immutep

LAG-3 IMMUNOTHERAPY

# The global leader in developing LAG-3 therapeutics

**Investor Presentation**
**29 April 2020**

***(ASX: IMM, NASDAQ: IMMP)***

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# Introduction and Corporate Overview

- Immutep is a biotechnology company developing novel immunotherapies for cancer and autoimmune disease
- Immutep released new TACTI-002 data at the American Association for Cancer Research (AACR) virtual conference on 27 April 2020
- The new TACTI-002 data further demonstrates an increased ORR (>50%) when patients are treated with Immutep's Eftilagimod Alpha ("efti") in combination with Merck's Keytruda
- Immutep is conducting a $10m - $12m institutional placement to fund its clinical development program through 2021

## Financial Overview

| | |
|---|---|
| **Ticker symbols** | IMM (ASX)<br>IMMP (NASDAQ) |
| **Securities on issue**(1)<br>(as at 24 April 2020) | 391.6 million ordinary shares |
| **Cash & Term Deposits**<br>(as at 31 March 2020) | ~A$16.1 million (US$10.0 million) |
| **Market Cap**(2)<br>(as at 24 April 2020) | A$68.5 million (US$43.5 million) |

*Notes:*
*(1) Currently ~30% 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.*

# Investment Highlights

**Global leader in development of LAG-3 therapeutics**

**Compelling clinical data illustrates potential of efti as a combination therapy**

**Near-term Phase II clinical data expected for efti**

**Commercial partnerships with pharma industry leaders**

- Global leadership position in **LAG-3 with four** related product candidates in **immuno-oncology** and **autoimmune diseases**
- Immutep's product candidates have **demonstrated clinical potential** in a range of indications with high unmet need
- **10 active clinical trials** (including partnered products) producing clinical **data** with read-outs during 2020
- Compelling data points e.g. ORR of 53% achieved in 1st line NSCLC with Merck´s blockbuster drug Keytruda(1) compared to historical ORR of ~20% for patients receiving Keytruda on its own (TACTI-002)
- Established commercial partnerships with multiple industry leaders including **Merck (MSD)**, **Pfizer / Merck KGaA**, **Novartis** and **GSK**

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

Notes:
(1) For efti in combination with KEYTRUDA® (pembrolizumab) in non-small cell lung carcinoma ("NSCLC")

# 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**
Current 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

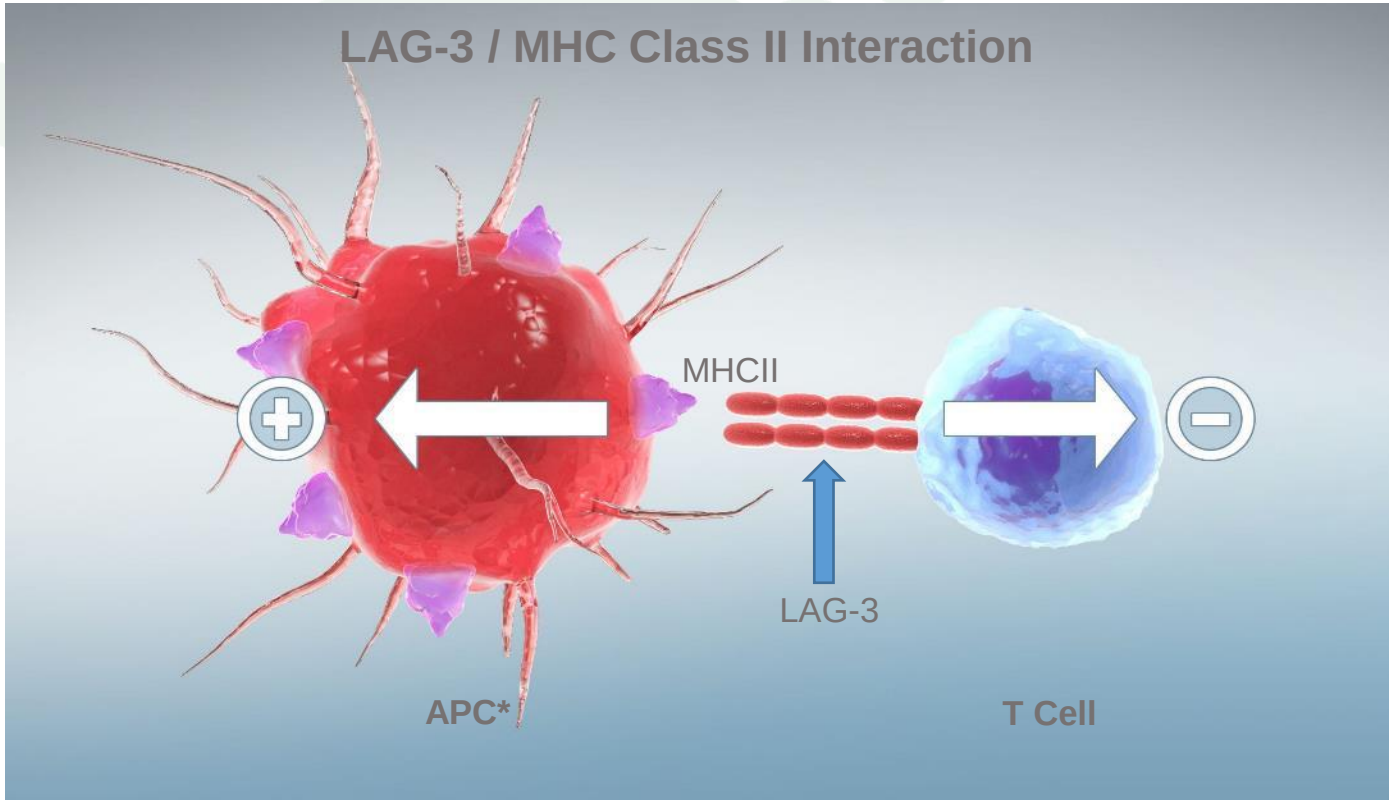
**Prof. Frédéric Triebel, MD PhD, Chief Scientific Officer & Chief Medical Officer**
Clinical haematologist, and PhD in immunology (Paris University) and successfully developed several research programs in immunogenetics and immunotherapy, leading to over 144 publications and 16 patents

**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 as a Therapeutic Target

LAG-3, an immune checkpoint, is widely expressed on tumor infiltrating lymphocytes (TILs) and cytotoxic T cells → **Prime target for immune therapy**



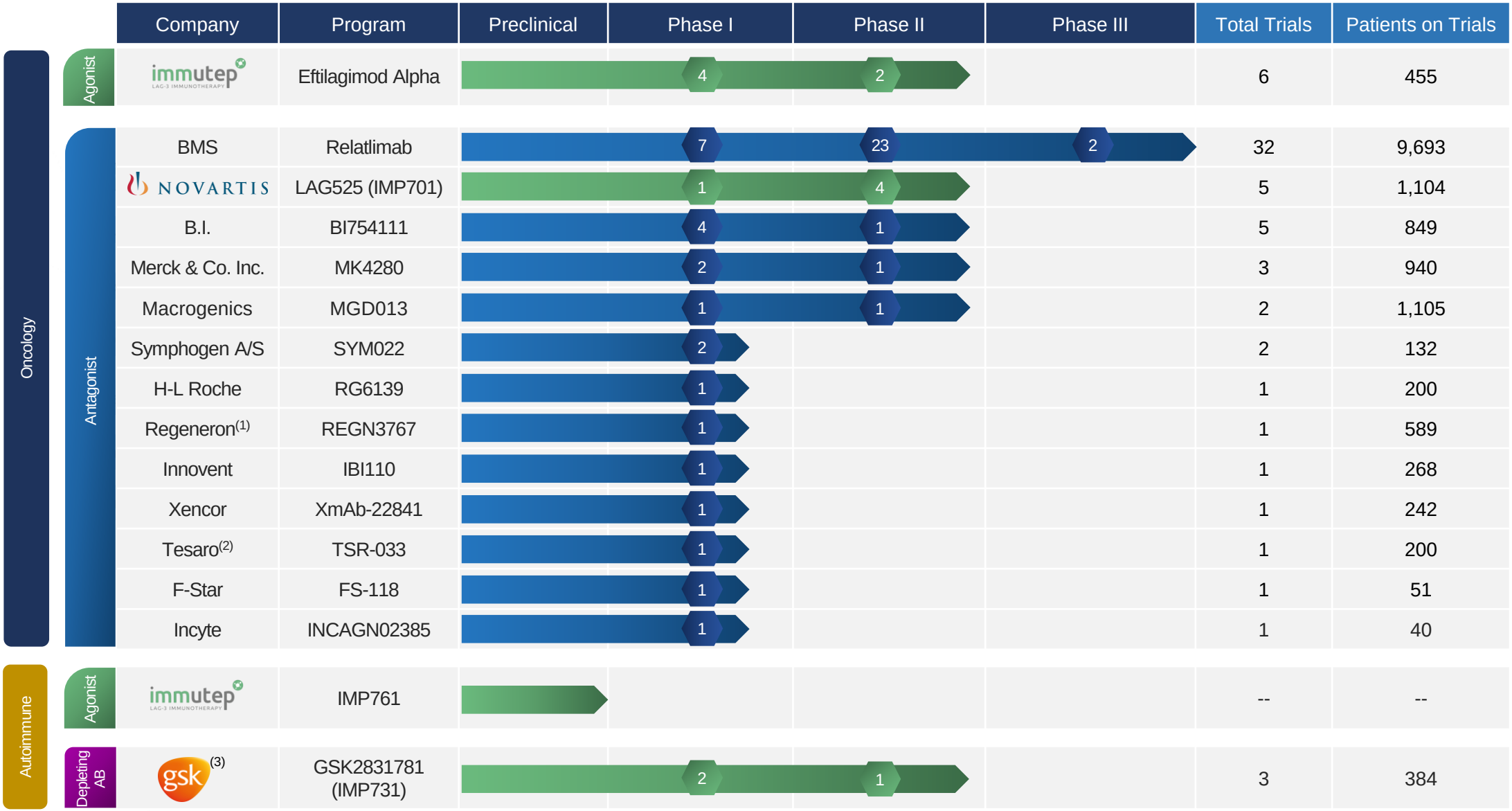

→ **Positive regulation** of antigen presenting cells (APCs) → increase in antigen presentation to cytotoxic $CD8^+$ T cells

→ **Negative regulation** of $LAG\text{-}3^+$ T Cells



*Notes:*
* APC: antigen presenting cell

# LAG-3 Therapeutic Landscape Overview




Notes:

Sources: Company websites, clinical trials.gov, and sec.gov, as of April 15, 2020

Note: 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
2) Tesaro was acquired by and is now part of GSK
3) Includes two completed Phase I study (see clinicaltrials.gov)

