immutep

LAG-3 IMMUNOTHERAPY

SITC 2021 Results: Management Update

GLOBAL WEBCAST

Date & Time: 8.00 am AEDT (Sydney) Wednesday 17 November 2021
4.00 pm EST (New York) Tuesday 16 November 2021
10.00 pm CET (Berlin) Tuesday 16 November 2021

Register: https://fnn.webex.com/fnn/onstage/g.php?MTID=ef12af93633b5d17a2e4e176fcac2f070

A replay of the webcast will also be available at www.immutep.com

(ASX: IMM, NASDAQ: IMMP)

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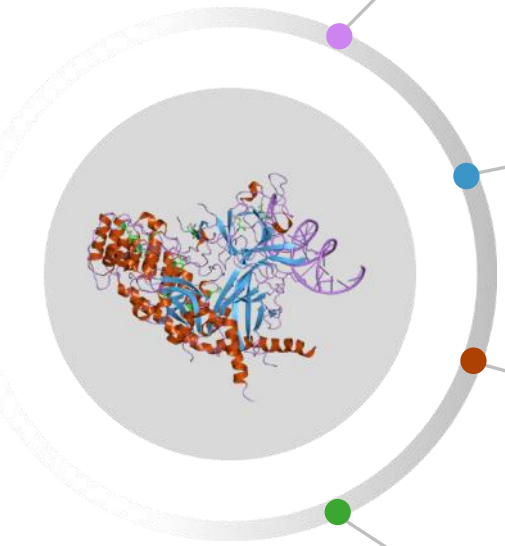
Overview

Immutep

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



Globally active

Leadership position in LAG-3

with 4 product candidates in immuno-oncology and autoimmune disease

Clinical Potential

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

Collaborating with industry leaders

NOVARTIS · Pfizer · gsk GlaxoSmithKline · Merck KGaA, Darmstadt, Germany · MERCK INVENTING FOR LIFE · EOC · CYTLIMIC Cytotoxic T Lymphocyte Immunotherapy in Cancer · LabCorp

LAG-3 Pioneer

French immunologist

Prof. Frédéric Triebel, Immutep CMO & CSO

LAG-3 Overview & Product Candidates

LAG-3 Therapeutic Landscape Overview

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

PDUFA goal date March 19, 2022

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

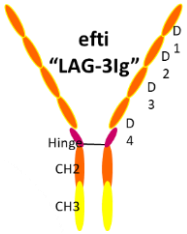
1) As of January 7, 2019 Regeneron is in full control of program and continuing development (https://www.sec.gov/Archives/edgar/data/872589/000110465919000977/a19-1325_18k.htm)
2) On 3 Apr. 2020 Les Laboratoires Servier acquired Symphogen
3) Tesaro was acquired by and is now part of GSK (www.gsk.com/en-gb/media/press-releases/gsk-completes-acquisition-of-tesaro-an-oncology-focused-biopharmaceutical-company/)
4) Includes two completed Phase I studies and one discontinued Phase 2 study
5) Including IITs, one planned trials (MBC trial by EOC)
6) RELATIVITY-047 (https://investors.bms.com/iframes/press-releases/press-release-details/2021/Bristol-Myers-Squibb-Announces-RELATIVITY-047-a-Trial-Evaluating-Anti-LAG-3-Antibody-Relatlimab-and-Opdivo-nivolumab-in-Patients-with-Previously-Untreated-Metastatic-or-Unresectable-Melanoma-Meets-Primary-Endpoint-of-Progression-Free-Survival/default.aspx)

Eftilagimod Alpha

Bringing APC Activation into Oncology

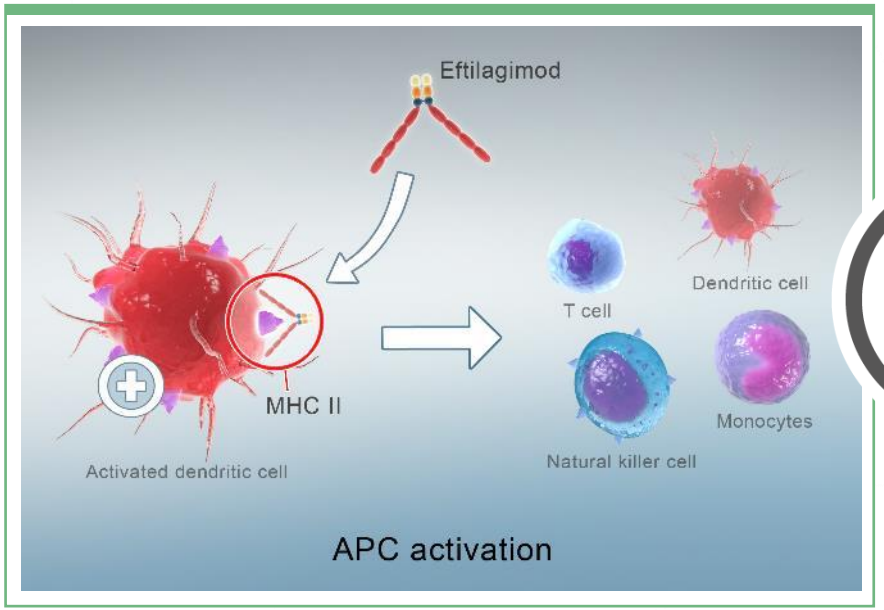
Eftilagimod alpha ~ Efti ~ IMP321

Efti: an Innovative LAG-3 I-O Product Candidate



- Efti is a soluble LAG-3 protein targeting a subset of MHC class II on APC
- Potentially synergistic with other therapeutic agents, e.g. Immuno-Oncology (I-O) agents or chemotherapies

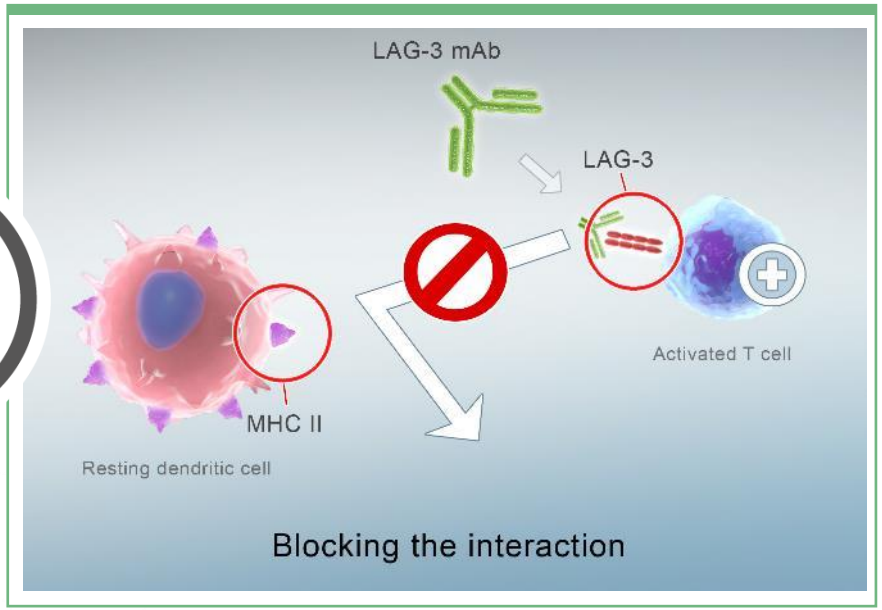
"PUSHING THE ACCELERATOR ON IMMUNE RESPONSES"



Efti is an **MHC II agonist:**
APC activator

- boost and sustain the $CD8^+$ T cell responses
- activate multiple immune cell subsets

"RELEASING THE BRAKE ON THE T CELL"



LAG-3 antagonist, or blocking, antibodies:
Immune checkpoint inhibitor

- increase cytotoxicity of the pre-existing CD8 T cell response

Notes:
* APC: antigen presenting cell

Clinical Development

Efti: Main Trials*

Program	Preclinical	Phase I	Phase II	Late Stage[5]	Commercial Rights
Oncology – Eftilagimod Alpha (Efti or IMP321) – APC activating soluble LAG-3 Protein	Metastatic Breast Cancer (Chemo – IO) [1] AIPAC-003				Global Rights immutep
	Metastatic Breast Cancer (Chemo – IO) AIPAC				
	Head and Neck Squamous Cell Carcinoma (IO – IO) [2] TACTI-003			MERCK	
	Head and Neck Squamous Cell Carcinoma (IO – IO) [2] TACTI-002			MERCK	
	Non-Small-Cell Lung Carcinoma (IO – IO) [2] TACTI-002			MERCK	
	Solid Tumors (IO – IO – Chemo) [3] INSIGHT-003				
	Solid Tumors (IO – IO) [3], [4a] INSIGHT-004		Pfizer / Merck KGaA, Darmstadt, Germany		
	Solid Tumors (IO – IO) [1], [3], [4b] INSIGHT-005		Merck KGaA, Darmstadt, Germany		
	Melanoma (IO – IO) [2] TACTI-mel				
	Solid Tumors (Cancer Vaccine)[5a] YNP01 / YCP02 / CRESCENT 1		CYTLIMIC		
	Metastatic Breast Cancer (Chemo – IO)[5b]			EOC	Chinese Rights EOC

Notes:

* Information in pipeline chart current as at November 2021. AIPAC-003 and INSIGHT-005 trial initiation are subject to further approvals.

