

**OSE** IMMUNO  
THERAPEUTICS



Breaking Through the  
Therapeutic Ceiling with  
First-In-Class Immunotherapies

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January 2025

# Forward Looking Statement

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# Investment highlights

## Late-stage compelling products

**Promising clinical data from the Phase 3 oncology asset Tedopi®**  
**Positive Phase 2 IBD asset Lusvertikimab**

## Large market opportunities

### Focus on multi-billion \$ markets

- **I/O:** NSCLC (2L, 3L), HCC (1L, 2L), HNSCC (2L), Leukemia
- **I&I:** IBD (Ulcerative Colitis), Kidney Transplantation, Cardiovascular-Renal-Metabolic diseases

## Strong pharma partnerships

**Sustainable business through multi-partnership strategy**  
**> €2.1bn milestones:** AbbVie, Boehringer Ingelheim, Veloxis

## Long duration IP portfolio

### IP extends to 2040's

**I/O:** Tedopi® (>2038), BI770371 (>2037), OSE-279 (>2039), CLEC-1 (>2040) **I&I:** OSE-127 (>2037), FR104 (>2035), ABBV-230 (>2040)

## Multiple upcoming catalysts

### Multiple key clinical and regulatory milestones expected in next 12 months

- **Tedopi®:** Confirmatory pivotal phase 3 NSCLC 2L and combination Phase 2 update
- **Lusvertikimab (OSE-127):** Full dataset efficacy results Ulcerative Colitis Phase 2
- **BI 770371:** Phase 1b results in solid tumors/Phase 2 update in MASH
- **FR104/VEL-101:** Phase 2 start in Kidney Transplantation
- **ABBV-230:** IND/Phase 1

## Financial position

### Cash visibility until 2027

**€80.7 million** level of cash as of June 30, 2024, providing solid financial position and visibility until 2027

# Delivering first-in-class immunotherapies from Target to Clinic

Key strategic pharma partnerships driving long-term value

- Founded in **2012**
- IPO/Euronext in **2015**
- **60+ FTEs**
- **500+ granted patents**

- **52 M€** : Equity
- **€219 M** : Partnerships\*  
+80% non-dilutive funding



## Phase 3 asset in **Oncology**

*Tedopi® most advanced cancer vaccine*  
NSCLC 2L post-CPI market: **+\$5b/year**



## Phase 2 asset in **Inflammation**

*Lusvertikimab anti-IL-7R mAb*  
Ulcerative colitis market: **+\$10b/year**

**3** Strategic Pharma Partners

**+€2.1b** potential milestones

abbvie



**5** Clinical stage assets

- 3 **Fully** owned (Phase 1, 2, 3)
- 2 **Partnered** (Phase 1, 2)

**3** **Pre-clinical** platforms  
Assets approaching development

- **Innovative MoA & Targets** to address critical unmet need
- International Research Collaboration



Memorial Sloan Kettering  
Cancer Center





# Strong foundation & recurrent track record of success

10 years of validated innovation in immunology thanks to an Extra[not]Ordinary R&D engine