# Transactions in oncology

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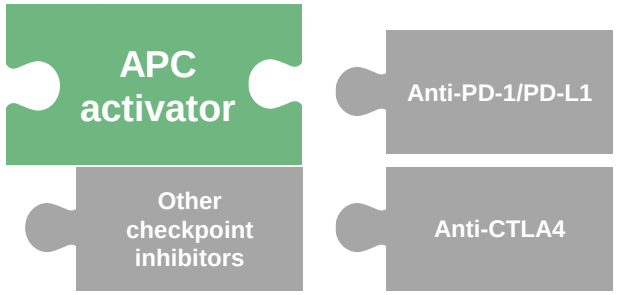
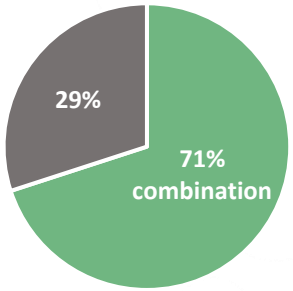
***"2019 has seen a boom in high-value M&A and licensing deals, with oncology and rare diseases as prominent themes"(1)***

***"Drug developers have directed almost half of their dealmaking firepower at oncology projects over the past five years, with cardiovascular a distant second"(2)***




**Combination therapies for greater efficacy:**

- Checkpoint inhibitors have become the backbone of cancer treatment, however only patients with "hot tumors" respond well to therapy.
- APC activation is the most advanced and promising way to turn a "cold" immune deserted tumor into a "hot tumor" infiltrated by immune cells.
- Overall, Big Pharma and Mid Pharma companies signed 435 immuno-oncology collaborations during 2014-18.(3)




- Proportion of deals involving combination immuno-oncology therapies, Big Pharma and Mid Pharma peer sets, 2014-18(3)

Notes:
(1) Biopharma dealmakers, December 2019
(2) Evaluate Pharma, February 2020
(3) Informa Pharma Intelligence, April 2019

# Transactions in oncology

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

= M & A

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

# Targeting LAG-3 / MHC II may lead to multiple therapeutics in numerous indications

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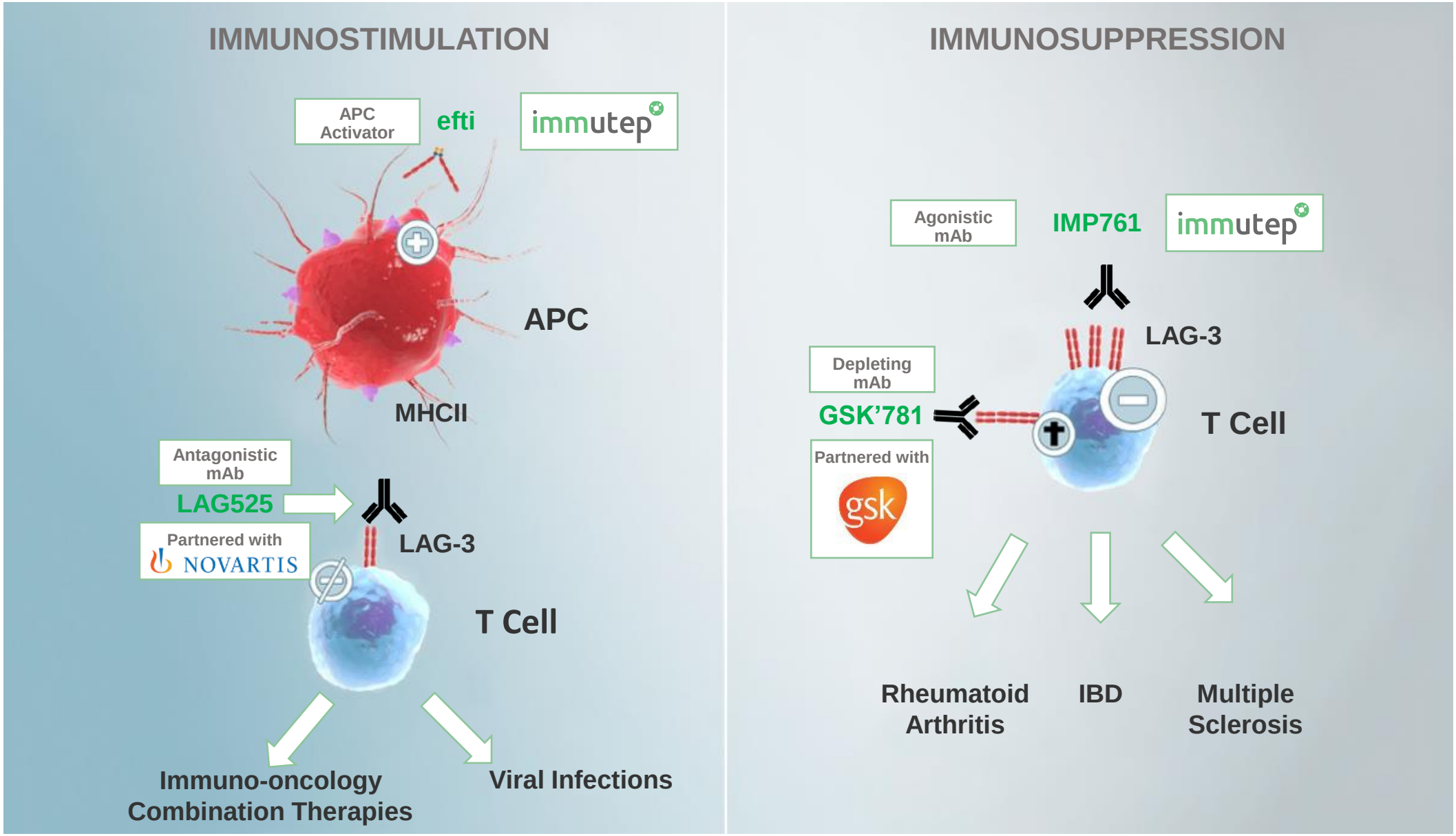

# Immutep Controlled Immunotherapy Pipeline*

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| Program | Preclinical | Phase I | Phase II | Late Stage[4] | Commercial Rights | Market Size[5] (by) |
|---|---|---|---|---|---|---|
| **Oncology** | | | | | | |
| **Eftilagimod Alpha (efti or IMP321)**<br>APC activating soluble LAG-3 protein | **Metastatic Breast Cancer (Chemo – IO)**<br>**AIPAC** | | | | Global Rights<br>immutep | US$12.7 billion (2024) |
| | **Non-Small-Cell Lung Carcinoma (IO – IO) [1]**<br>**TACTI-002** | | | MERCK INVENTING FOR LIFE | | US$33.9 billion (2026) |
| | **Head and Neck Squamous Cell Carcinoma (IO – IO) [1]**<br>**TACTI-002** | | | MERCK INVENTING FOR LIFE | | US$2.8 billion (2026) |
| | **Solid Tumors (IO – IO) [2], [3]**<br>**INSIGHT-004** | | Pfizer<br>Merck KGaA, Darmstadt, Germany | | | |
| | **Melanoma (IO – IO)**<br>**TACTI-mel** | | | | | US$7.8 billion (2026) |
| | **Solid Tumors (In situ Immunization) [2]**<br>**INSIGHT** | | | | | |
| | **Metastatic Breast Cancer (Chemo – IO)** | | EOC | | Chinese Rights<br>EOC | |
| **Autoimmune** | | | | | | |
| **IMP761 (Agonist AB)** | | | | | Global Rights<br>immutep | US$149.4 billion (2025) |

Notes

* Information in pipeline chart current as at 15 April 2020

(1) In combination with KEYTRUDA® (pembrolizumab) in non-small cell lung carcinoma ("NSCLC") or head and neck carcinoma ("HNSCC")

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

(3) In combination with BAVENCIO® (avelumab)

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

(5) Estimation of Datamonitor Healthcare, Informa Pharma Intelligence for US, JP, EU (5) and KBV Research (Breast cancer: HR+/HER2- Forecast, January 2017; Non-small cell lung cancer (NSCLC) Forecast, August 2018; Head and neck cancer Forecast, December 2017; Melanoma Forecast, May 2018; July 2019)

# Immutep Out-Licensed Immunotherapy Pipeline*

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| Program | Preclinical | Phase I | Phase II | Late Stage(1) | Commercial Rights/Partners |
|---|---|---|---|---|---|
| Oncology – LAG525 (Antagonist AB) | Solid Tumors + Blood Cancer (IO-IO Combo) | | | | Global Rights – NOVARTIS |
| | 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) | | | | |
| Autoimmune – GSK'781 (Depleting AB) | Ulcerative Colitis | | | | Global Rights – gsk |
| | Healthy Japanese and Caucasian Subjects | | | | |
| | Psoriasis(2) | | | | |

Notes
* Information in pipeline chart current as at 15 April, 2020
(1) Late stage refers to Phase IIb clinical trials or more clinically advanced clinical trials
(2) Reflects completed Phase I study in healthy volunteers and psoriasis

# Lead Program Eftilagimod Alpha (efti or IMP321) - APC activation -

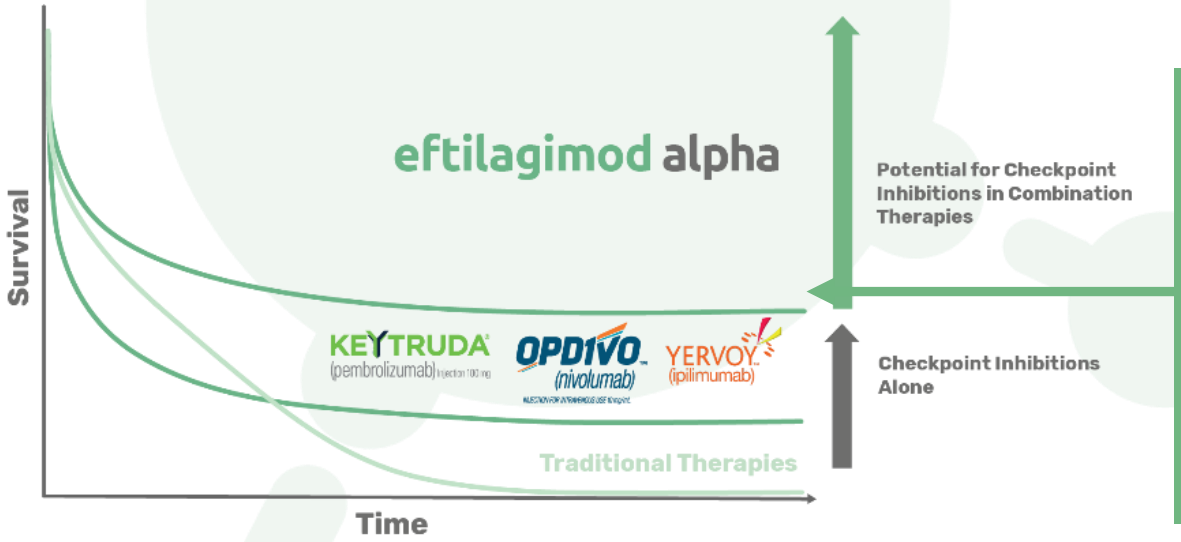
# Efti: Immuno-Oncology Therapy Response Rates

What is the current problem: Approximately 70-80% of patients do not respond to SOC anti-PD-1 monotherapy(1)

**How can we enable more efficacious T-cell responses?**

- immunogenic cell death to liberate/uncover tumor antigens
- cross-presentation of those antigens
- recruitment of T cells into the tumor microenvironment
- reversing the pathways driving a repressive tumor environment

**This could be achieved through the right APC activation**

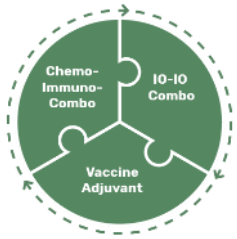



**APC activators:**

- MHC II agonism
- TLR or STING agonism
- CD40 agonism
- Oncolytic viral therapies



Notes:
(1) See, for example, Callahan et al Front. Oncol. (2015) 4:385 and Gauci et al Clin Cancer Res. (2019) Feb 1;25(3):946-956.