(1) Planned trial

(2) In combination with KEYTRUDA® (pembrolizumab)

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

(4) a) In combination with BAVENCIO® (avelumab); b) in combination with [illegible]ntrafusp alfa

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

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

Clinical Development

Operational Update

TACTI-002

- ✓ **Recruitment** into Part A (1st line NSCLC) is expected to be completed **ahead of time,** due to great interest from sites.
- ✓ 70+ of 74 patients for part A extension already enrolled.

TACTI-003

- ✓ Full CTA approvals received in 5 of 8 countries → no roadblocks or any major comments received from authorities.
- ✓ Recruitment initiated, first patients randomized.

INSIGHT

- ✓ **INSIGHT-003** (efti+SoC (e.g. doublet chemo + PD-1) in e.g. 1st line NSCLC) has enrolled **already 5 patients**.
- ✓ Preparation for **INSIGHT-005** collaboration with Merck KGaA are ongoing, but under review due to bintrafusp alfa performance.

AIPAC-003

- ✓ Positive feedback from EMA received.
- ✓ FDA discussion ongoing as planned.

Efti + Chemo Combination

AIPAC trial

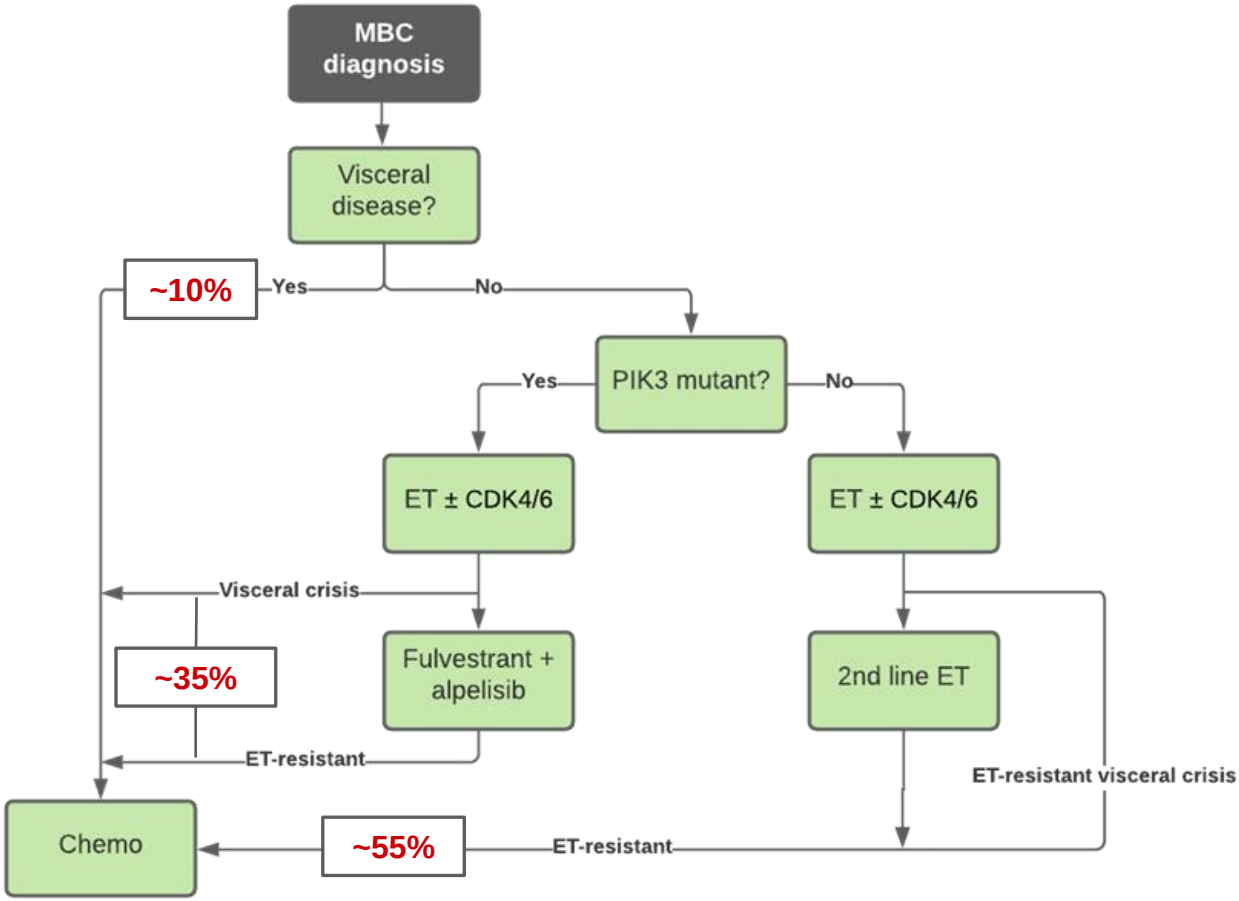
Final OS results presented at SITC, 10-14 November 2021

Goal: Improving OS while maintaining QoL in HR^{+}/HER2^{-} MBC patients

Epidemiology:

- Breast cancer (BC) is the **most frequently diagnosed cancer**. More than 2 million breast cancer (thereof ~70% HR^{+}/HER2^{--}) diagnoses per annum worldwide.
- Up to 550,000 patients in total and app. 350,000 patients younger than 65 develop metastatic disease and are **eligible to receive chemotherapy**(1) (2)

HIGH UNMET MEDICAL NEED



Lack of Innovation

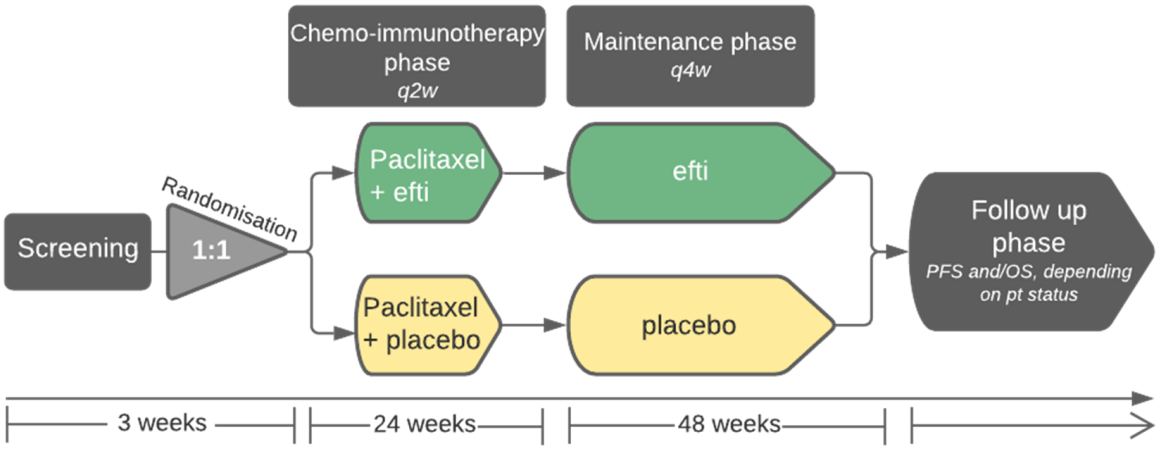
*Weekly **paclitaxel** well established SOC*

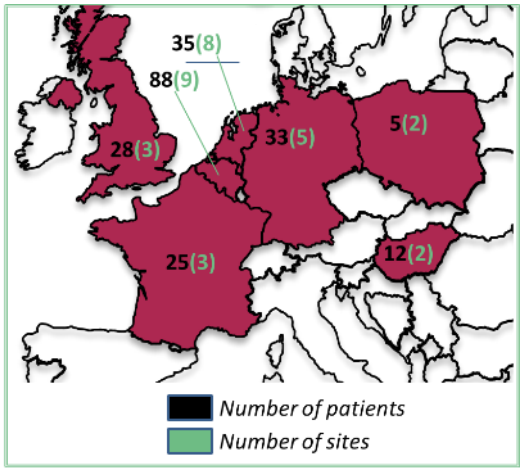
Notes

(1) Source: WHO Global Cancer Observatory 2020 and Informa Intelligence October 2020
(2) Wang et al. BMC Cancer (2019) 19:1091
MBC – metastatic breast cancer; BC – Breast Cancer

Efti: AIPAC (Phase IIb) design

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





Hypothesis-Generating Study

Primary endpoint(*) (presented Mar. 2020) included:

- Assessment of Progression-Free Survival (PFS)

Secondary endpoints(*) (presented Dec. 2020) included:

- Overall Survival (OS)
- 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
- ✓ Last Patient In enrolled Jun. 2019
- ✓ Primary analysis PFS (immature OS) Mar. 2020
- ✓ Follow-up 1 analysis OS Sep. 2020 (SABCS Dec. 2020) – ~60% OS events
- ✓ **Final OS analysis at SITC 2021**

Notes:

* No hypothesis testing

ORR – overall response rate, DCR – disease control rate, PFS – progression free survival, OS – overall survival, QoL – Quality of life

AIPAC Phase IIb Clinical Results

Baseline Characteristics

- ***Well balanced treatment groups.***
- ***Difficult to treat patient population:***
  - *Very late stage disease: 92% with visceral disease and 69% with elevated LDH*
  - *Heavily pre-treated subjects: 84% endocrine resistant; 44% received prior CDK 4/6; median of 2 prior systemic anticancer regimens.*
  - *HR⁺/HER2⁻ tumor is traditionally not considered immunogenic.*
- **227 patients** were randomized to efti (N=114) or to placebo (N=113) between January 2017-July 2019. All except one patient received at least 1 dose of study medication and were included in the full analysis and safety populations.

