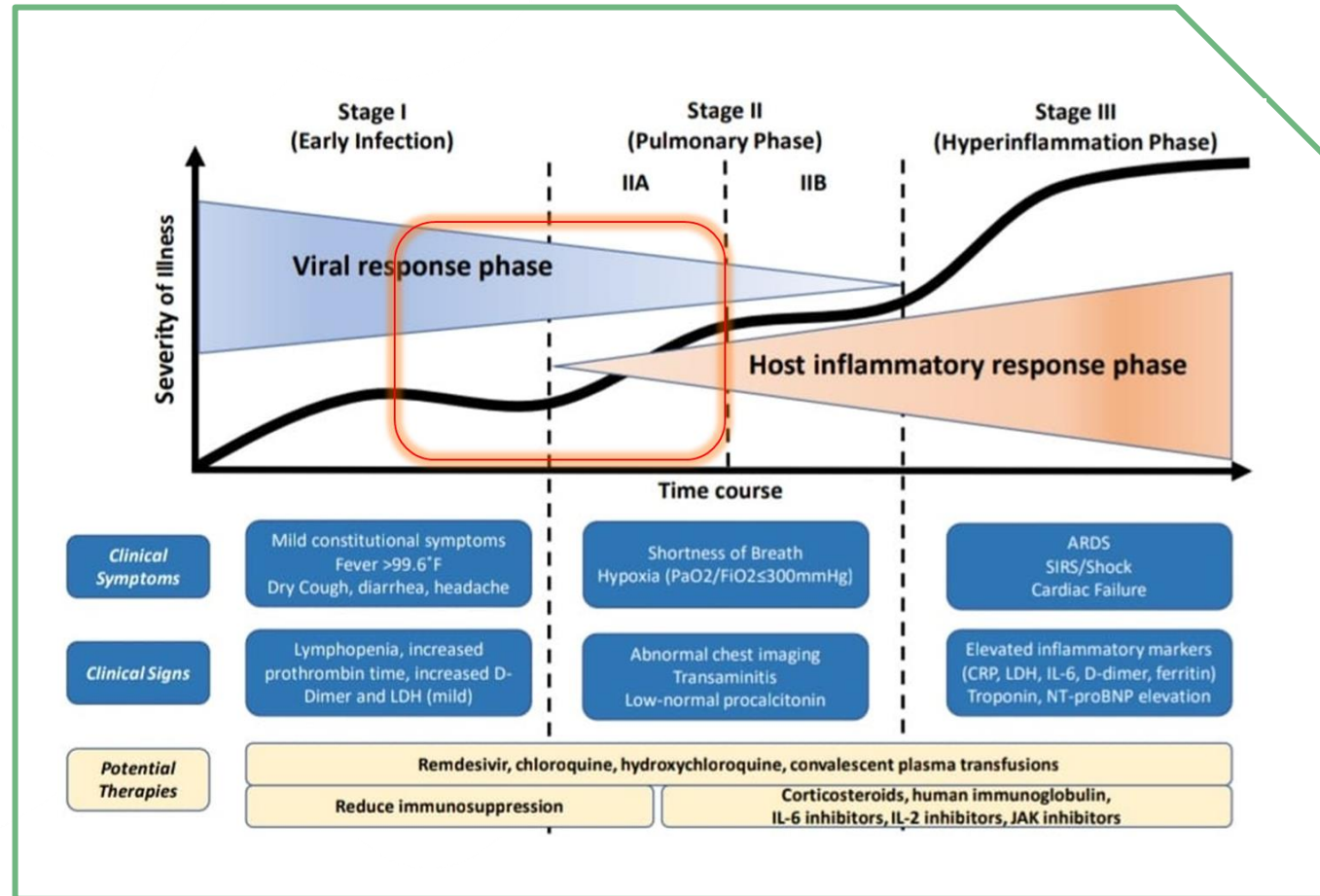
**Thank you**

# 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

**Next:**

Recruitment for open label safety run-in of 6 patients, then first cohort of 26 randomised patients

Initial interim results expected from early 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**

# 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**

# **International Selling Restrictions & Risks Factors**

# International Offer Restrictions

This document does not constitute an offer of Shares of the Company in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

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This document has not been, and will not be, registered with or approved by any securities regulator in the European Union. Accordingly, this document may not be made available, nor may the Shares be offered for sale, in the European Union except in circumstances that do not require a prospectus under Article 1(4) of Regulation (EU) 2017/1129 of the European Parliament and the Council of the European Union (the "Prospectus Regulation").