# Efti: a pipeline in a product

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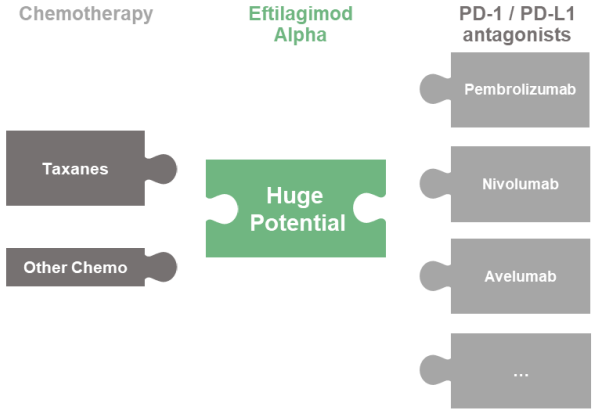
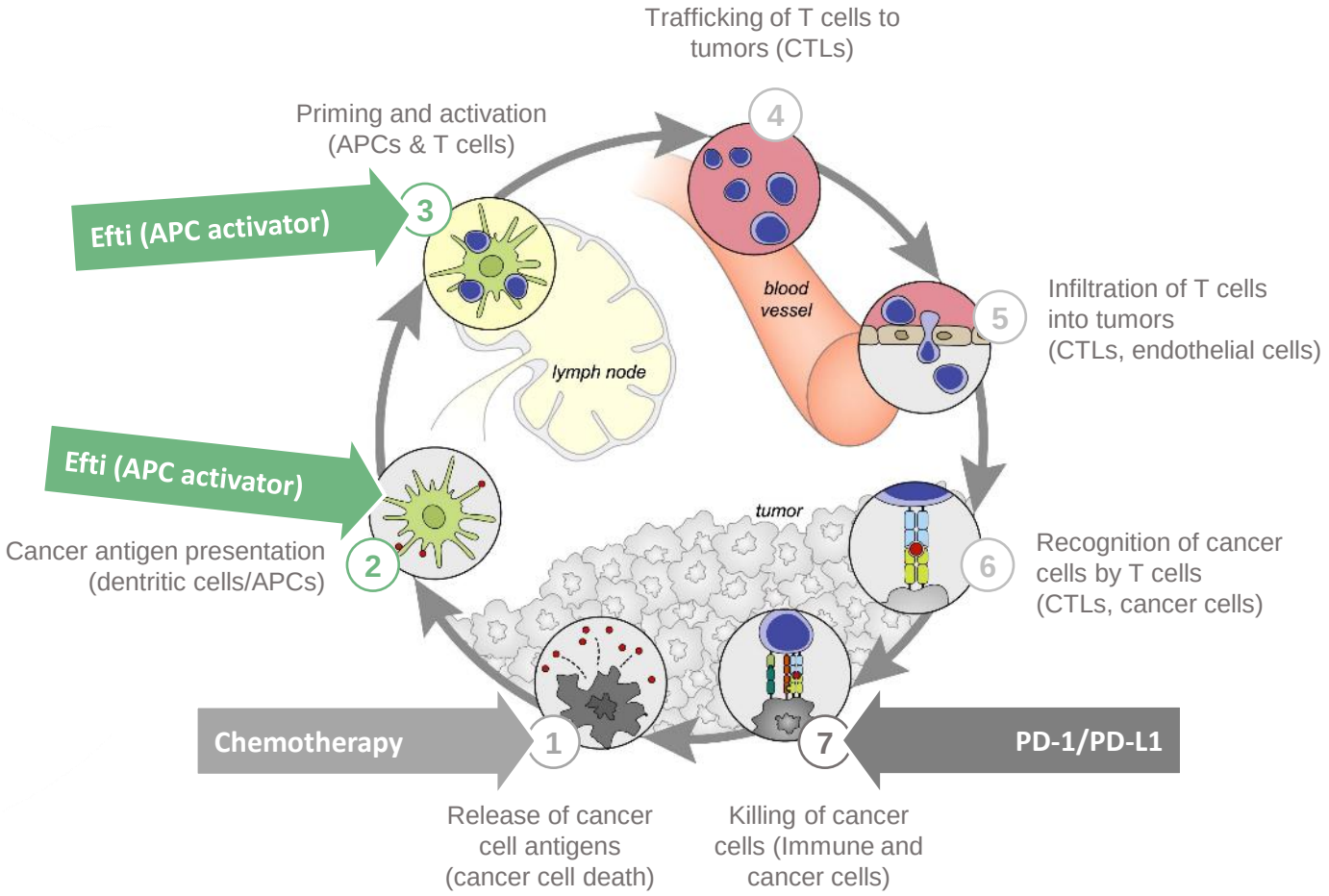
## Efti has disruptive potential for oncology

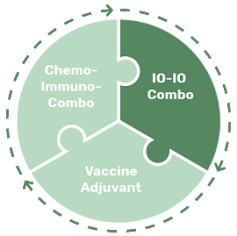
- ✓ **First-in-Class** MHCII agonist
- ✓ good safety profile
- ✓ encouraging efficacy data
- ✓ low cost of goods
- ✓ potential for use in various combination settings –> **efti is a "pipeline in a product"**

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




Notes
*Figure reproduced from DS Chen, I Mellman: Oncology Meets Immunology: The Cancer-Immunity Cycle. Immunity, Volume 39, Issue 1, 25 July 2013, Pages 1-10.




# Rationale for combining efti with PD-1 antagonists

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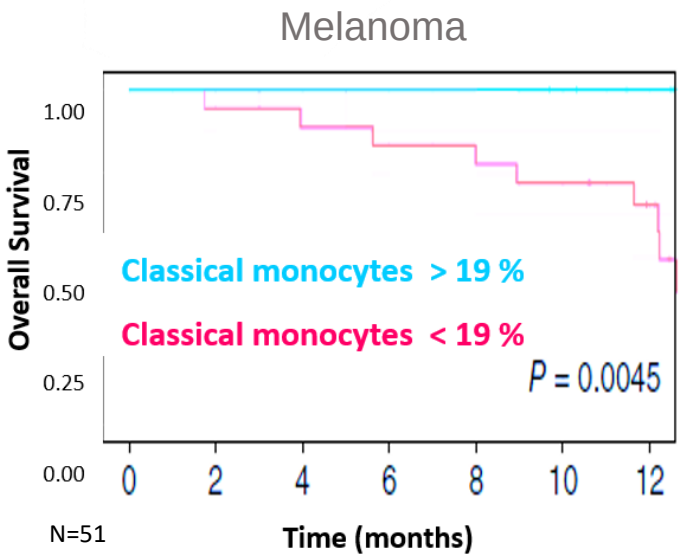
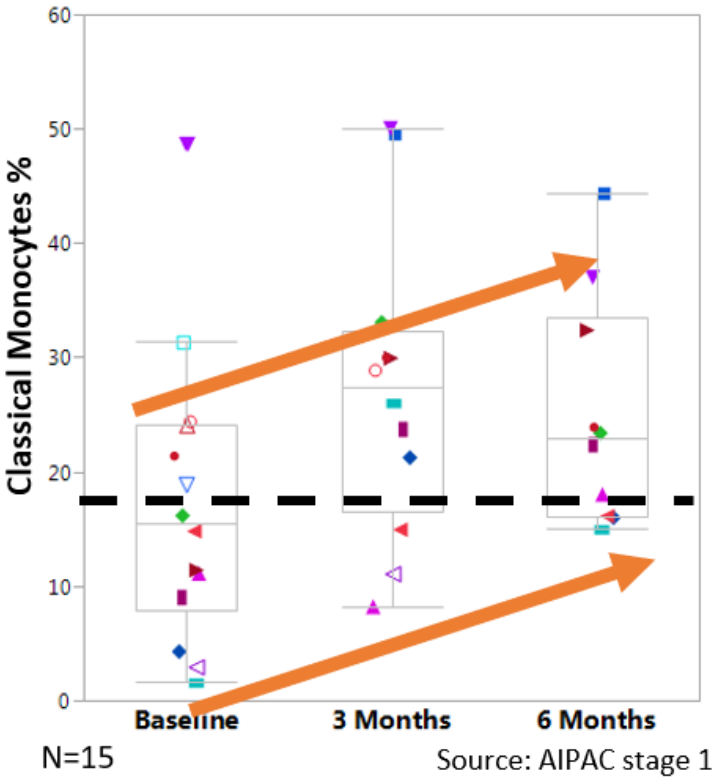
## Efti increases monocyte number in cancer patients

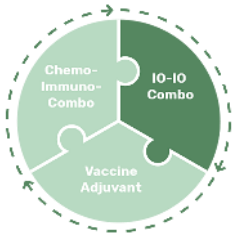



Source: Krieg et al., Nat. Med. 24, 2018.