**Validated science**  
in high-impact publications



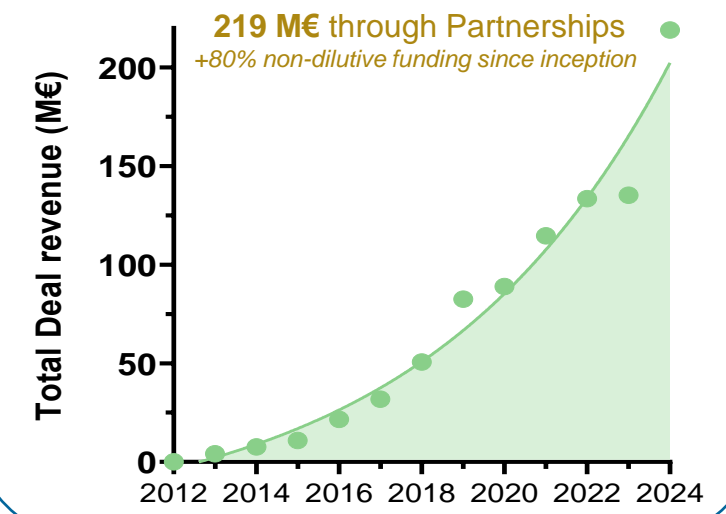
500+ granted patents



**Strong track record**  
of Pharma partnerships









**Recurrent revenues**  
Robust first-in-class business model



# Clinical pipeline

Combining a clinical portfolio of first-in-class immunotherapies and diversified assets in IO and I&I

IO	Product candidate	Target	Indication	Research	IND-enabling	Phase Ia/Ib	Phase II	Phase III
		Tedopi®	Neopeptide Vaccine	NSCLC Mono post-ICI 3L <b>NSCLC Mono post-ICI 2L</b> PDAC Combo ( <i>exploratory eIIS</i> ) OC Mono or Combo ( <i>eIIS</i> ) NSCLC Combo 2L post-ICI ( <i>eIIS</i> )	[Progress bars]			
	OSE-279	Anti-PD1	Solid tumors	[Progress bars]				
	BI 770371	Anti-SIRPα 	Solid tumors (HNSCC, HCC)	[Progress bars]				
	IL-7R CAR-T	IL-7R CAR-T 	IL-7R+ tumors	[Progress bars]				
	Anti-PD1/cytokine	Undisclosed 	Solid tumors	[Progress bars]				


I&I	Product candidate	Target	Indication	Research	IND-enabling	Phase Ia/Ib	Phase II	Phase III
		OSE-127 <i>Lusvertikimab</i>	Anti-IL-7R	<b>Ulcerative Colitis</b>	[Progress bars]			
	BI 770371	Anti-SIRPα 	MASH	[Progress bars]				
	FR104/VEL-101	Anti-CD28 	Kidney Transplantation	[Progress bars]				
	ABBV-230	Anti-ChemR23 	Chronic Inflammation	[Progress bars]				