	Efti + Paclitaxel N=114	Placebo + Paclitaxel N=112	Overall N=226
Baseline characteristics, n (%)			
Age, median (range), years	58 (24-87)	61 (35-79)	60 (24-87)
<65 years	76 (66.7)	71 (63.4)	147 (65.1)
Body mass index, median (range)	24.7 (18.1-48.1)	24.9 (15.4-44.5)	24.7 (15.4-48.1)
ECOG 0	69 (60.5)	70 (62.5)	139 (61.5)
Visceral disease	103 (90.4)	104 (92.9)	207 (91.6)
Luminal A / B / Other¶, %	34.1 / 48.8 / 17.1	36.7 / 49.4 / 13.8	35.5 / 49.1 / 15.4
Monocytes <0.25/nl	25 (21.9)	22 (19.8)	47 (20.9)
Elevated (>250 U/L) LDH	74 (65.5)	81 (73.0)	155 (69.2)
Prior therapy, n (%)			
Prior surgery	92 (80.7)	94 (83.9)	186 (82.3)
Prior radiotherapy	87 (76.3)	84 (77.7)	174 (77.0)
Prior systemic therapy	106 (93.0)	108 (96.4)	214 (94.7)
Prior adjuvant therapy	85 (74.6)	81 (72.3)	166 (73.5)
Prior therapy for metastatic disease	78 (68.4)	80 (71.4)	158 (69.9)
Prior taxanes (adjuvant)	51 (44.7)	43 (38.4)	94 (41.6)
Prior CDK4/6	50 (44.6)	50 (43.9)	100 (44.2)
Prior endocrine therapy	103 (90.4)	104 (92.9)	207 (91.6)
Endocrine resistantΔ	*85 (82.5)*	*89 (85.6)*	*174 (84.1)*

Notes:

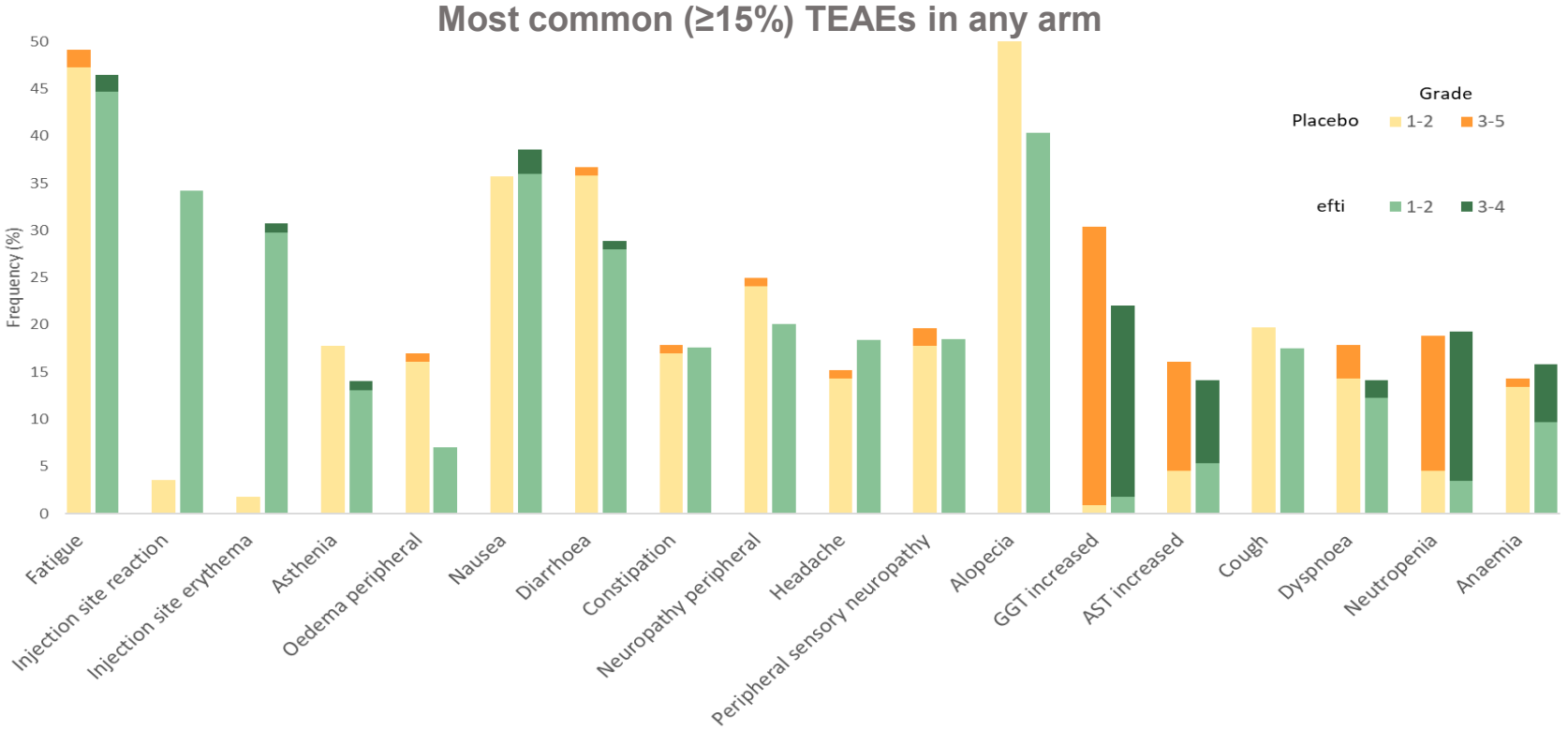
¶ Central assessment performed on available and evaluable primary or metastatic tissues (n=169). Classified using PgR and Ki67 index according to St Gallen International Expert Consensus guidelines[1].

Δ Defined according to ESMO Internal Consensus Guidelines (Advanced Breast Cancer 4)[2].

1. Goldhirsch A, Winer EP, Coates AS, et al. 2013;24(9):2206–2223. doi:10.1093/annonc/mdt303

AIPAC Phase IIb Clinical Results

Outstanding Safety Profile



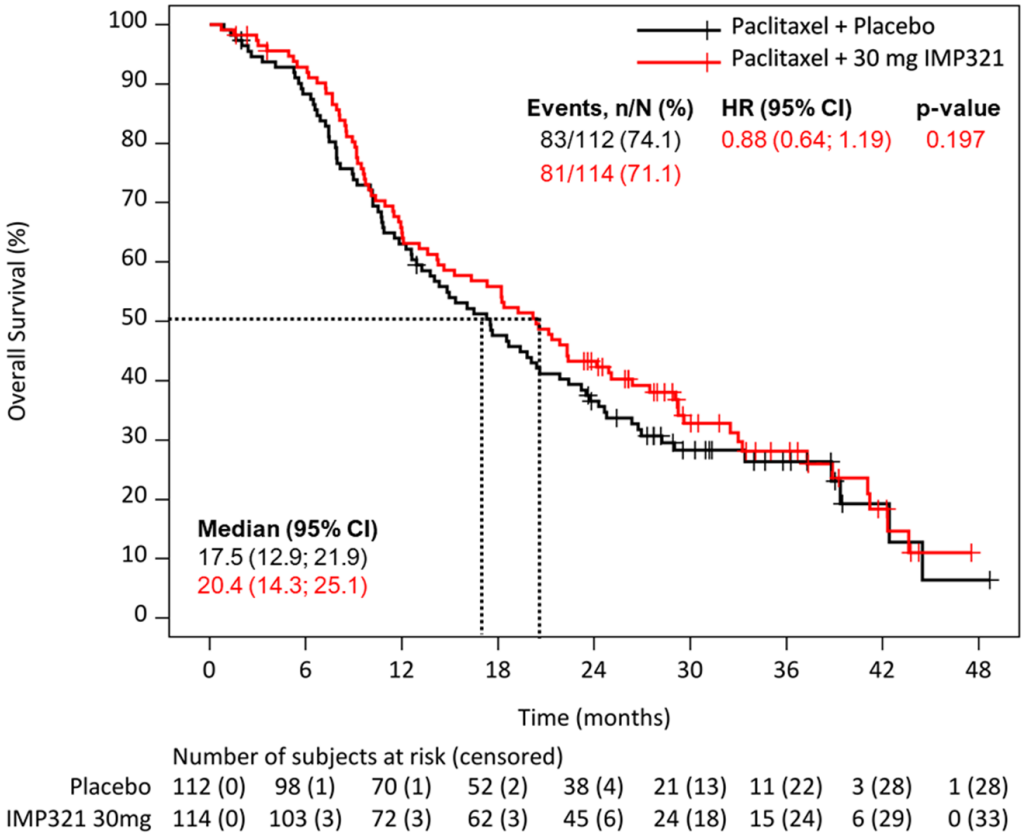
Summary of treatment-emergent adverse events (TEAEs) ¶	Efti + Paclitaxel N=114, n (%)	Placebo + Paclitaxel N=112, n (%)
≥1 TEAE	113 (99.1)	112 (100)
≥1 TEAE leading to death	2 (1.8)	3 (2.7)
≥1 TEAE leading to efti/placebo discontinuation	6 (5.3)	7 (6.3)
≥1 Grade ≥3 TEAE	78 (68.4)	73 (65.2)