- →baseline innate immunity status seems to be important for the response (OS) to pembrolizumab **(Keytruda)**
- →data suggests that low monocyte numbers at baseline are associated with poor efficacy of anti-PD-1 therapy in melanoma patients
- →data shows that the APC activator, efti, boosts innate immunity




Source: AIPAC stage 1




# Efti Clinical Development
# TACTI-002 (Phase II)

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## Trial Design + Introduction

- ***Phase II, multi-national, open label, Simon's 2 stage design; PD-L1 all comer***
- ***In collaboration with Merck Sharp & Dohme (MSD)*** MERCK INVENTING FOR LIFE

**Eligiblity**

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

Part A:
1st line met. NSCLC

Part B:
2nd line met. NSCLC, refractory for PD-1/PD-L1

Part C:
2nd line met. HNSCC after platinum

30 mg efti SC
+
200 mg pembrolizumab IV

Up to 12 months then pembrolizumab alone for another 12 months

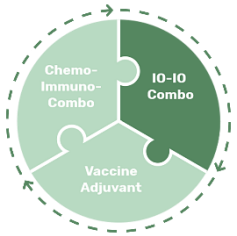
**Primary endpoint: iORR (iRECIST)**

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

| Study - Part* | Stage 1 (N) Actual/target | Stage 2 (N) Actual/target |
|---|---|---|
| Part A | 17/17 | 17/19 |
| Part B | 18/23 | -/13 |
| Part C | 18/18 | 6/19 |



*Notes:*
NSCLC – non-small-cell lung cancer, HNSCC – head and neck squamous cell cancer, ORR – overall response rate, PFS – progression free survival, OS – overall survival, PK –pharmacokinetics, PD-X – any PD-1 or PD-L1 treatment
*as of Feb 20th 2020




# Efti Clinical Development
# TACTI-002: 1st line NSCLC (Part A)

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## TACTI-002: Preliminary[1] results 1st line NSCLC - part A, stage 1

- *PD-L1 distribution as expected → PD-L1 all comer trial*
- *Patients are typical NSCLC 1st line patients*

| Baseline Parameters (n=17) | N (%) |
|---|---|
| Median age, yrs (range) | 65 (53-76%) |
| Sex<br>Female<br>Male | <br>6 (35.3%)<br>11 (64.7%) |
| ECOG<br>0<br>1 | <br>12 (70.6%)<br>5 (29.4%) |
| Smoking status<br>Never<br>Current / former | <br>1 (5.9%)<br>16 (94.1%) |
| Histology<br>Squamous<br>Non-squamous | <br>10 (58.8%)<br>7 (41.2%) |
| Location of disease at study entry<br>Lung<br>Bone | <br>8 (47.1%)<br>5 (29.4%) |

| Central assessment of tumor cell PD-L1 expression done post enrollment | | |
|---|---|---|
| PD-L1 (n=13)[2] | N (%) | Historical[3] Distribution |
| < 1% | 3 (23%) | 35% |
| 1-49% | 6 (46%) | 35% |
| ≥ 50% | 4 (31%) | 30% |

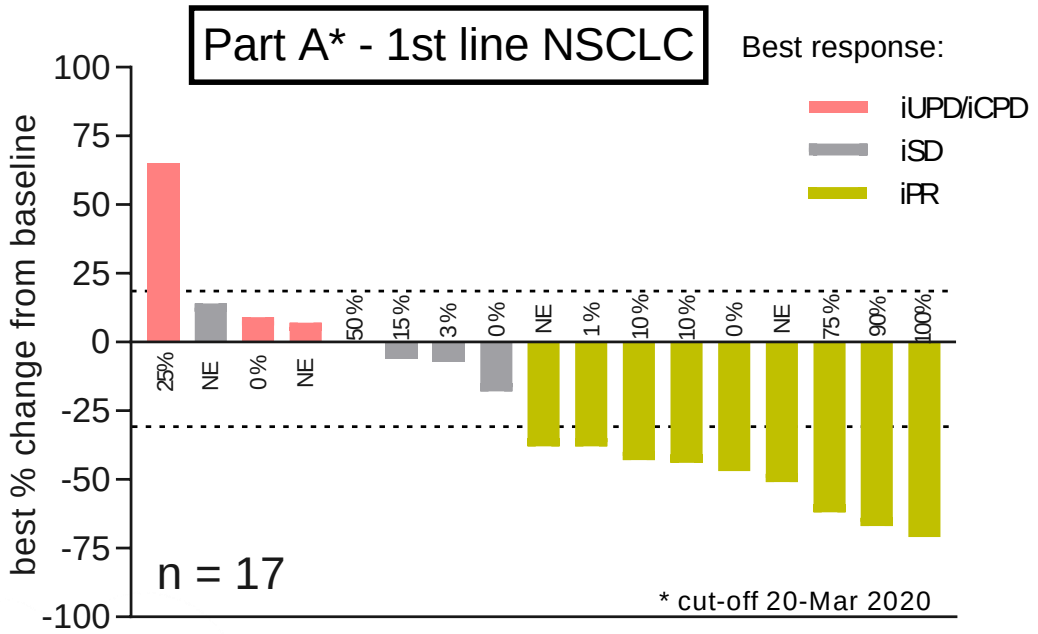
*Notes:*
(1) Preliminary data, cut-off January 31 2020
(2) % in reference to evaluable samples; 4 specimens not evaluable by central lab using standard IHC kit
(3) Garon et al N Engl J Med 2015;372:2018-28

# Efti Clinical Development
# TACTI-002: 1st line NSCLC (Part A, Stage 1)[1]

## Responses and Waterfall plot

- ***52.9% iORR acc. to iRECIST in this PD-L1 all comer trial***
- ***Responses in all PD-L1 subgroups***

| Tumor response - iBOR as per iRECIST | N (%) Total N=17 |
|---|---|
| Complete Response (iCR) | 0 (0.0%) |
| Partial Response (iPR) | 9 (52.9%) |
| Stable Disease (iSD) | 5 (29.4%) |
| Progressive Disease (iPD) | 3 (17.7%) |
| **Objective Response Rate (iORR)** | **9 (52.9%)** |
| **Disease Control Rate (iDCR)** | **14 (82.4%)** |




| Patients by PD-L1 category | No. of Responses | iORR |
|---|---|---|
| Low (< 1%) | 1 | 33% |
| Medium (1-49%) | 3 | 50% |
| High (≥ 50%) | 3 | 75% |
| Not evaluable | 2 | 25% |
| **Overall** | **9** | **53%** |

- Responses in all PD-L1 subgroups
- 6/9 iPR with confirmed 2nd CT scan → 7/9 patients with iPR still under therapy (none discontinued due to PD)
- 12/17 (71%) patients with target lesion decrease

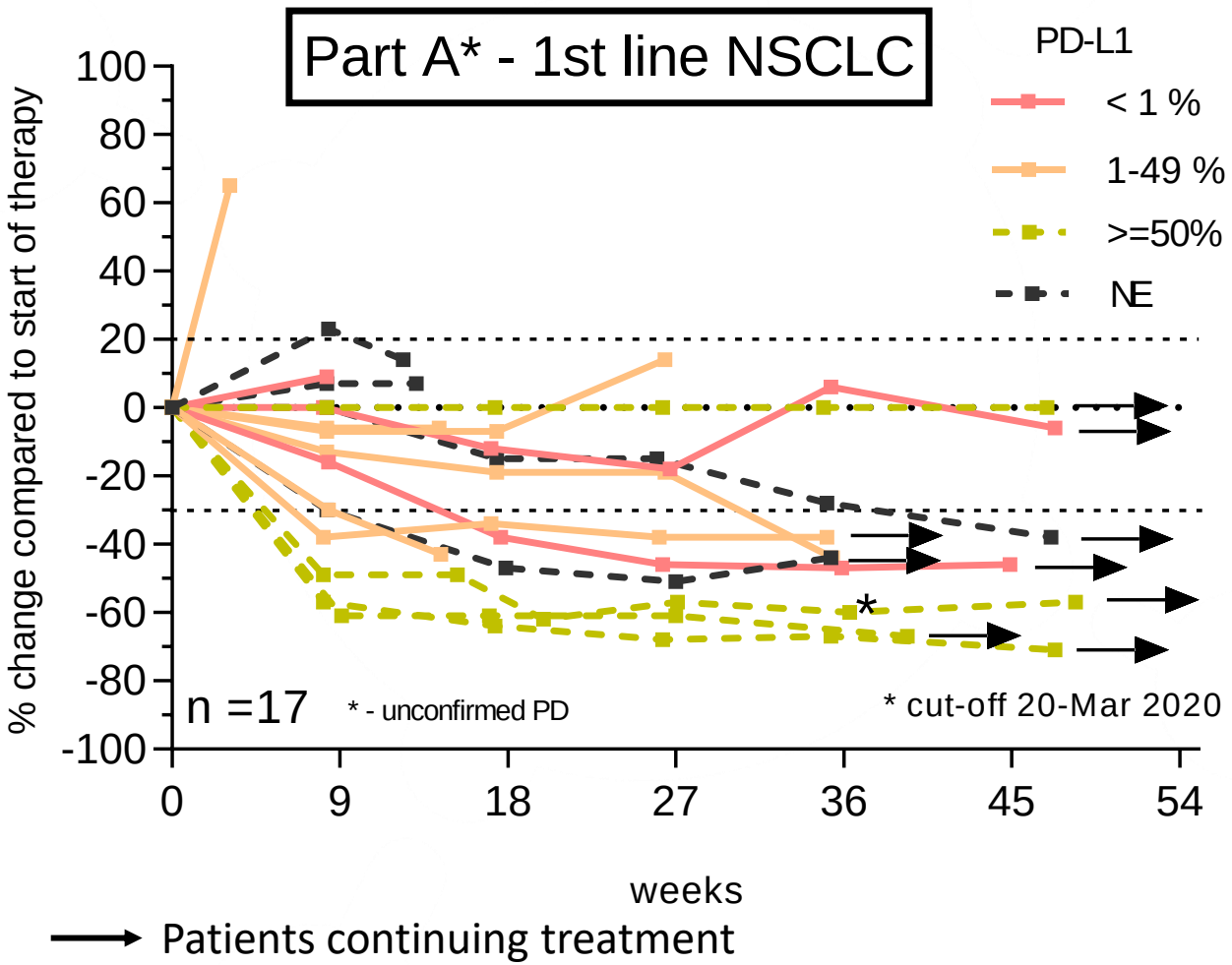


*Notes:*
(1) Preliminary data, cut-off 20-Mar 2020

# Efti Clinical Development
# TACTI-002: 1st line NSCLC (Part A, Stage 1)[1]

## Spiderplot

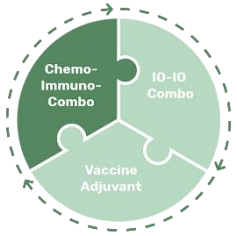
***As at data cut-off, still 9 patients (53%) under treatment at 8+ months → median PFS not yet reached***




- 2 late responders at 8 / 11 months!
- 9 patients still under therapy at 8+ months → median PFS cannot be calculated so far
- 5/17 (29%) died as of March 2020; survival of all others 10+ months