# Research platforms

Extra(not) Ordinary Research PowerHouse




**Myeloid Checkpoint**

- ▶ Anti-SIRPα 
- ▶ Anti-CLEC-1 mAbs




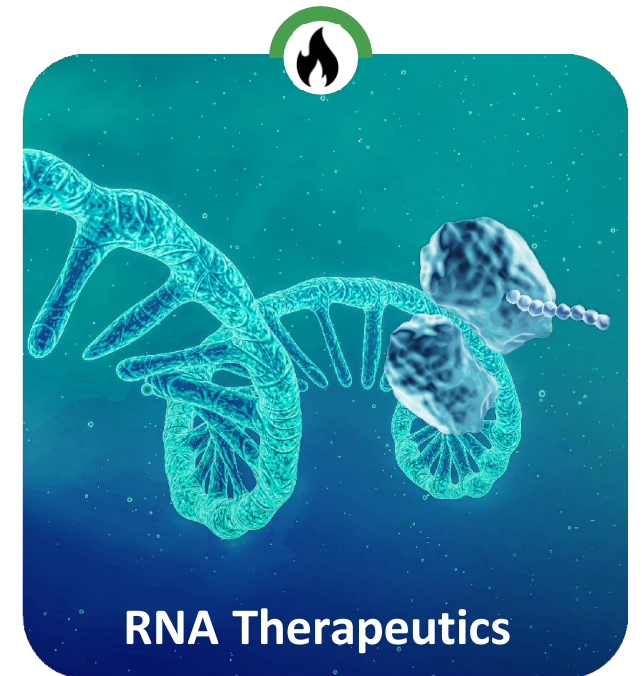
**Cis-targeted Cytokine**

- ▶ Anti-PD1/cytokine 
- ▶ Cis-Demasking technology



**Pro-Resolutive mAb**

- ▶ Anti-ChemR23 
- ▶ Undisclosed new pro-resolutive GPCRs



**RNA Therapeutics**


- ▶ IL-35 mRNA
- ▶ Undisclosed programs

 Partnered Asset


# Strategic partners provide industry-leading clinical support & strong financial foundations

Over €2.1bn in potential milestones; €219m\* already received

■ Immuno-Oncology
 ■ Immuno-Inflammation
 ■ Potential
 ■ Received



**BI 770371**  
+ anti-PD1/cytokine  
Solid tumors & Metabolic Diseases




**Boehringer  
Ingelheim**


Up to **€1.1bn**

**€104m** received

+ Tiered royalties  
on Global Sales




**ABBV-230**  
Chronic  
Inflammation




Up to **\$713m**

**\$48m** upfront

+ Tiered royalties  
on Global net Sales



**FR104/VEL-101**  
Kidney  
transplant




Up to **€315m**

**€13.9m** received

+ Tiered royalties  
on Global Sales

8

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\* Including upfront, milestones and invoiced R&D costs + previous license agreement with J&J and Servier



# Key potential catalysts\*

## Readouts

- **Lusvertikimab**  
Full dataset Phase 2 induction UC [results](#)  
First-OLE Phase 2 UC [results](#)  
UC phase 2 safety [results](#)
- **Tedopi®**  
Phase 2 PDAC [results](#)
- **BI 770371 (partnered)\***  
Phase 1b [results](#) in solid tumors

## Progress

- **Lusvertikimab**  
Strategic update
- **Tedopi®**  
Phase 3 NSCLC 2L update  
Phase 2 combination completion
- **FR104/VEL-101 (partnered)\***  
Phase 2 start in Kidney Tx
- **ABBV-230 (partnered)\***  
IND/Phase 1
- **R&D programs & Lusvertikimab**  
**New partnering opportunities**

## Readouts

- **Tedopi®**  
Phase 3 [results](#) in NSCLC 2L  
Phase 2 combination [results](#)
- **Lusvertikimab**  
New study [results](#)
- **BI 770371 (partnered)**  
Phase 1b onco + Phase 2 MASH [results](#)
- **FR104/VEL-101 (partnered)**  
Phase 2 [results](#) in Kidney Transplantation
- **ABBV-230 (partnered)**  
Phase 1 [results](#) + Phase 2 [results](#)

## Progress

- **Lusvertikimab**  
Phase 2b/3 start
- **Undisclosed Program**  
IND/Phase 1
- **New R&D programs/platforms**
- **New partnering opportunities**

2025

2026-2027

A petri dish with a petri dish lid, a petri dish, and a petri dish lid, with a petri dish lid and a petri dish lid, and a petri dish lid and a petri dish lid.

Proprietary clinical programs

An anatomical illustration of human lungs, rendered in a blue-tinted style. The left lung (viewer's right) is shown with a glowing, multi-colored tumor (yellow, orange, and red) in its upper lobe. The right lung (viewer's left) is shown with a network of dark, branching bronchial structures. The background is a dark blue gradient.

# TEDOPI®

**Most Advanced Therapeutic Cancer Vaccine**

*Bringing new hope to patients in the fight against ICI resistant NSCLC*



# Tedopi® (OSE-2101): Product description

Tedopi® is a therapeutic cancer vaccine composed of modified epitopes restricted to HLA-A2+ targeting 5 Tumor-Associated Antigens frequently expressed in lung cancer<sup>1,2</sup>