In accordance with Article 1(4)(a) of the Prospectus Regulation, an offer of Shares in the European Union is limited to persons who are "qualified investors" (as defined in Article 2(e) of the Prospectus Regulation).

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## United Kingdom

Neither this document nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the Shares.

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# Risk Factors

This Section identifies some of the major risks associated with an investment in the Company. Potential investors should read the risk factors in their entirety in order to appreciate such matters and the manner in which the Company intends to operate before making any decision to invest in the Company.

As an early stage biotechnology company, there are significant risks and no guarantee of the trading price/s at which the Company's Shares may trade nor any guarantee of any return or dividends in respect of holding Shares in the Company.

***The Company has a history of operating losses and may not achieve or maintain profitability in the future.***

The Company is at an early stage in the development of pharmaceutical products, with a focus on the development of immunotherapeutic products for the treatment of cancer. There is a risk that the Company will be unable to complete its clinical development program and/or commercialise some or all of its products in development. There is a risk that the Company, or its development partners, may not be able to complete the development of our current product candidates or develop other pharmaceutical products. It is possible that none of them will be successfully commercialised, which would prevent the Company from ever achieving profitability.

The Company has no medicinal products approved for commercial sale. Currently, the Company has no products approved for commercial sale. The Company is largely dependent on the success of its product candidates, particularly those related to LAG-3.

The LAG 3 product candidates were acquired by the Company through the acquisition of the French privately owned and venture capital backed company Immunetep SA, a biopharmaceutical company in the rapidly growing field of Immuno-Oncology, in December 2014. This acquisition significantly expanded the Company's clinical development product portfolio to other categories of immunotherapies. It has also provided the Company with partnerships with several of the world's largest pharmaceutical companies.

The Company has several LAG-3 product candidates. The most advanced of is IMP321. IMP321 is a recombinant protein typically used in conjunction with chemotherapy to amplify a patient's immune response. Another LAG-3 product candidate is IMP701, an antagonist antibody that acts to stimulate T cell proliferation in cancer patients. IMP701 has been licensed to CoStim (Novartis), which is solely responsible for its development and manufacturing. A third LAG-3 product candidate is IMP731, a depleting antibody that removes T cells involved in autoimmunity. IMP731 has been licensed to GlaxoSmithKline, or GSK, which is solely responsible for its development and manufacturing. Finally, in January 2017, the Company announced it had conducted research on a new early stage product candidate, a humanized IgG4 monoclonal antibody known as IMP761.

In addition to these products, the Company also has a dedicated R&D laboratory outside Paris with other research candidates in development. The Company also currently generates modest revenues from sales of LAG-3 research reagents.

There can be no assurance that the Company will be successful in developing any product candidate, or that the Company's will be able obtain the necessary regulatory approvals with respect to any or all of its product candidates. While a portion of the net proceeds of the Offer will be used to fund the further development of IMP321, the Company will require additional funds to achieve its long-term goals of further development and commercialisation of IMP321 and other product candidates. In addition, the Company will require funds to pursue regulatory applications, protect and defend intellectual property rights, increase contracted manufacturing capacity, potentially develop marketing and sales capability and fund operating expenses. The Company intends to seek such additional funding through public or private financings and/or through licensing of its assets or other arrangements with corporate partners. However, such financing, licensing opportunities or other arrangements may not be available from acceptable or any sources on acceptable terms, or at all. Any shortfall in funding could result in the Company having to curtail or cease its operations, including research and development activities, thereby harming its business, financial condition and/or results of operations.

The Company's ability to generate product revenue depends on a number of factors, including its ability to successfully complete clinical development of, and receive regulatory approval for, its product candidates; set an acceptable price for our products, if approved, and obtain adequate coverage and reimbursement from third-party payors; obtain commercial quantities of our products, if approved, at acceptable cost levels; and successfully market and sell its products, if approved.

In addition, because of the numerous risks and uncertainties associated with product candidate development, the Company is unable to predict the timing or amount of increased expenses, or when, or if, it will be able to achieve or maintain profitability. The expenses of the Company could increase beyond current expectations if the applicable regulatory authorities require further studies in addition to those currently anticipated and even if its product candidates are approved for commercial sale, the Company anticipates incurring significant costs associated with the commercial launch of such products and there can be no guarantee that the Company will ever generate significant revenues.