*Notes:*
(1) Preliminary data, cut-off 20 Mar 2020




# Efti positioning in NSCLC

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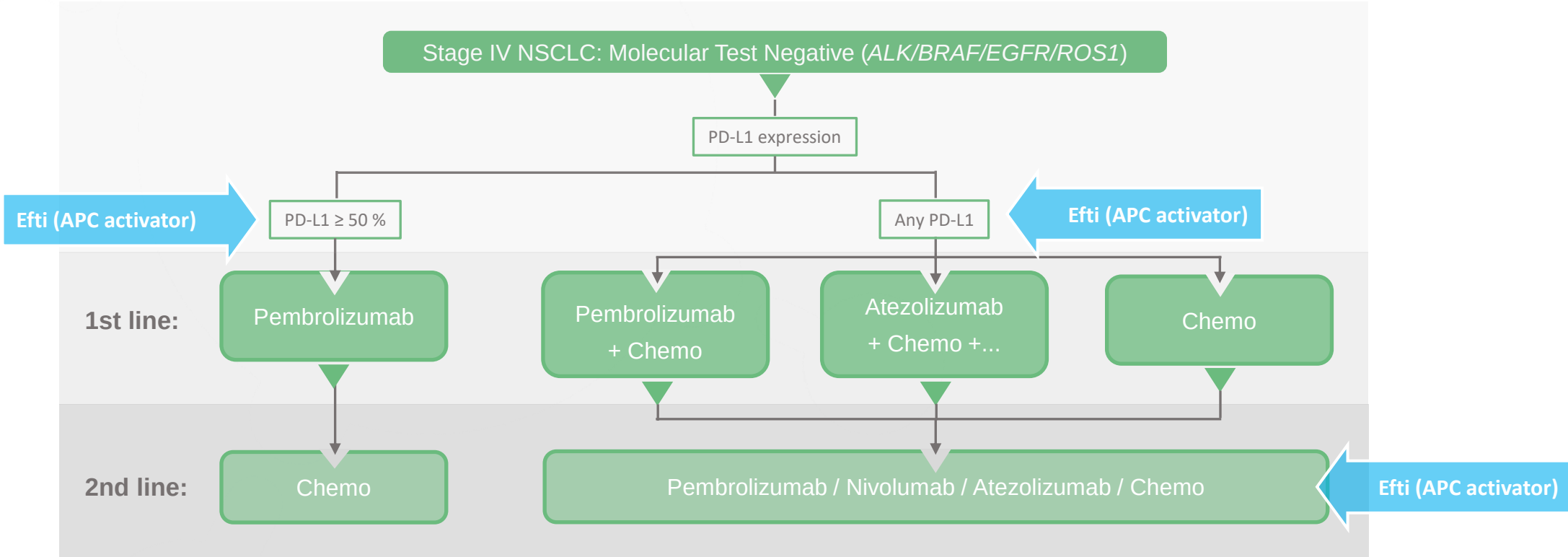
LAG-3 IMMUNOTHERAPY

**Epidemiology:**

- 1,800,000 NSCLC diagnoses per annum worldwide(1)
- Approximately 1,300,000 develop metastatic disease and are eligible to receive anti-PD-1/PD-L1 monotherapy or in combination with chemotherapy

**US$33.9 billion**

estimated market size by 2026(2)






Notes
(1) Calculated from Global Cancer Observatory (WHO), 2018 data
(2) Informa Pharma Intelligence Report 2018 for US, Japan and EU5

# Historical comparison 1st line NSCLC

## Current SoC and key characteristics SQ + NSQ NSCLC, PD-L1 all-comer

| Regimen | ORR[1,2] | Median DoR (months) | Median PFS (months)[1,2] | Median OS (months) [1,2] | G3-5 AEs; Discont.; AEs → to death[2] | Main downside/limitations[1,2] |
|---|---|---|---|---|---|---|
| Double Chemo | 20-30% | 4.9 - 7.7 | 5-6.5 | 10.7-13.9 | | Short DOR, short PFS, OS etc. |
| Ipi + Nivo | 33% | 23.2 (>1%) | TBD | 17.1 | 30%; 20%, < 2% | Toxicity, costs |
| Chemo + Pembro | 48% | 8 - 11.2 | 8.8 | 22.0 | 60-70%; 23-33%; 3-8% | Costs, nothing to offer in 2nd line except Taxanes!, shorter DOR compared to IO alone, toxicity |
| Pembro alone[3] | ~20% (~17% in 1-49%) | 20.2 (>1%) | ~5-6 | ~16 | 20-30%; 10-15%; < 2% | Not approved for <1 % PD-L1 and not really used for 1-49% |

- High unmet medical need in 1st line despite Pembro + chemo combo

## Current results TACTI-002 → efti in 1st line NSCLC

- 53% iORR PD-L1 all-comer; 50% in 1-49%
- In total 12 pts (71%) with tumor shrinkage
- Median PFS expected of >9 months

✓ iORR & PFS comparable & higher Durability of Response (DOR) compared to Pembro + Doublet-Chemo in NSQ and SQ with considerably less toxicity

✓ **iORR doubled compared to pembro (Keytruda) alone without substantial additional toxicity**



(1) Internal evaluation (EXCEL);
(2) ESMO 2019
(3) Internal calculation based on published data: Garon et al, N Engl J Med 2015; 372:2018-2028

# Efti Clinical Development
# TACTI-002: 2nd line HNSCC (Part C, Stage 1)[1]

## Responses and Waterfall plot

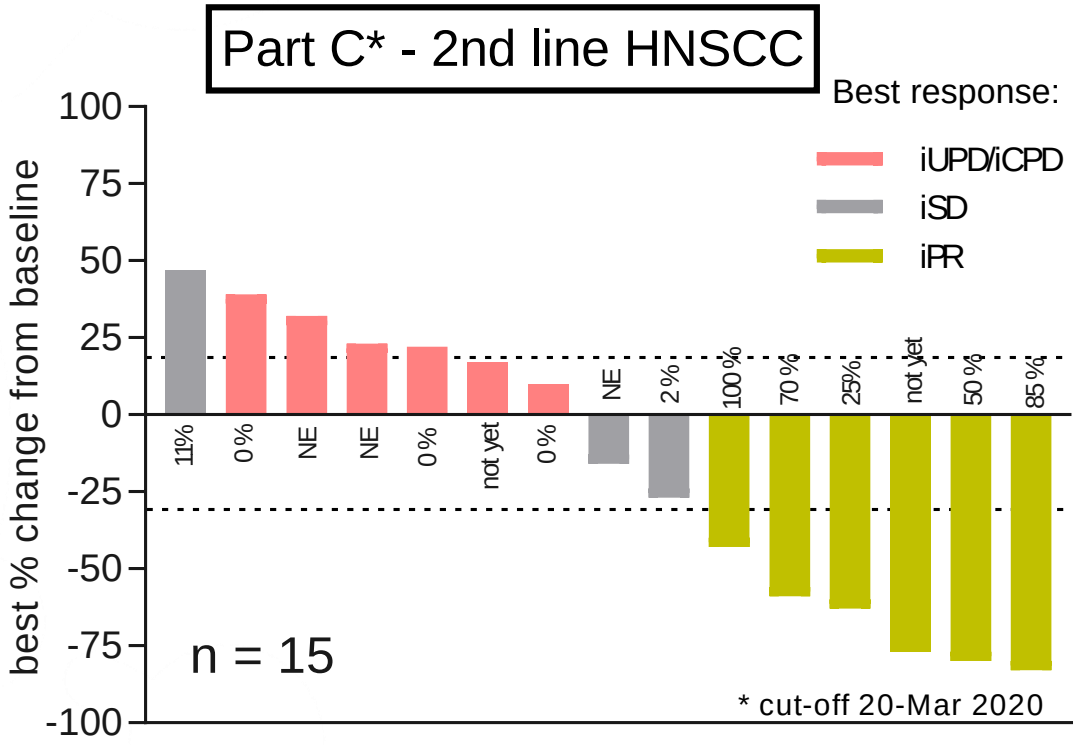
➢ ***Initial iORR of 33.3% in this PD-L1 all comer HNSCC 2nd line trial***

- Median Age of 66, mostly male (94%)
- ECOG 1 in 47%
- Different subtypes

| Tumor response - iBOR as per iRECIST | N (%) Total (N=18) |
|---|---|
| Complete Response (iCR) | 0 (0.0%) |
| Partial Response (iPR) | 6 (33.3%) |
| Stable Disease (iSD) | 3 (16.6%) |
| Progressive Disease (iPD) | 6 (39.9%) |
| Not evaluable* | 2 (11.1%) |
| Not yet evaluated** | 1 (5.6%) |
| **Objective Response Rate (iORR)** | **6 (33.3%)** |
| **Disease Control Rate (iDCR)** | **9 (50.0%)** |

* - dropped out prior to first restaging

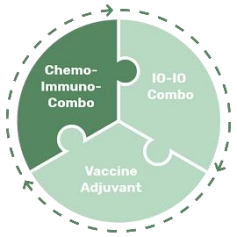
** - not yet staged (on therapy < 9 weeks)




- LPI - December 2019 → 1 patient with outstanding imaging
- 5 responses confirmed; all 6 patients with PR still under therapy

*Note:*

(1) Preliminary data, cut-off 20 Mar 2020




# Efti positioning in HNSCC

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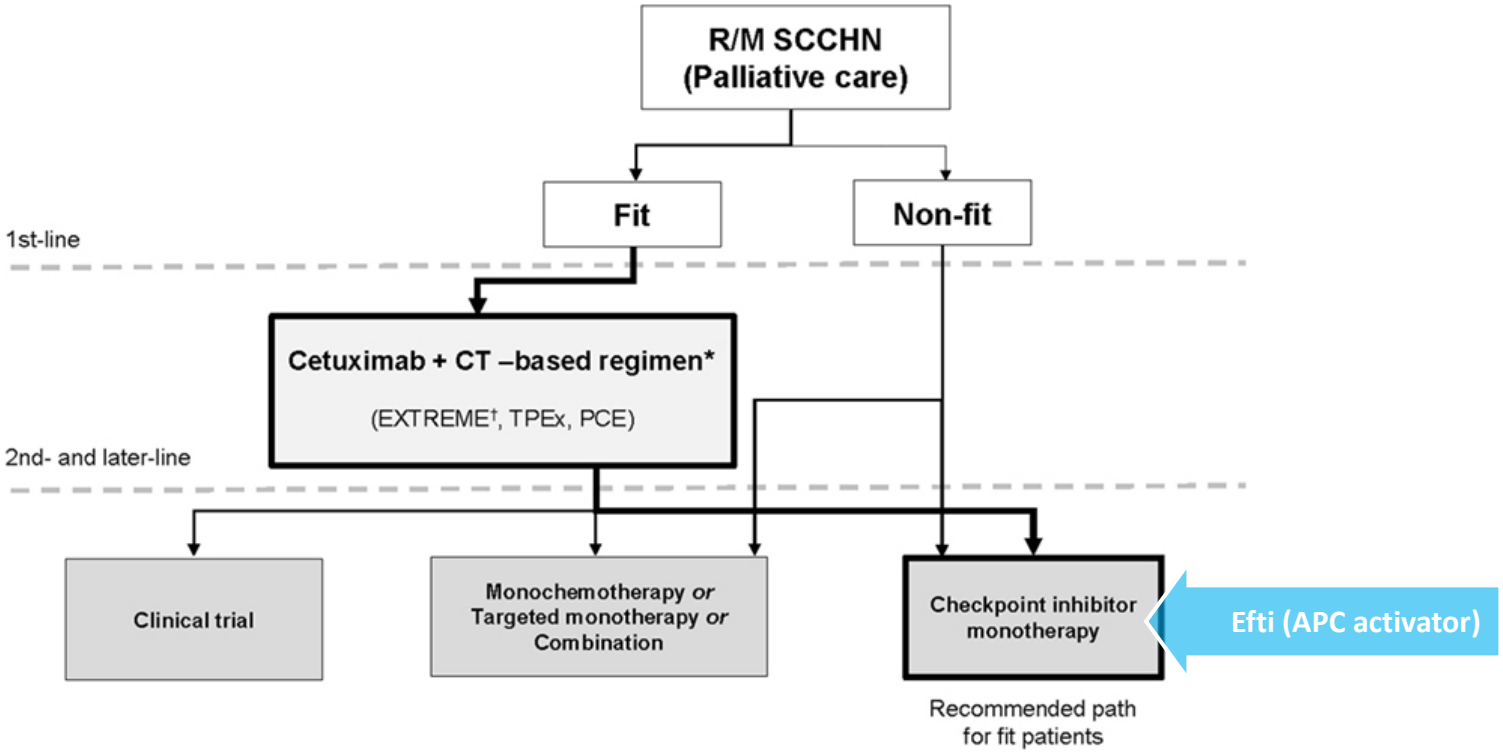
LAG-3 IMMUNOTHERAPY