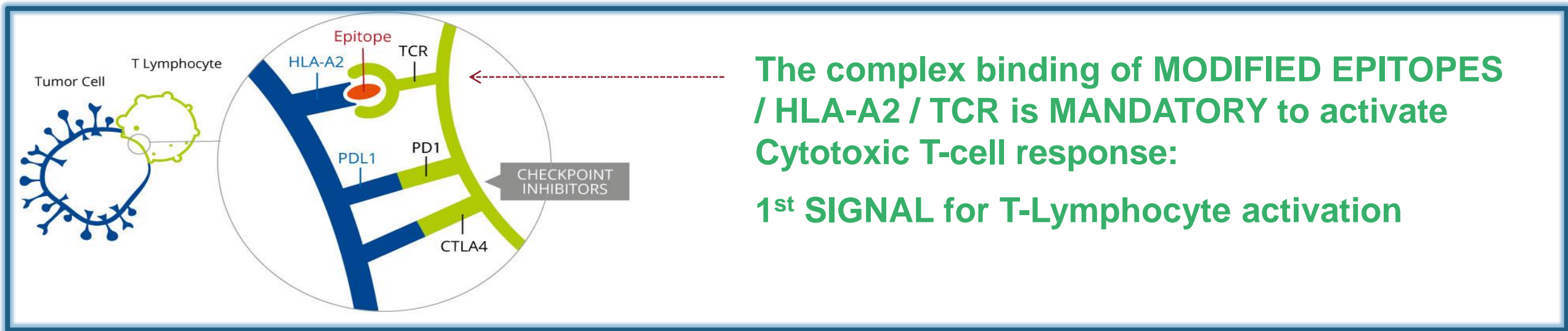
**9 EPITOPES (TAA PEPTIDES) TARGETING 5 TAAs FREQUENTLY OVEREXPRESSED IN MANY CANCERS:**

TAAs	Wild-type and neo-epitopes
CEA	1 heteroclitic* 1 heteroclitic
p53	1 fixed-anchor** 1 fixed-anchor
HER-2	1 fixed-anchor 1 fixed-anchor
MAGE-2	1 wild-type*** 1 wild-type
MAGE-3	1 heteroclitic