- No fatal TEAE related to efti
- 3 pts discontinued due to hypersenstivity reactions developing after efti injections and 4 pts due to paclitaxel-induced hypersensitivity, respectively
- Most common efti related adverse event was any kind of local injection site reaction up to grade 3 reported in 75 (65.8%) pts in the efti arm

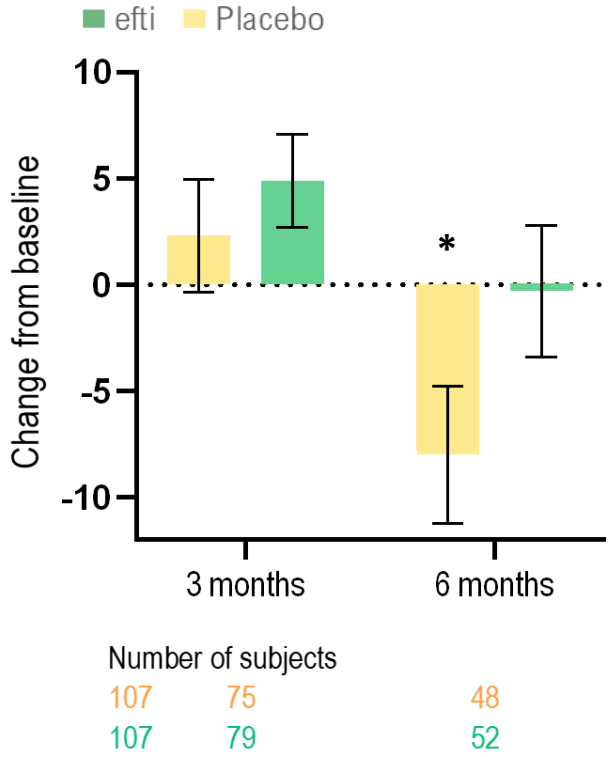
Notes:
ORR – overall response rate, DCR – disease control rate, PFS – progression free survival, OS – overall survival, QoL – Quality of life

Overall Unselected Population*

Improving OS with better QoL



Global Health Status / QoL QLQC30-B23



- Increase in OS: +2.9 months from median of 17.5 (95% CI: 12.9-21.9) in placebo to 20.4 (95% CI: 14.3 -25.1) in the efti group.
- Post-study treatment similar: 86 % (efti) vs. 90 %(placebo); majority received chemotherapy 70.2% (efti) vs. 76.8% (placebo)

- Preserving QoL in the efti arm, while significant deterioration of QoL (QLQ-C30-B23) observed in the placebo group at 6 months.
- Note: Paclitaxel treatment intensity was similar between groups

Notes:

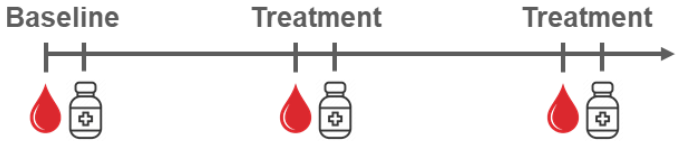
* These results were presented at SITC 2021. Database cut-off date was May 14, 2021 (73% of events) with minimum follow up of 22 months

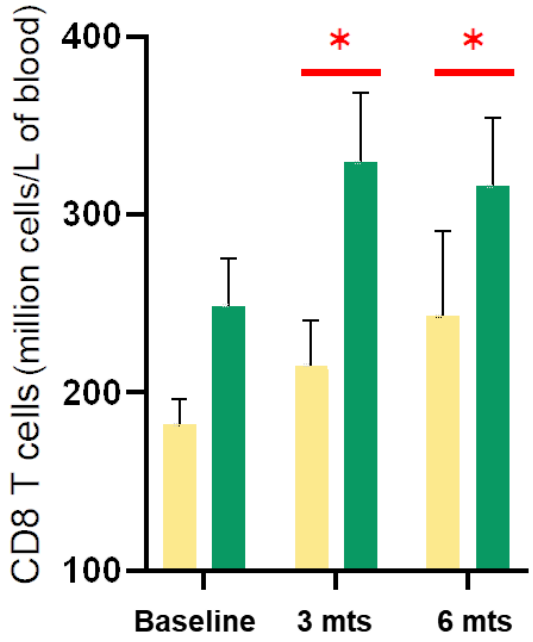
AIPAC Phase IIb Clinical Results

Immune Monitoring on Fresh Blood (up to 70 patients)

Significant Increase of CD8+ T Cell Count

Minimal Residual Effect: samples taken just before next treatment

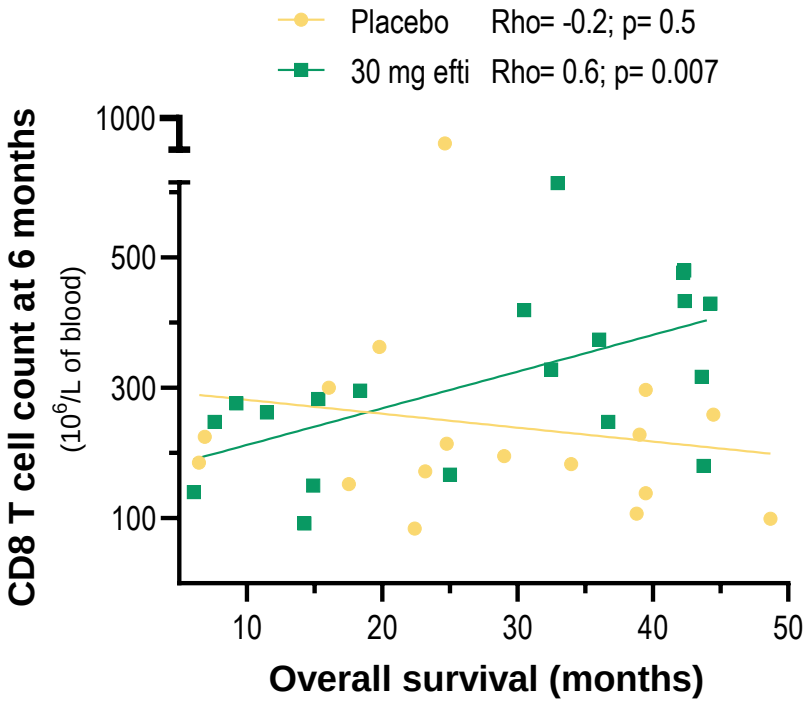




Proof of Principle
Number of T cells increased in efti group, especially cytotoxic CD8+ T cells

Significant Correlation:

OS and cytotoxic CD8^{+} T cell count



Proof of Concept
Increased number of cytotoxic CD8+ T cells correlated with improved OS in the efti arm

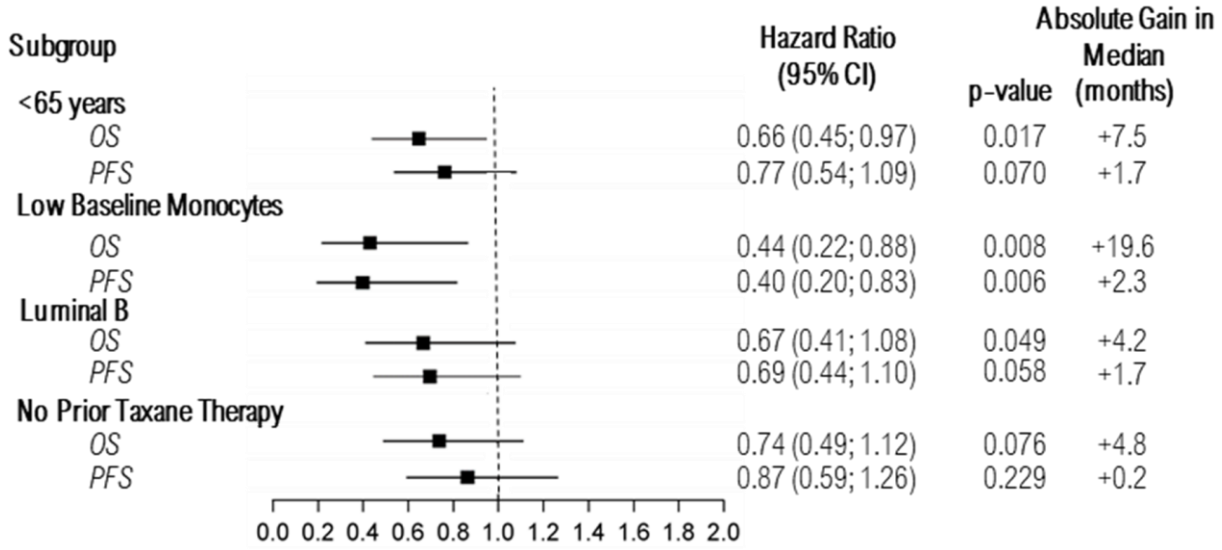
Notes:
* These results were presented at SITC 2021. Database cut-off date was May 14, 2021

Prespecified Subgroups*

Exploratory Analysis

Exploratory multivariate analyses → **Prior CDK 4/6 treatment is an independent poor prognostic factor with a 37% increase in risk for death**.