**Epidemiology:**

- More than 585,000 HNSCC diagnoses per annum worldwide(1)
- Approximately 350,000 develop metastatic disease and are eligible to receive anti-PD-1 monotherapy or in combination with chemotherapy

**US$ 2.8 billion**

Estimated market size by 2026(3)




Notes

(1) F Bray et al.: Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA CANCER J CLIN 2018;68:394–424
(2) Athanassios Argiris et al.: Evidence-Based Treatment Options in Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck. Front. Oncol., 09 May 2017
(3) Estimation of Datamonitor Healthcare, Informa Pharma Intelligence for US, JP, EU (5): Head and neck cancer Forecast, December 2017

# Historical comparison HNSCC

## Current SoC and key characteristics HNSCC, PD-L1 all-comer

| Regimen | ORR[1] | Median PFS (months)[1] | PFS rate at 3 / 6 months[2] | Median OS (months) [1] | Main downside/limitations[1,2] |
|---|---|---|---|---|---|
| Chemo | 10.1% | 2.3 | 45% / 20% | 6.9 | Not effective in >> 50% of patients |
| Pembro | 14.6% | 2.1 | 40% / 25% | 8.4 | Not effective in >> 50% of patients |
| Pembro ≥ 1% CPS | 17.3% | ~2.3 | 45% / 30% | 8.7 | Not effective in >> 50% of patients |

Triple combination (chemo plus pembro) in 1st line toxic/costly → take up will be limited → enough patients in 2nd line PD-1 naive

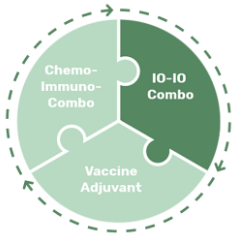
### Current results TACTI-002

- 33% ORR; 50% DCR (18 patients)
- 44% patients with tumor shrinkage

✓ **iORR doubled compared to pembro alone without substantial additional toxicity**



(1) Keynote-040 results
(2) Internal calculations based on the published results of the Keynote-040 clinical trial (internal calculation done in 2019)




# Efti Clinical Development
# TACTI-mel: Results (Part A, Single Case)

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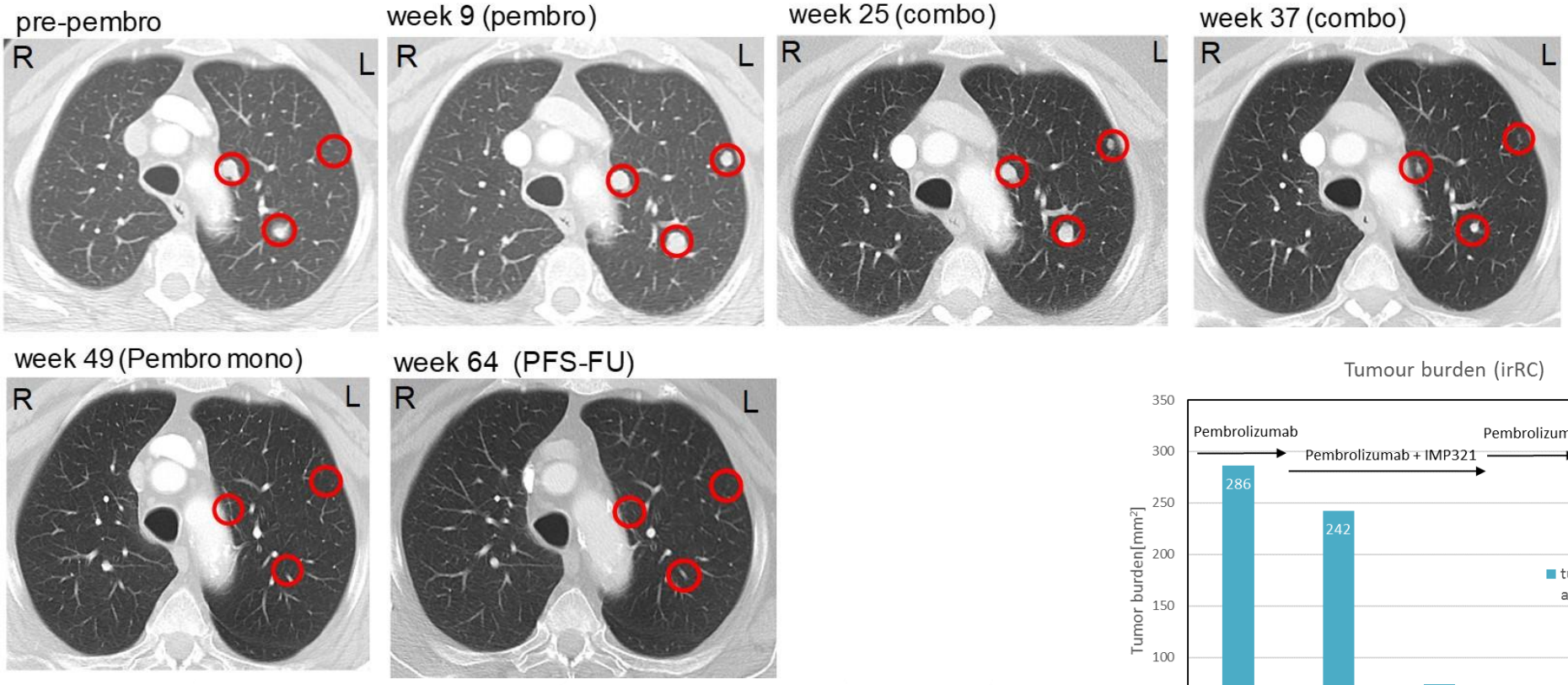
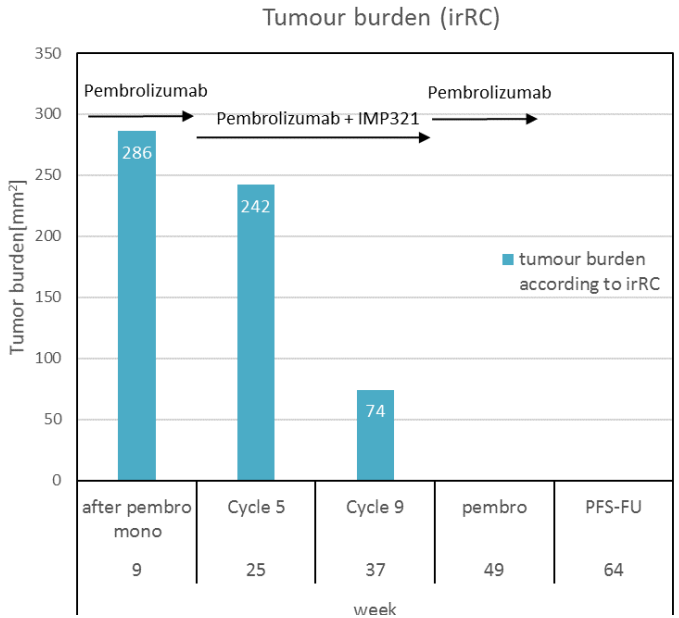
## Efficacy: Metastatic Melanoma

Tumor progression → Tumor regression →

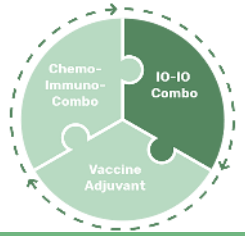



- Patient progressing on pembrolizumab monotherapy
- At 1 yr all lesions disappeared → CR (confirmed)
- Patient without treatment and disease free → now lost to FU



*Notes:*
Data-cut-off: Oct 2019




# Efti Clinical Development
# INSIGHT-004 (Phase I)

immutep
LAG-3 IMMUNOTHERAPY

## INSIGHT-004: dose escalation of efti in combination with avelumab

Dose escalation, solid tumors, 2 cohorts of 6 patients each → efti + avelumab (Bavenico®) for 6 months + 6 months avelumab monotherapy → Phase I, monocenter DE, open label, IIT → **RP2D, Safety,** ORR, PFS, PK, PD

| | |
|---|---|
| **Patient Population** | Solid tumors after failure of standard therapy |
| **Treatment** | 6 / 30 mg efti s.c.<br>800 mg avelumab i.v.<br>Both every 2 weeks |

**In collaboration with:**

Pfizer

Merck KGaA, Darmstadt, Germany I.K.F.

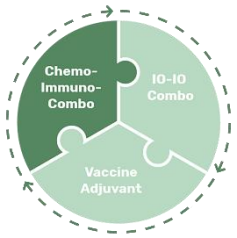
### Status Report

- ✓ 1 site in Germany
- ✓ Protocol approved by CA / ED
- ✓ Six patients dosed thus far at 6 mg w/o DLT
- ✓ 1 PR at 6 mg[1]
- ✓ 30 mg cohort fully enrolled, completing trial recruitment[2]
- • Initial results expected to be presented at a major medical conference Q2 CY2020

**Key features: safety with a PD-L1 antagonist avelumab**



*Notes:*
R2PD – recommended phase 2 dose, ORR – overall response rate, PFS – progression free survival, OS – overall survival, PK –pharmacokinetics
[1] As reported to the ASX by Immutep on 19 December 2019
2 As reported to the ASX by Immutep on 22 April 2020




# Efti Clinical Development AIPAC (Phase IIb)

immutep
LAG-3 IMMUNOTHERAPY

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

Patients with HR+/HER2- MBC

→ Arm 1, *114* patients: paclitaxel + efti
Arm 2, *112* patients: paclitaxel + placebo