# Risk Factors

***The Company will require additional financing and may be unable to raise sufficient capital, which could have a material impact on its research and development programs or commercialisation of its products or product candidates.***

The Company has historically devoted most of its financial resources to research and development, including pre-clinical and clinical development activities. To date, the Company financed a significant amount of its operations through public and private financings. The amount of the Company's future net losses will depend, in part, on the rate of its future expenditures and the Company's ability to obtain funding through equity or debt financings or strategic collaborations. The amount of such future net losses, as well as the possibility of future profitability, will also depend on the success of the Company in developing and commercialising products that generate significant revenue. The Company's failure to become and remain profitable would depress the value of its Shares and could impair its ability to, or prevent it from being able to, raise capital, expand its business, maintain its research and development efforts (or grow them as required), diversify its product offerings or continue its operations at the same levels, or at all.

If the Company is unable to secure sufficient capital to fund its operations, it may be required to delay, limit, reduce or terminate its product development or future commercialisation efforts or grant rights to third parties to develop and market products or product candidates that it would otherwise prefer to develop and market on its own. For example, additional strategic collaborations could require the Company to share commercial rights to its product candidates with third parties in ways that the Company does not intend currently to do, or on terms that may not be favourable to the Company. Moreover, the Company may also have to relinquish valuable rights to its technologies, future revenue streams, research programs and/or product candidates or grant licenses on terms that may not be favourable to it.

***The Company is exposed to significant risks related to its ongoing research and development efforts and might not be in a position to successfully develop any product candidate. Any failure to implement its business strategy could negatively impact the Company's business, financial condition and results of operations.***

The development and commercialization of IMP321, IMP701, IMP731 and IMP761, or any other product candidate the Company may develop, is subject to many risks, including:

- additional clinical trials may be required beyond what its currently expected;
- regulatory authorities may disagree with the Company's interpretation of data from its preclinical studies and clinical studies or may require that it to conduct additional studies;
- regulatory authorities may disagree with the Company's proposed design of future clinical trials;
- regulatory authorities may not accept data generated at its clinical study sites;
- the Company may be unable to obtain and maintain regulatory approval of its product candidate in any jurisdiction;
- the prevalence and severity of any side effects of any product candidate could delay or prevent commercialisation, limit the indications for any approved product candidate, require the establishment of a risk evaluation and mitigation strategy, or REMS, or prevent a product candidate from being put on the market or cause an approved product candidate to be taken off the market;
- regulatory authorities may identify deficiencies in the Company's manufacturing processes or facilities or those of its third-party manufacturers;
- regulatory authorities may change their approval policies or adopt new regulations;
- the third-party manufacturers the Company expects to depend on to supply or manufacture its product candidates may not produce adequate supply, and other appropriate third-party manufacturers may not be available;
- the Company or its third-party manufacturers may not be able to source or produce cGMP materials for the production of the Company's product candidates;
- the Company may not be able to manufacture its product candidates at a cost or in quantities necessary to make commercially successful products;
- the Company may not be able to obtain adequate supply of its product candidates for its clinical trials;
- the Company may experience delays in the commencement of, enrolment of patients in and timing of its clinical trials;
- the Company may not be able to demonstrate that its product candidates are safe and effective as a treatment for its indications to the satisfaction of regulatory authorities, and may not be able to achieve and maintain compliance with all regulatory requirements applicable to its product candidates;
- the Company may not be able to maintain a continued acceptable safety profile of its products following approval;
- the Company may be unable to establish or maintain collaborations, licensing or other arrangements;
- the market may not accept the Company's product candidates;
- the Company may be unable to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations, and the effectiveness of its own or any future strategic collaborators' marketing, sales and distribution strategy and operations will affect the Company's profitability;

# Risk Factors

- the Company may experience competition from existing products or new products that may emerge;
- the Company and its licensors may be unable to successfully obtain, maintain, defend and enforce intellectual property rights important to protect the Company's product candidates; and
- the Company may not be able to obtain and maintain coverage and adequate reimbursement from third-party payors.

If any of these risks materialises, the Company could experience significant delays or an inability to successfully commercialise IMP321, IMP701, IMP731 and IMP761, or any other product candidate the Company may develop, which would have a material adverse effect on its business, financial condition and/or results of operations.

***The Company's research and development efforts will be jeopardised if it is unable to retain key personnel and cultivate key academic and scientific collaborations.***

The Company's success depends largely on the continued services of its senior management and key scientific personnel and on the efforts and abilities of its senior management to execute its business plan. The Company's research and development activities of IMP321 will be overseen by Dr. Frédéric Triebel, the inventor of the technology.

Changes in the Company's senior management may be disruptive to its business and may adversely affect its operations. For example, when the Company has changes in senior management positions, it may elect to adopt different business strategies or plans. Any new strategies or plans, if adopted, may not be successful and if any new strategies or plans do not produce the desired results, the Company's business may suffer.