- Prior CDK 4/6 has a negative impact on OS in placebo group (median reduced from 20.4 to 14.9 months), but **not** in the efti group (median OS 21.9 vs. 20.2 months).
- CDK4/6 treatment are now standard, and most patients will have received it → favorable for efti.



- Prespecified (prior to unblinding) exploratory univariate analysis showed that younger **patients (<65 years),** those with **low baseline monocytes (<0.25/nL)** or breast cancer subtype **luminal B** had significant and clinical meaningful improvement in median OS compared to placebo.
- In a post-hoc multivariate analysis “no prior taxanes” were found to be an additional predictive marker

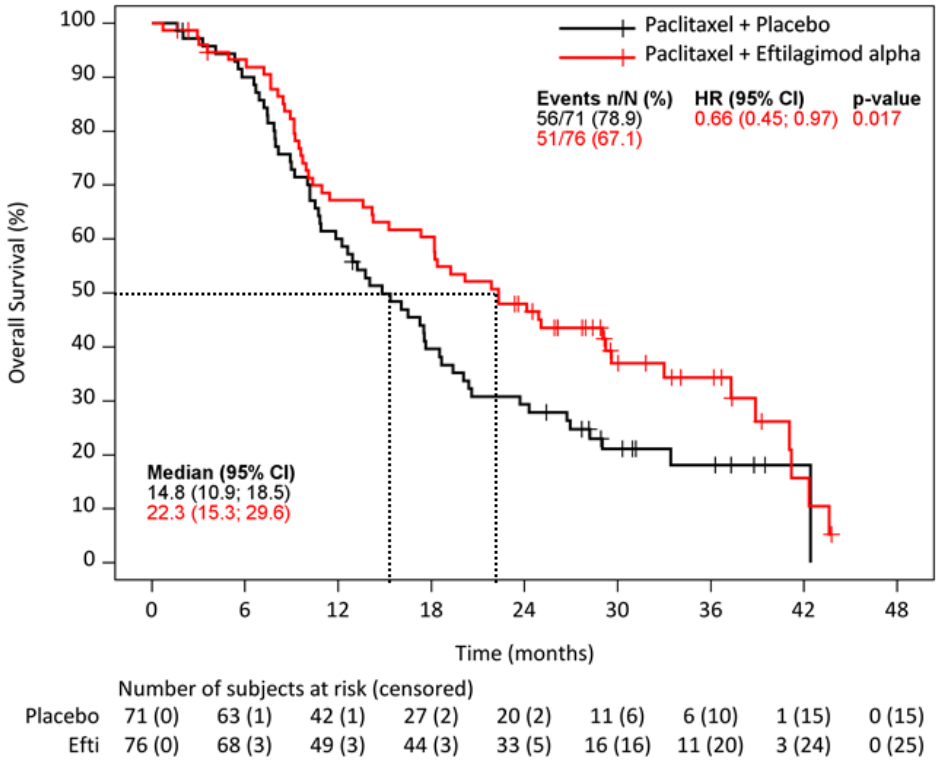
Notes:

* These results were presented at SITC 2021. Database cut-off date was May 14, 2021 (73% of events) with minimum follow up of 22 months

Prespecified Subgroup <65 years*

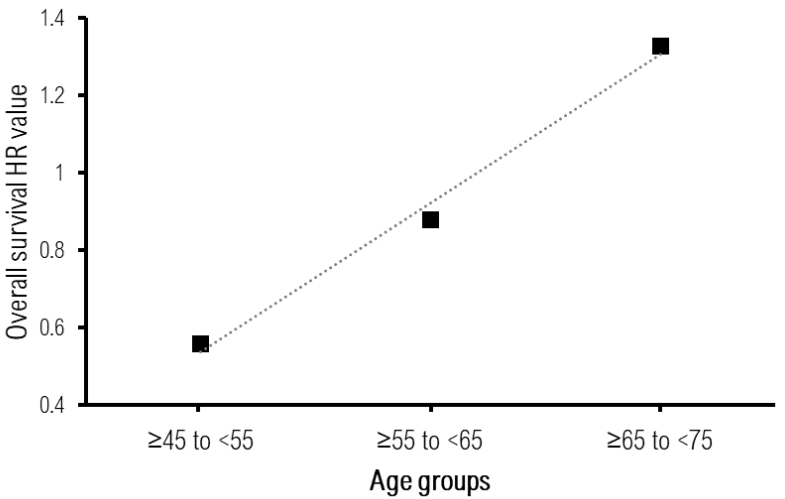
Clinically meaningful improvement for OS, PFS and ORR

+7.5 months median OS (HR 0.66; p=0.017)



	mOS	mPFS	ORR
Benefit	**+7.5 months**	**+2.0 months**	**+8%**
	HR 0.66 (p=0.02)	HR 0.77 (p=0.07)	(46% vs. 38%)

Effect of age on OS



- Prespecified subgroup showed **significant** (p=0.017, one-sided) **improvement in OS** with a **HR of 0.66** (95% CI: 0.45-0.97).
- ESMO scale of magnitude** = level 4/5 (would be very supportive for reimbursement).

- HR point estimates for different age groups.
- Age had an almost **linear effect** on HR for OS.

Notes:

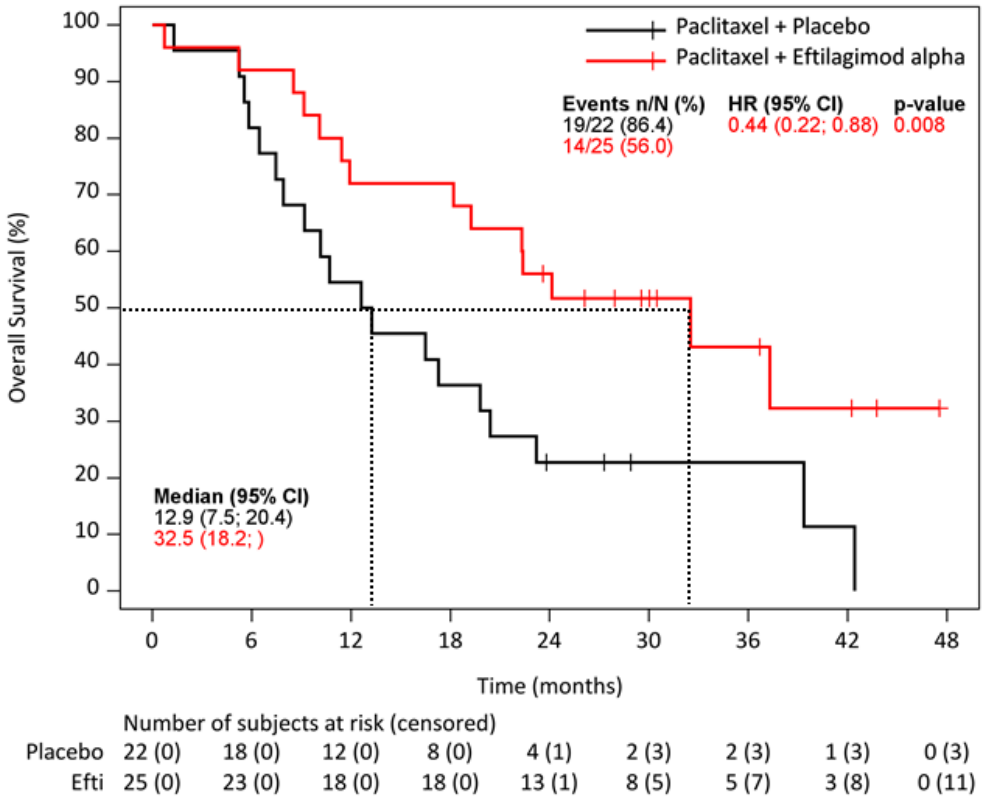
* These results were presented at SITC 2021. Database cut-off date was May 14, 2021

** Company assessment. ESMO-MCBS used for reimbursement in Europe: https://www.esmo.org/guidelines/esmo-mcbs/scale-evaluation-forms-v1.0-v1.1

Prespecified Subgroup Low Monocytes*

Clinically meaningful improvement for all efficacy parameters

+19.6 months median OS (HR 0.44; p=0.008)



	Efti + Paclitaxel	Placebo + Paclitaxel	Benefit
mOS	32.5 months	12.9 months	**+19.6 months** HR 0.44 (p=0.008)
mPFS	7.5 months	5.2 months	**+2.3 months** HR 0.40 (p=0.006)
ORR	44%	32%	**+12%**

- Clinically meaningful, absolute and relative improvement for all efficacy parameters.
- Statistical significance for PFS and OS.
- ESMO scale of magnitude** = level 4/5 (would be very supportive for reimbursement).