→ Phase IIb, multinational, randomized, double-blind

→ **Primary: PFS**
Secondary: OS, safety, ORR, QoL

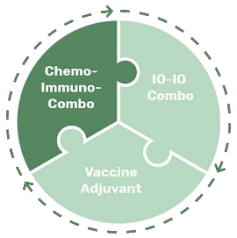
| Baseline Characteristics | Paclitaxel + Efti N=114 | Paclitaxel + Placebo N=112 |
|---|---|---|
| Median age (range) | 58 yrs (24-87) | 61 yrs (35-79) |
| ECOG 0 | 60.5% | 62.5% |
| % visceral disease | 90.4% | 92.9% |
| % pre-treated with CDK4/6 for met disease | 43.9% | 42.9% |
| One or more systemic therapies for metastatic disease | 68.4% | 71.4% |
| Tumor type (central pathology)<br>Luminal A<br>Luminal B | <br>34.1%*<br>48.8%* | <br>36.7%*<br>49.4%* |
| Monocytes at baseline < 0.25 x $10^9$/L | 21.9% | 19.8% |

### Fact Sheet

- ✓ Conducted in 7 EU countries
- ✓ Local and blinded independent central read
- ✓ LPI enrolled June 2019
- ✓ Cut-off for primary analysis 10 January 2020 (Data received 24 March 2020)
- ✓ PFS data reported
- ❑ OS data expected by end of 2020



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




# Efti Clinical Development AIPAC (Phase IIb)

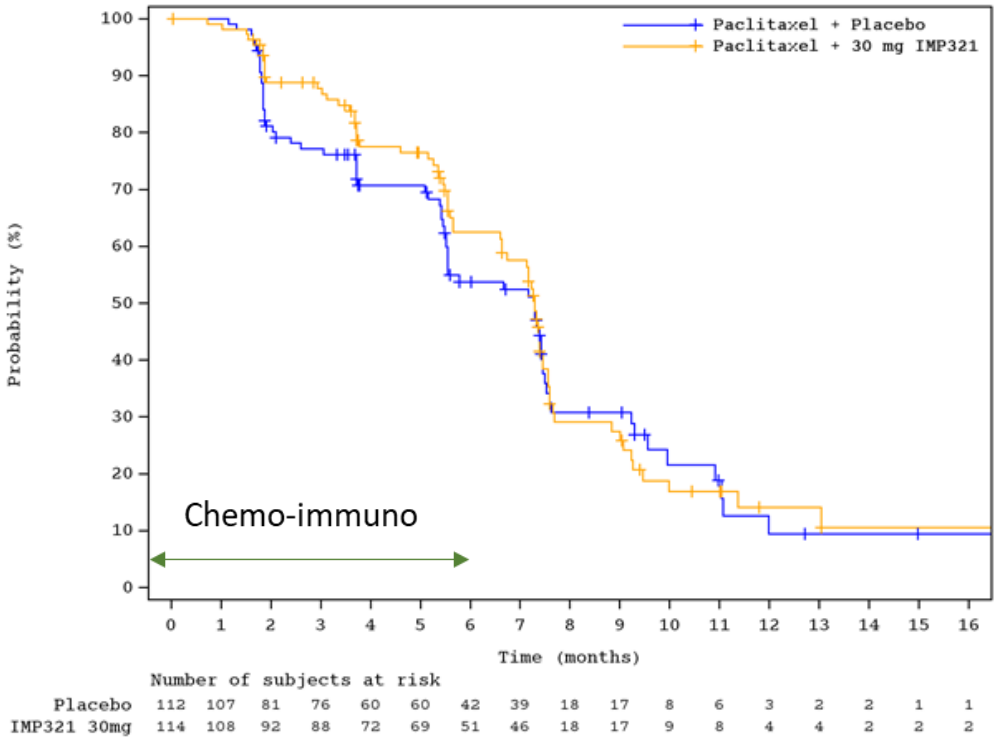
immutep
LAG-3 IMMUNOTHERAPY

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

- ***Efficacy improvement observed from efti compared to placebo in terms of ORR***
- ***Effect on PFS as long as paclitaxel is given together with efti***

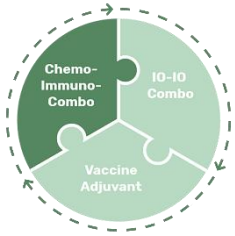
| BOR acc. to RECIST 1.1 by BICR | Paclitaxel + Efti N=114 | Paclitaxel + Placebo N=112 |
|---|---|---|
| Complete Response | 0.9% | 1.8% |
| Partial response | 47.4% | 36.6% |
| Stable disease | 36.8% | 37.5% |
| Progressive Disease | 8.8% | 18.8% |
| Non-evaluable | 6.1% | 5.4% |
| **Overall Response Rate** | **48.3%** | **38.4%** |
| **Disease Control Rate** | **85.1%** | **75.9%** |
| **PFS estimates - primary analysis* BICR** | | |
| **HR [95% CI ]** | 0.93 [0.67-1.30], p=0.341 | |
| Median in months [95% CI ]<br>Mean in months [SE]<br>**% progression free at 6 months** | 7.29 [6.64-7.46]<br>7.12 [0.37]<br>**63% [52%-71%]** | 7.29 [5.52-7.46]<br>6.64 [0.38]<br>**54% [43%-63%]** |

Blinded independent investigator read (BICR)






*Notes:*
ORR – overall response rate, DCR – disease control rate, PFS – progression free survival, OS – overall survival, QoL – Quality of life
First presented on Thursday at viavid.webcasts.com, March 26th, 8am Australian Eastern Daylight Time / Wednesday, March 25th, 5pm US Eastern Daylight Time; A replay of the webcast is available at www.immutep.com



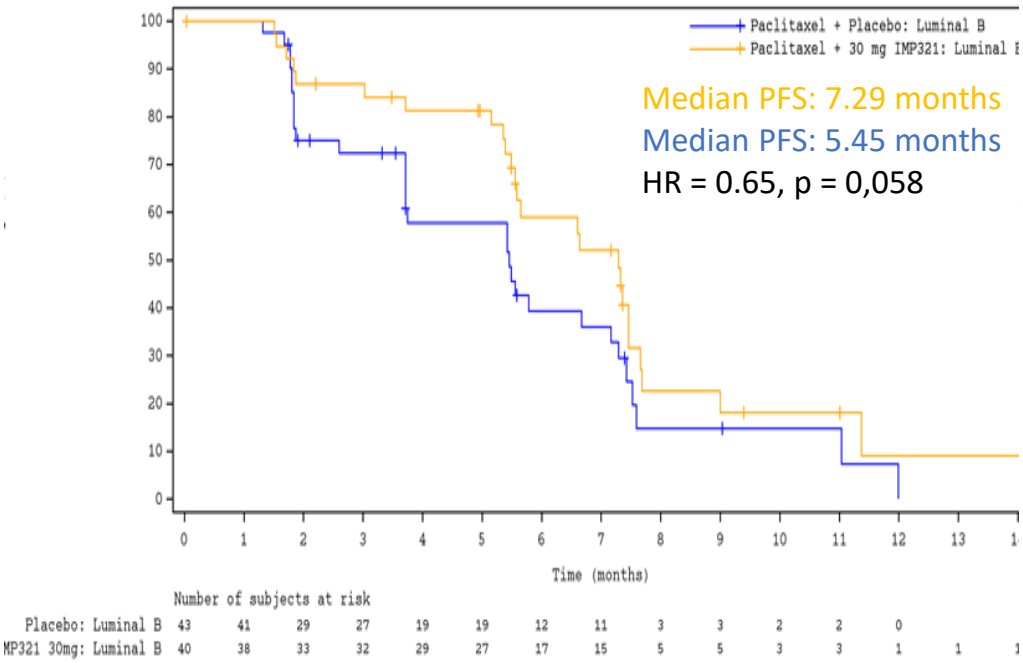

# Efti Clinical Development
# AIPAC (Phase IIb)

immutep
LAG-3 IMMUNOTHERAPY

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

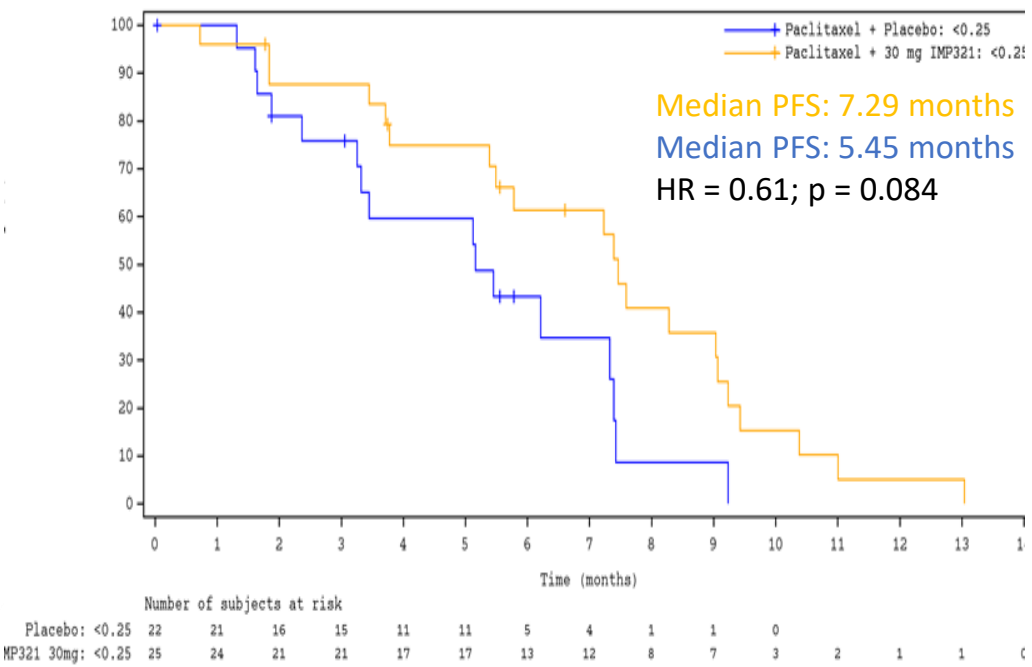
*Compelling results observed in multiple patient subgroup populations*

### Subgroup 1 - luminal B - mPFS




Luminal B (more aggressive tumor growth subtype): an interesting observation indicating that fast growing tumors (e.g. NSCLC in TACTI-002) are better targets for APC activators like efti

### Subgroup 2 - low monocytes - mPFS




Low monocyte counts (i.e. compromised innate immunity) fit with mechanism of action of efti and are very interesting for other studies e.g. TACTI-002

**Next steps: further data analysis & regulatory interaction**



*Notes:*
HR – Hazard Ratio; mPFS – median Progression Free Survival
First presented on Thursday at viavid.webcasts.com, March 26th, 8am Australian Eastern Daylight Time / Wednesday, March 25th, 5pm US Eastern Daylight Time; A replay of the webcast is available at www.immutep.com

# Eftilagimod Alpha Partnerships

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EOC

- EOC, an Eddingpharm spin-off holding the Chinese rights for efti, Phase I study in MBC ongoing
- Milestone and royalty bearing partnership

CYTLIMIC
Cytotoxic T Lymphocyte Immunotherapy in Cancer

- 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 IMM); Phase I completed

WuXi Biologics
Global Solution Provider

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

DD CRO SMS oncology

CSM® A CLINIGEN COMPANY

ERT®

SGS

NT NOVOTECH The Asia Pacific CRO

median

atlanbio

mlm medical labs

COVANCE

PhinC Development

# Eftilagimod Alpha in Infectious Diseases

- In preclinical studies, efti has been shown to bind to antigen presenting cells (APCs) such as dendritic cells, macrophages and monocytes via MHC class II, activating the APCs which detect and engulf infected cells. This process is known as the innate immune response.