Moreover, competition among biotechnology and pharmaceutical companies for qualified employees is intense and, as such, the Company may not be able to attract and retain personnel critical to its success. The Company's success depends on its continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel, manufacturing personnel, sales and marketing personnel and on the Company's ability to develop and maintain important relationships with clinicians, scientists and leading academic and health institutions. If the Company fails to identify, attract, retain and motivate these highly skilled personnel, it may be unable to continue its product development and commercialisation activities.

In addition, biotechnology and pharmaceutical industries are subject to rapid and significant technological change. The Company's product candidates may be or become uncompetitive. To remain competitive, the Company must employ and retain suitably qualified staff that are continuously educated to keep pace with changing technology, but may not be in a position to do so.

***Future potential sales of the Company's products may suffer if they are not accepted in the marketplace by physicians, patients and the medical community.***

There is a risk that IMP321 may not gain market acceptance among physicians, patients and the medical community, even if they are approved by the regulatory authorities. The degree of market acceptance of any of the Company's approved products will depend on a variety of factors, including:

- timing of market introduction, number and clinical profile of competitive products;
- the Company's ability to provide acceptable evidence of safety and efficacy and its ability to secure the support of key clinicians and physicians for its products;
- cost-effectiveness compared to existing and new treatments;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payers;
- prevalence and severity of adverse side effects; and
- other advantages over other treatment methods.

Physicians, patients, payers or the medical community may be unwilling to accept, use or recommend the Company's products which would adversely affect its potential revenues and future profitability.



# Risk Factors

***The Company's success depends on its ability to protect its intellectual property and its proprietary technology.***

The success of the Company is, to a certain degree, also dependent on its ability to obtain and maintain patent protection or, where applicable, to receive/maintain orphan drug designation/status and resulting marketing exclusivity for its product candidates.

The Company may be materially adversely affected by its failure or inability to protect its intellectual property rights. Without the granting of these rights, the ability to pursue damages for infringement would be limited. Similarly, any know-how that is proprietary or particular to its technologies may be subject to risk of disclosure by employees or consultants, despite having confidentiality agreements in place.

Any future success will depend in part on whether the Company can obtain and maintain patents to protect its own products and technologies; obtain licenses to the patented technologies of third parties; and operate without infringing on the proprietary rights of third parties. Biotechnology patent matters can involve complex legal and scientific questions, and it is impossible to predict the outcome of biotechnology and pharmaceutical patent claims. Any of the Company's future patent applications may not be approved, or it may not develop additional products or processes that are patentable. Some countries in which the Company may sell its product candidate or license its intellectual property may fail to protect the Company's intellectual property rights to the same extent as the protection that may be afforded in the United States or Australia. Some legal principles remain unresolved and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States, the United Kingdom, the European Union, Australia or elsewhere. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the United States, Australia, the United Kingdom, the European Union or elsewhere may diminish the value of the Company's intellectual property or narrow the scope of its patent protection. Even if the Company is able to obtain patents, the patents may not be issued in a form that will provide the Company with any meaningful protection, prevent competitors from competing with the Company or otherwise provide the Company with any competitive advantage. The Company's competitors may be able to circumvent its patents by developing similar or alternative technologies or products in a non-infringing manner.

Moreover, any of the Company's pending applications may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, IP Australia and/or any patents issuing thereon may become involved in opposition, derivation, reexamination, inter partes review, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging the Company's patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, the Company's patent rights, and allow third parties to commercialise its technology or products and compete directly with the Company, without payment to it. In addition, if the breadth or strength of protection provided by the Company's patents and patent applications is threatened, it could dissuade companies from collaborating with the Company to exploit its intellectual property or develop or commercialise current or future product candidate.

The issuance of a patent is not conclusive as to the inventorship, scope, validity or enforceability, and the Company's patents may be challenged in the courts or patent offices in the U.S., the EU, Australia and elsewhere. Such challenges may result in loss of ownership or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit the duration of the patent protection of our technology and products. As a result, the Company's patent portfolio may not provide it with sufficient rights to exclude others from commercialising products similar or identical to the Company's.

In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity that the Company obtains under applicable legislation, which may require it to allocate significant resources to preventing such circumvention. Such developments could enable other companies to circumvent the Company's intellectual property rights and use its clinical trial data to obtain marketing authorisations in the EU, Australia and in other jurisdictions. Such developments may also require the Company to allocate significant resources to prevent other companies from circumventing or violating its intellectual property rights.

The Company's attempts to prevent third parties from circumventing its intellectual property and other rights may ultimately be unsuccessful. The Company may also fail to take the required actions or pay the necessary fees to maintain its patents.