Notes:

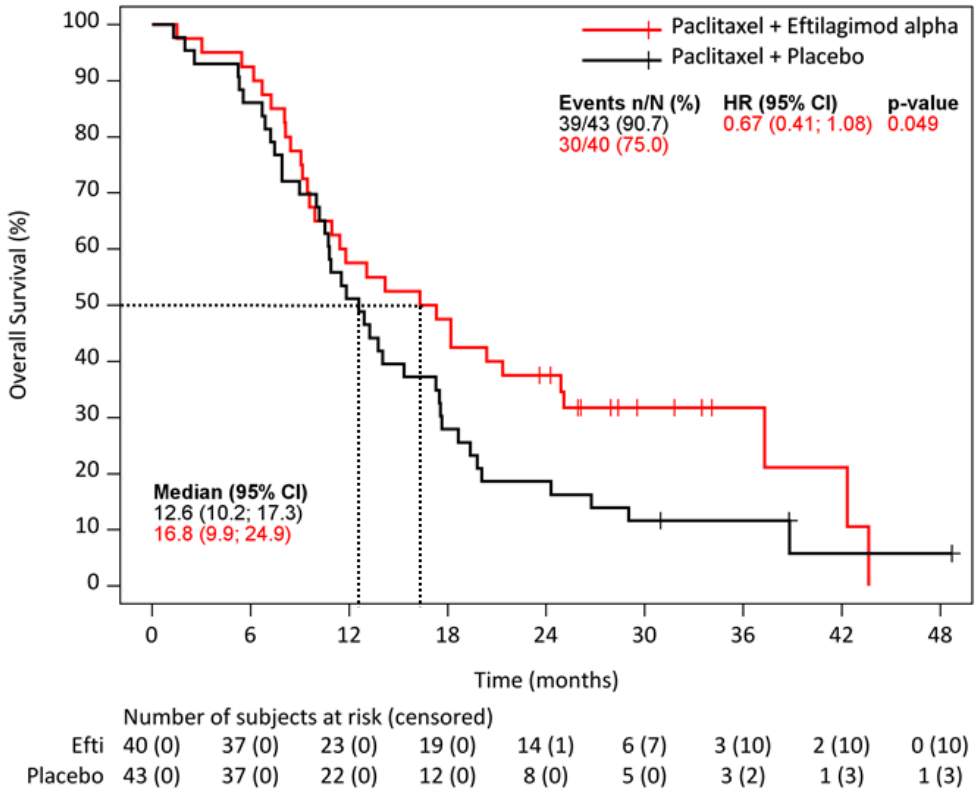
* Database cut-off date was May 14, 2021

** Company assessment. ESMO-MCBS used for reimbursement in Europe: https://www.esmo.org/guidelines/esmo-mcbs/scale-evaluation-forms-v1.0-v1.1

Prespecified Subgroup Luminal B*

Overall Survival

+4.2 months median OS (HR 0.67, p=0.049)



	Efti + Paclitaxel	Placebo + Paclitaxel	Benefit
mOS	16.8 months	12.6 months	**+4.2 months** HR 0.67 (p=0.049)
mPFS	7.2 months	5.6 months	**+1.6 months** HR 0.69 (p=0.158)
ORR	43%	33%	**+10%**

- Clinically meaningful improvement.
- Statistical significance for OS.
- ESMO scale of magnitude** = = level 3/5 (would be supportive for reimbursement).

Notes:

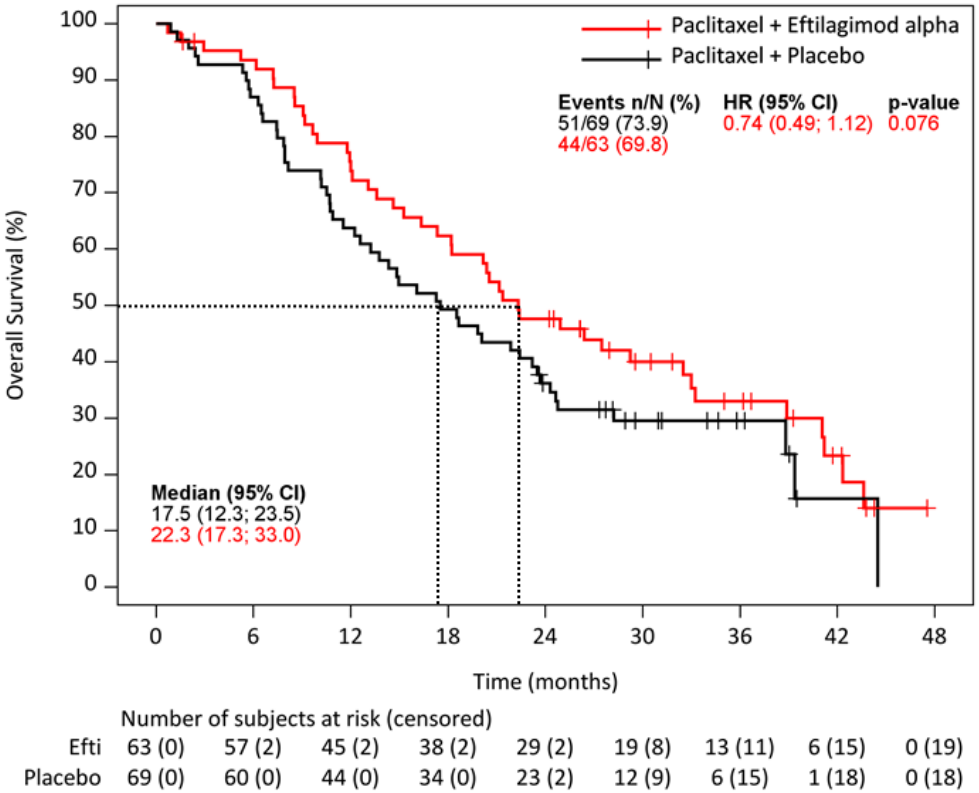
* Database cut-off date was May 14, 2021

** Company assessment. ESMO-MCBS used for reimbursement in Europe: https://www.esmo.org/guidelines/esmo-mcbs/scale-evaluation-forms-v1.0-v1.1

Prespecified Subgroup No Prior Taxane*

Overall Survival

+4.8 months median OS (HR 0.74, p=0.076)



	Efti + Paclitaxel	Placebo + Paclitaxel	Benefit
mOS	22.3 months	17.5 months	**+4.8 months** HR 0.74 (p=0.08)
mPFS	7.4 months	7.2 months	**+0.2 months** HR 0.87 (p=0.229)

- Clinically meaningful improvement.
- Important in multivariate predictive model
- ESMO scale of magnitude** = = level 3/5 (would be supportive for reimbursement).

Notes:

* Database cut-off date was May 14, 2021

AIPAC-003: Phase III in MBC

General Concept (subject to further regulatory interactions)

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1) Primary Endpoint: Overall Survival

- Preferred endpoint for Phase III and approval by regulatory agencies in such a patient population.
- Seems to be a better fit for active immunotherapies such as efti.

2) Treatment

- Paclitaxel will be allowed to be continued beyond 6 cycles to accommodate for EU & US standards and as a lesson from AIPAC.

3) Patient Population on Target

- Immutep will define the patient population and statistical read-out in a way to increase likelihood of success.

4) Statistical Design

- Will be robust and pre-agreed with regulatory agencies to ensure success later during MAA/BLA procedures.