- Engulfing the infected cells leads to the production and presentation of foreign antigens which prompts the activation and proliferation of cytotoxic CD8+ T cells to kill the infected cells. This is known as the adaptive immune response.

- Efti has been shown to activate innate immunity and as a consequence, to boost adaptive immunity.

- Immutep has two patent families with claims drawn to the use of efti in the treatment of infectious disease: see, for example, the Japanese patent grant announced in September 2017 and the European grant announced in November 2018.

- Immutep has been approached by an investigator and is in discussions and planning for an investigator-initiated Phase II clinical trial in a European country evaluating eftilagimod alpha ("efti" or "IMP321") in patients with COVID-19. Potential investors should note that, at this stage, discussions with the investigator are incomplete and subject to negotiation. While the Company has reason to believe that agreement will be reached, there is currently no agreement with the investigator or hospital, and no assurance can be given that an agreement on terms acceptable to the Company will be reached. Once an agreement is reached, the study can only commence once necessary approvals are obtained such as approval of the clinical trial application by the relevant Competent Authority.

- If a binding agreement with the investigator and hospital is reached and the necessary regulatory approvals are obtained, the potential study is expected to be funded by the investigator and hospital and would aim to boost a patient's immune response and prevent COVID-19 disease from progressing into severe cases, which can lead to respiratory failure and death. The Company cannot guarantee that the proposed study and any development work will result in an efficacious drug, or even if they do, that the drug will be approved by regulatory authorities.

- If approved, the trial could commence with recruitment of the first cohort of patients by the middle of this calendar year, and with successive cohorts being recruited following a positive recommendation from the Data Monitoring Committee (DMC), which will evaluate safety and efficacy of the treatment.[1]



(1) NB: There is a trend towards expedited timelines for approval and completion of COVID-19 studies. Assuming approvals are received to recruit successive cohorts interim analysis could be expected throughout calendar year 2020 with final readouts expected in 2021. Even if positive results are achieved, competing products for the treatment of COVID-19 may mean that efti is unable to be commercialized for this disease however, the study could provide useful data relating to efti's potential for the treatment of infectious diseases in general.

# Out-Licensed Immunotherapy Pipeline

# LAG525 (IMP701) for Cancer

- Novartis holds an exclusive WW licence to develop and commercialise LAG525 (which is derived from Immutep's antagonist antibody known as IMP701)
- 1st and 2nd milestone payments received by Immutep 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
- Novartis currently has five clinical trials ongoing for LAG525 in multiple cancer indications for over 1,100 patients(1)

- **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**



Notes
(1) Details on all ongoing trials of LAG525 being conducted by Novartis

# GSK'781 (IMP731) for Autoimmune Diseases

- GSK holds an exclusive WW licence to develop and commercialise GSK'781 (which is derived from Immutep'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
- March 2018: Phase I trial in psoriasis completed in 67 subjects/patients(2)
- September 2019: 1st patient dosed in Phase II trial in ulcerative colitis in 280 patients triggered a £4 million (~US$5.0 million) milestone payment to Immutep(1)
- Phase I clinical study ongoing evaluating GSK'781 in 36 healthy Japanese and Caucasian subjects, PK/PD study
- Clinical Proof of Concept expected H2 2020

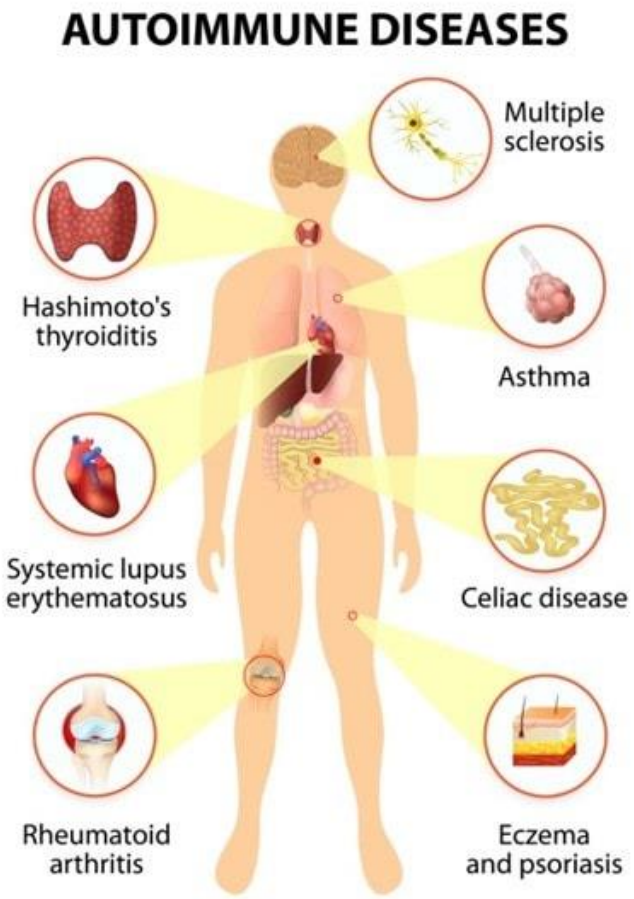
**GSK's investigational product, GSK2831781, which is derived from IMP731 antibody, aims to kill the few activated LAG-3+ T cells that are auto-reactive in autoimmune disease leading to long term disease control without generalized immune suppression**



Notes
(1) For additional information on this clinical trial
(2) For additional information on this clinical trial

# IMP761
# (Autoimmune Diseases)

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




**THE PRESENT: FIGHTING THE SYMPTOMS**

**Treating general inflammation**:
corticoids, methotrexate,
anti-TNF-α, -IL-6, -IL-17, -IL-23 mAbs

**THE FUTURE: FIGHTING THE CAUSE**

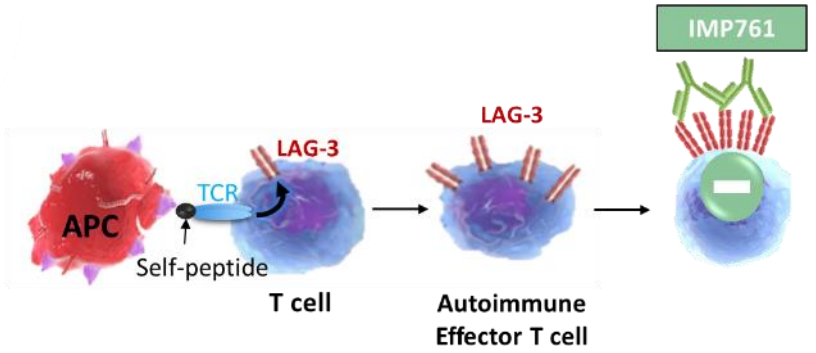
**Treating the disease process**:
silencing the few autoimmune memory T cells accumulating at the disease site with IMP761

**POTENTIAL GAME CHANGER IN AUTOIMMUNE DISEASES (149.4 bn $ market size by 2025)[1]**

Notes
(1) Source: KBV Research July 2019

# IMP761 Overview

- **The Concept**: treating the cause of autoimmune diseases, not just the symptoms
- **The Target**: the self-peptide specific memory T cells harboring LAG-3




- **The Tool**: an agonistic LAG-3-specific mAb down-modulating self-peptide-induced TCR signaling
- **The Evidence** (1)*: *in vitro* down-modulation of peptide-induced human T cell proliferation and activation
- **The Evidence** (2)*: *in vivo* down-modulation of peptide-induced T cell infiltration / inflammation at the tissue site in a non-human primate model
- **IP**: composition of matter & methods of treatment - expiry 2036
- **The Status**: cell line development ongoing and GMP manufacturing preparations underway in order to progress to clinical development



*Notes:*
* Based on: M Angin, C Brignone, F Triebel: A LAG-3–Specific Agonist Antibody for the Treatment of T Cell–Induced Autoimmune Diseases. J Immunology (2020), Vol. 204, Issue 2.

# Immutep Outlook & Offer Details

# 2020 & 2021 Outlook* and News Flow

## Upcoming in 2020:

- **MBC** - Overall Survival data from AIPAC: End of 2020
- **NSCLC 1st line** - more data from Stages 1 and 2 from TACTI-002 throughout 2020
- **HNSCC 2nd line** - initial data from Stages 1 and 2 from TACTI-002 throughout 2020
- **NSCLC 2nd line** - initial data from Stage 1 from TACTI-002 throughout 2020
- **Combination with avelumab** - initial data from Phase I trial throughout 2020
- Regulatory progress
- Progress from partnered programs

## Expected in 2021:

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

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



*Notes:*

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

# Capital Raising Overview

**Immutep is conducting a capital raising of up to A$12.0 million to fund clinical development of its product candidates**

**Capital Raising Structure:**

- Placement of approximately A$10.0 million to A$12.0 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$0.125 per share under the Placement represents a 22.3% discount to the 5 day VWAP over the 5 days up to and including 24 April 2020

**Use of Proceeds:**

| Description | A$m |
|---|---|
| Clinical Development | 6.5 |
| Manufacturing | 1.5 |
| Working Capital | 4.0 |
| Total | 12.0 |

# Capital Raising Timetable

## Indicative timetable for the capital raising is provided below

| | |
|---|---|
| Company enters trading halt | Monday, 27 April 2020 |
| Placement announced and Company resumes trading on ASX | Pre-market open, Wednesday, 29 April 2020 |
| Settlement of new shares to be issued under Placement | Monday, 4 May 2020 |
| Issue of new shares under Placement | Tuesday, 5 May 2020 |

All times are AEST
This timetable is indicative only. The company and lead manager reserve the right to change the dates.

# 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.

**European Union**

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).

**Hong Kong**

WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the "SFO"). No action has been taken in Hong Kong to authorise or register this document or to permit the distribution of this document or any documents issued in connection with it. Accordingly, the Shares have not been and will not be offered or sold in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

**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.

The Shares may not be offered or sold in the United Kingdom by means of this document or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This document is issued on a confidential basis in the United Kingdom to "qualified investors" (within the meaning of Article 2(e) of the Prospectus Regulation (2017/1129/EU), replacing section 86(7) of the FSMA). This document may not be distributed or reproduced, in whole or in part, nor may its contents be disclosed by recipients, to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received in connection with the issue or sale of the Shares has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of the FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

**United States**

This document does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States. The Shares have not been, and will not be, registered under the US Securities Act of 1933 and may not be offered or sold in the United States or to US Persons (as defined in Rule 902(k) under the US Securities Act) except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and applicable US state securities laws.

# 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 Immutep 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;

- 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 it 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.

# Thank you