Efti + anti-PD-1 Combination

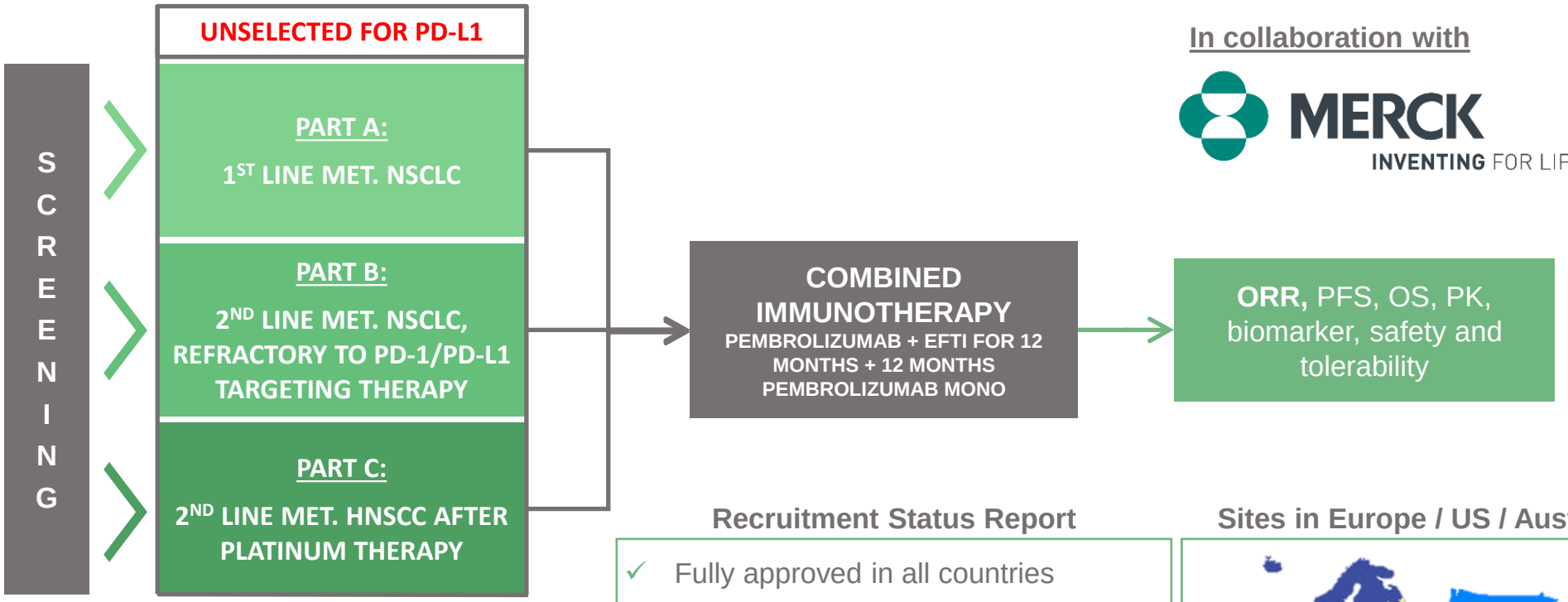
TACTI-002 trial

Update from SITC, 10-14 November 2021

TACTI-002 (Phase II)

Design & Status

TACTI-002: Two ACTive Immunotherapeutics in NSCLC and HNSCC



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Treatment	30 mg efti (IMP321) s.c. 200 mg pembrolizumab (Keytruda®) i.v.

Recruitment Status Report

- ✓ Fully approved in all countries
- ✓ Up to 183 patients in three indications
  - Part A (N=36) completed; extension cohort (N=74 recruiting)
  - ✓ Part C (N=39) completed
  - ✓ Part B (N=36); completed

Sites in Europe / US / Australia

Notes:
ORR – overall response rate, DCR – disease control rate, PFS – progression free survival, OS – overall survival, QoL – Quality of life

TACTI-002 Results(1)

2nd line HNSCC (Part C)

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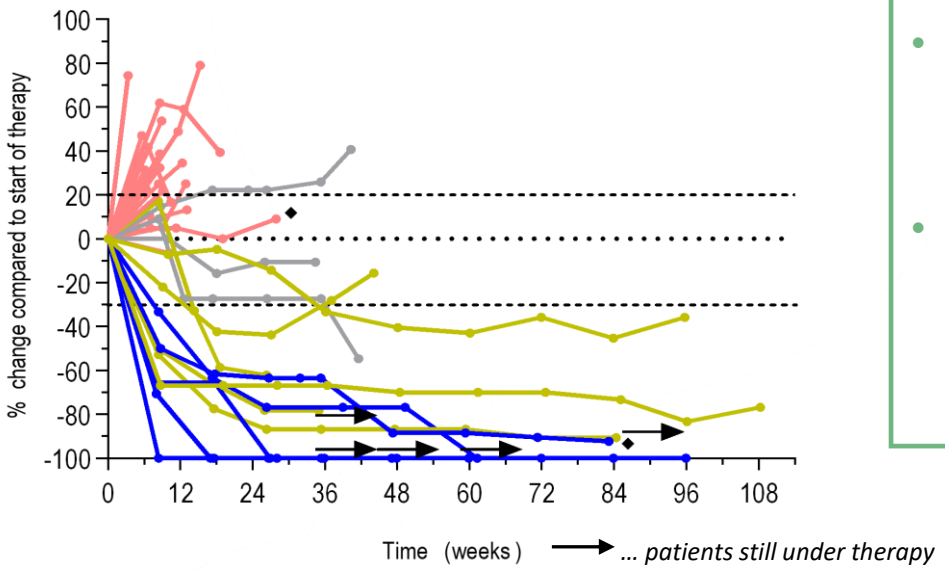
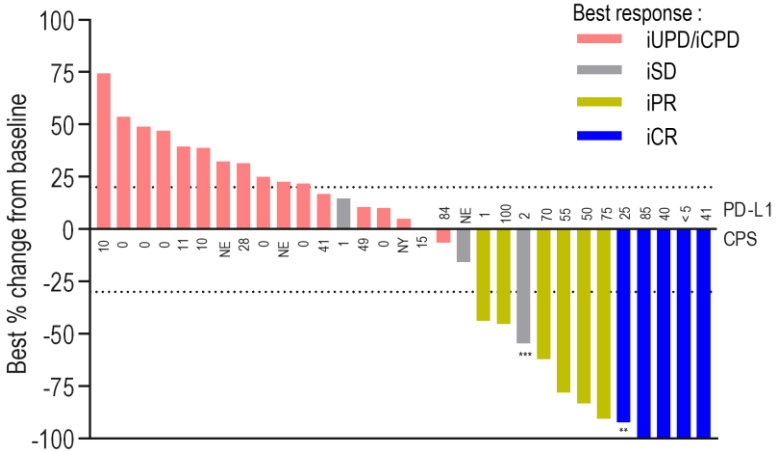
Best overall response, iRECIST	Investigator assessment N (%)
Complete Response	5 (13.5)
Partial Response	6 (16.2)
Stable Disease	3 (8.1)
Progression	17 (45.9)
Not evaluable¶	6 (16.2)
Disease Control Rate	14 (37.8)
Overall Response Rate [95% CI]	11 (29.7) [15.9 – 47.0]
Overall Response Rate – Evaluable pts* [95% CI]	11 (35.5) [19.2 – 54.6]



- ORR (iRECIST) in ITT of 29.7% and 35.5% evaluable pts
- Responses are deep with 5 (13.5%) CRs and long lasting
- ORR of 64.3% (40.7) in pts with CPS ≥ 20 (≥1)
- OS rates at 12 months for all PD-L1 groups in the range of 50% or above

CPS score	All comer (N=37)	≥1 (N=27)	≥20 (n=14)
ORR (iRECIST)			
ORR, %	29.7	40.7	64.3
Overall survival			
No. of events	23	17	7
6-month OS, %	54.7	55.5	71.4
12-month OS, %	48.4	48.2	64.3
Progression-free survival			
No. of events	30	17	8
3-month PFS, %	37.8	48.2	64.3
6-month PFS, %	32.4	40.7	57.1



Notes:

(1) Database cut-off date was August 4, 2021 (efficacy)

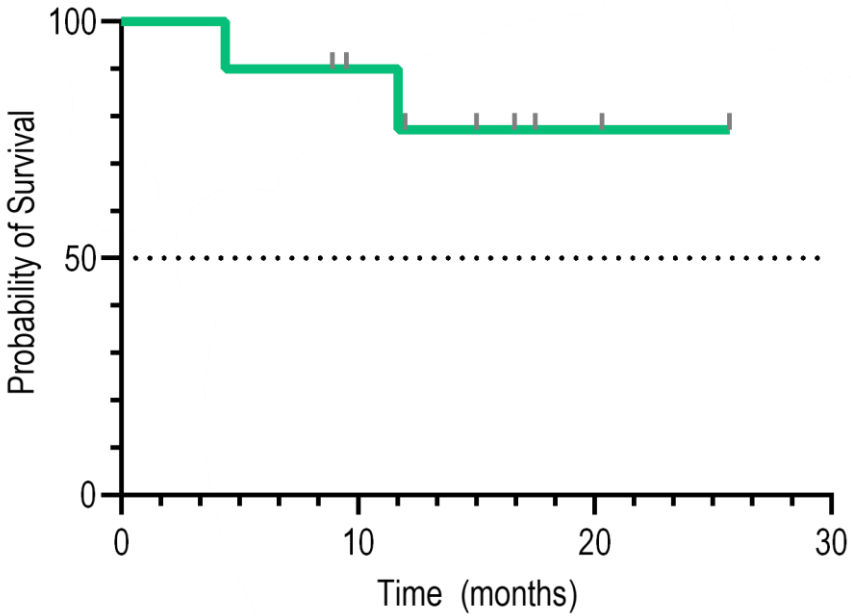
Graphs represent all patients with at least one post baseline assessment. One patient has no official RECIST assessment as this was done < 6 weeks and this does not qualify according to RECIST. Per local investigator assessment.

iRECIST = Immune Response Evaluation Criteria In Solid Tumors

TACTI-002 Results(1)

2nd line HNSCC (Part C), DoR and Benchmarking

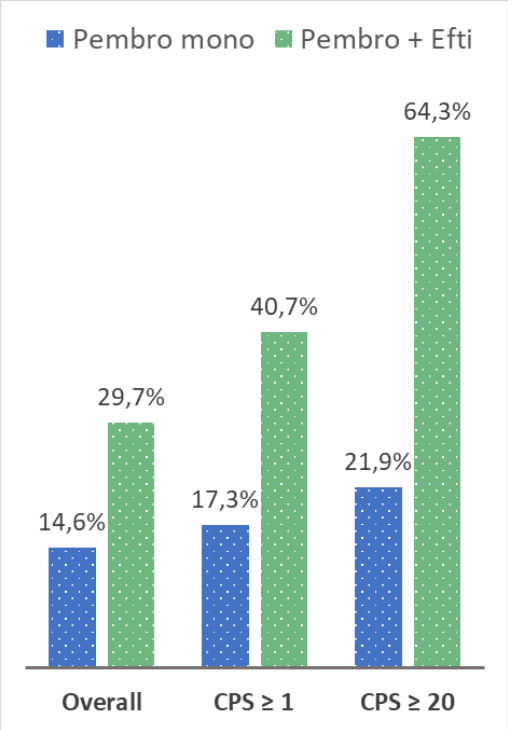
Duration of Response (DoR)
for confirmed responders (N=10)



- Median duration of response not yet reached
- all ongoing responses lasting **9+ months**

Benchmarking against Pembro

- ORR clearly higher (≥ factor 2) in all PD-L1 subgroups and overall
- PFS and OS rates at 6 and12 months respectively are higher in all PD-L1 subgroups and overall with efti combination



	PD-L1 (CPS)	Pembro alone**	TACTI-002
ORR (%)	≥ 20	**21.9%**	**64.3%***
	≥ 1	**17.3%** (2% CR)	**40.7%*** (20.8% CR*)
	Overall pop.	**14.6%**	**35.5%#**
mDoR (mths)	Overall pop.	18.4	Not reached with min. 9+ months at cut-off

Notes:
(1) Database cut-off date was August 4, 2021 (efficacy)
* - only patients evaluated where PD-L1 results available (N=14 for CPS ≥ 20) (N=27 for CPS ≥ 1); # - ITT(N=37); ** Data for pembro derived from KN040 (EEW Cohen et al., *The Lancet* 2018)

1st line HNSCC

Treatment options and positioning for efti + pembro

Median OS from KN-048 (1), unselected for PD-L1

Chemo + Cetuximab: 10.7-11.0 months

Pembrolizumab: 11.6 months
↑ to 14.9 for CPS ≥ 20

Chemo + Pembrolizumab: 13.0 months
↑ to 14.7 for CPS ≥ 20

- OS slightly improved by ~2 months with chemo + pembro, but pembro alone non-inferior to chemo
- Substantially more toxicities in the chemo + pembro setting compared to pembro alone

→ Buy moderate OS benefit with a lot add. toxicity

Median DoR from KN-048 (1), unselected for PD-L1

Chemo + Cetuximab: 4.3

Pembrolizumab: 22.6

Chemo + Pembrolizumab: 6.7

- ORR increased with chemo plus pembro (36% vs. 17% pembro alone)(1)
- DoR drops dramatically if you add chemo → not the case with efti

→ Buy ORR by much shorter DoR → less benefit for pts on the long run and may explain moderate OS improvement

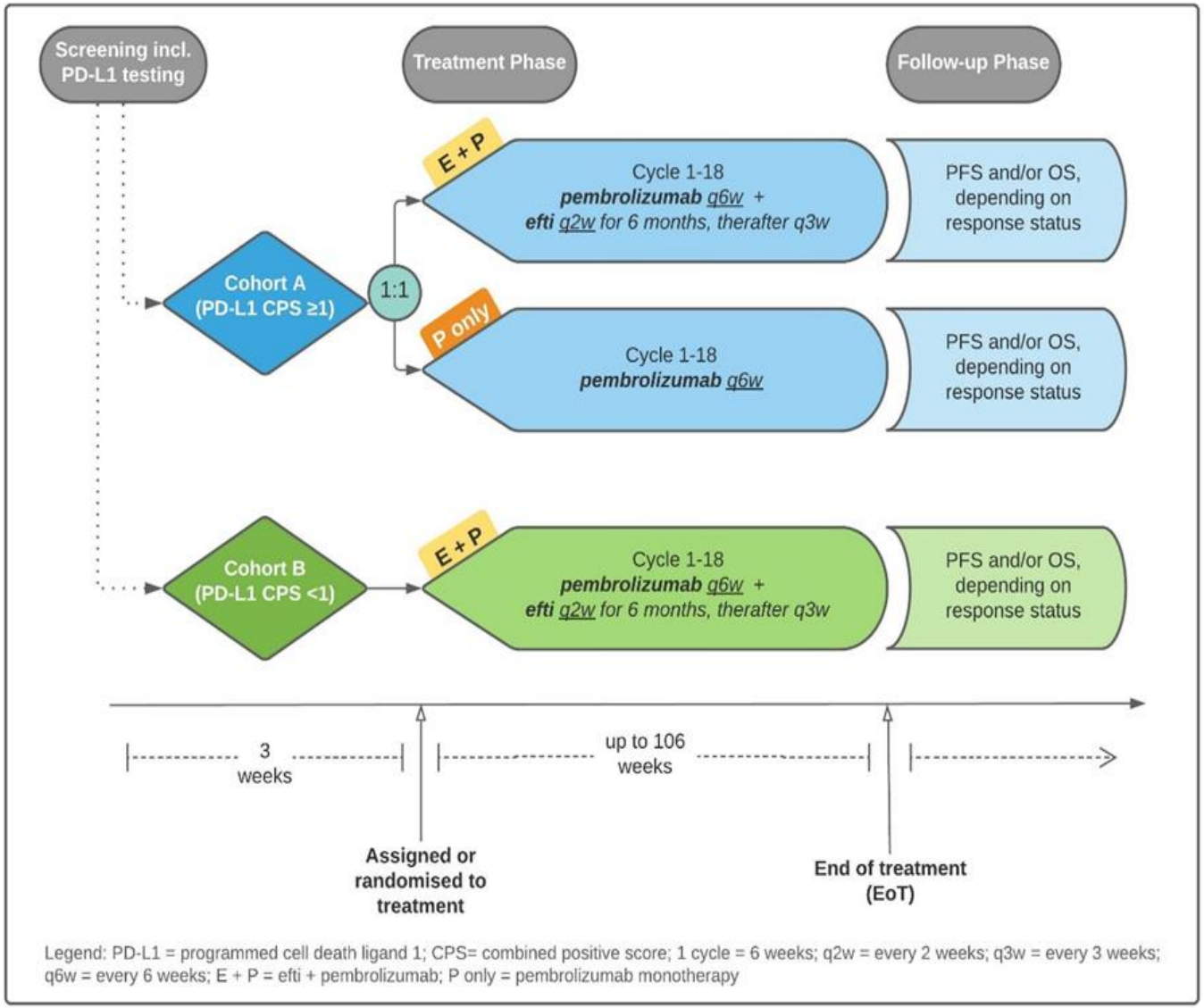
Combination of efti + pembro
May lead to higher ORR with same DoR and excellent safety profile

Notes:

(1) B Burtness et al.: Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomised, open-label, phase 3 study. *The Lancet* 2019, https://doi.org/10.1016/S0140-6736(19)32591-7

TACTI-003 Trial in 1st line HNSCC

Current Design + Status



Legend: PD-L1 = programmed cell death ligand 1; CPS= combined positive score; 1 cycle = 6 weeks; q2w = every 2 weeks; q3w = every 3 weeks; q6w = every 6 weeks; E + P = efti + pembrolizumab; P only = pembrolizumab monotherapy

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Design:

- Randomised study with ORR as primary endpoint
- Sites worldwide (AU, US, Europe)
- Approx. 154 pts: either to be randomized to have sufficient pts in each group or in an experimental arm

Status:

- Ongoing, recruiting.
- **Fast Track designation granted by FDA in April 2021**

Summary and Outlook

Near-Term Milestones

Advancing Registration Relevant Trials

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2021 till today

- ✓ **Final Results** from randomized, placebo controlled MBC trial (AIPAC)
- ✓ **Fast Track designation** in 1st line HNSCC from US FDA
- ✓ **TACTI-002** – recruitment & data delivered e.g. at ASCO & SITC for
  - ✓ 2nd line NSCLC
  - ✓ 2nd line HNSCC
- ✓ **TACTI-003** – Start randomized trial in 1st line HNSCC
- ✓ Final results of **INSIGHT-004**
- ✓ Progress from **IMP761**
- ✓ Expansion of **IP portfolio**
- ✓ Strong **financial position**

- ✓ Validation of LAG-3/MHC-II interaction by RELATIVITY-047 results

Remainder of 2021 and 2022

Registration relevant trials

Phase III preparations in MBC (AIPAC-003)

1st line HNSCC: Recruitment and updates from **randomized trial** (TACTI-003)

1st line NSCLC: Completion of recruitment & first data from the extension cohort (TACTI-002)

Ongoing **regulatory (EMA/FDA)** engagement

INSIGHT-003: Data from Efti + a-PD-1 + Chemo combination

Extension of **IP portfolio**

Potential new studies (financed)

Updates from **IMP761**

Updates from partnered programs (e.g. GSK, Novartis, CYTLIMIC and EOC Pharma)

Notes:
N.B. The actual timing of future data readouts may differ from expected timing shown above. These dates are provided on a calendar year basis.
A tick denotes that the item has been completed.

Summary

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

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

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

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

Thank you!