**+ 1 Pan DR T Helper cell epitope (PADRE)**

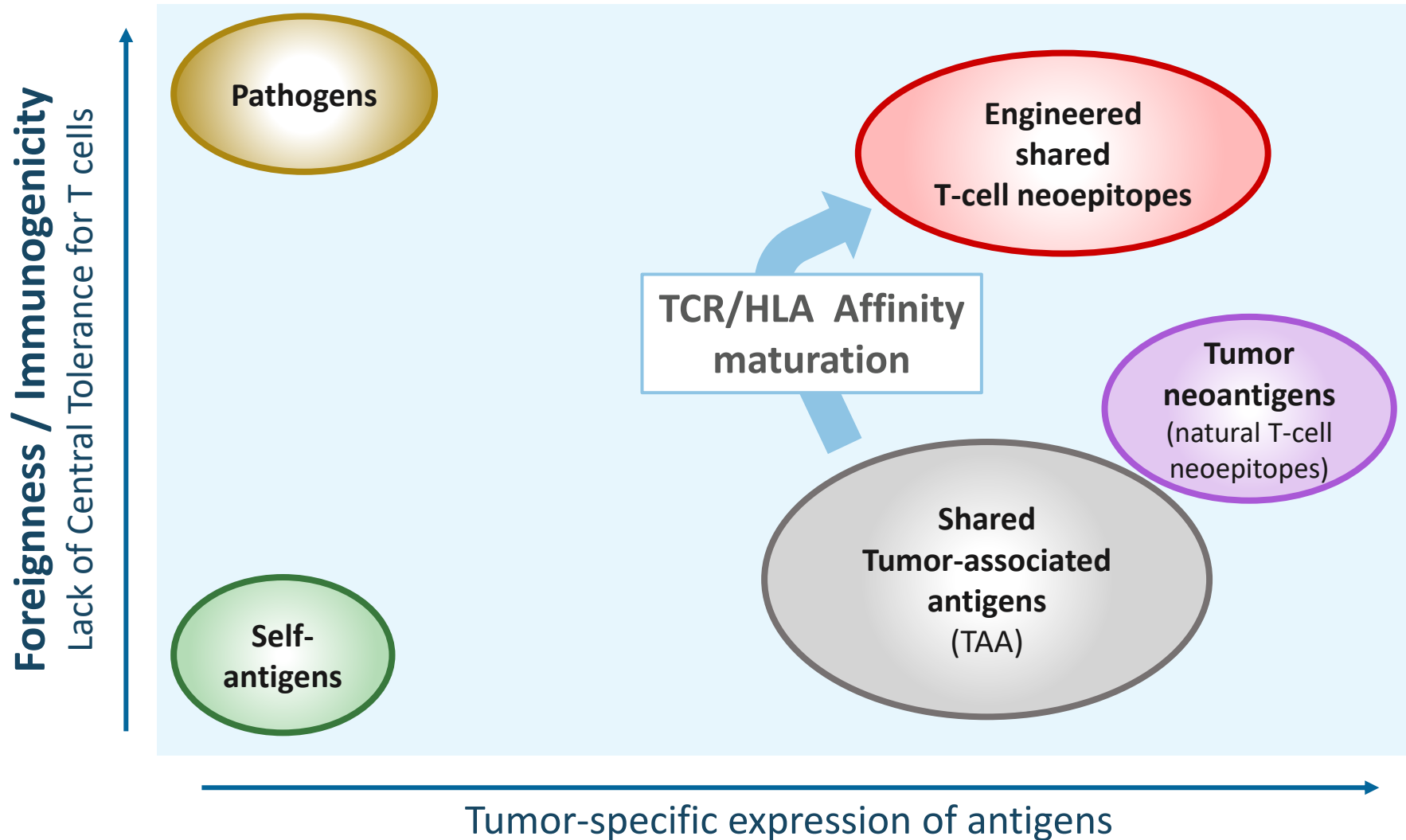
*Emulsified in mineral oil adjuvant.*

\* Heteroclitic analogs have an increased TCR affinity<sup>¶</sup>.  
\*\* Anchor analogs have an increased affinity to HLA binding<sup>¶</sup>.  
\*\*\* Wild-type epitopes with a high HLA-A2 binding.



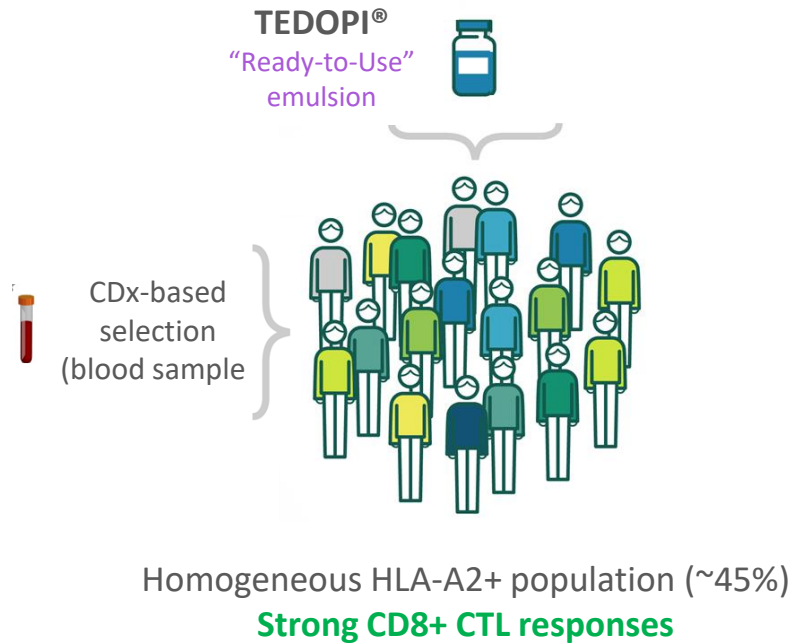


# Cancer antigens immunogenicity



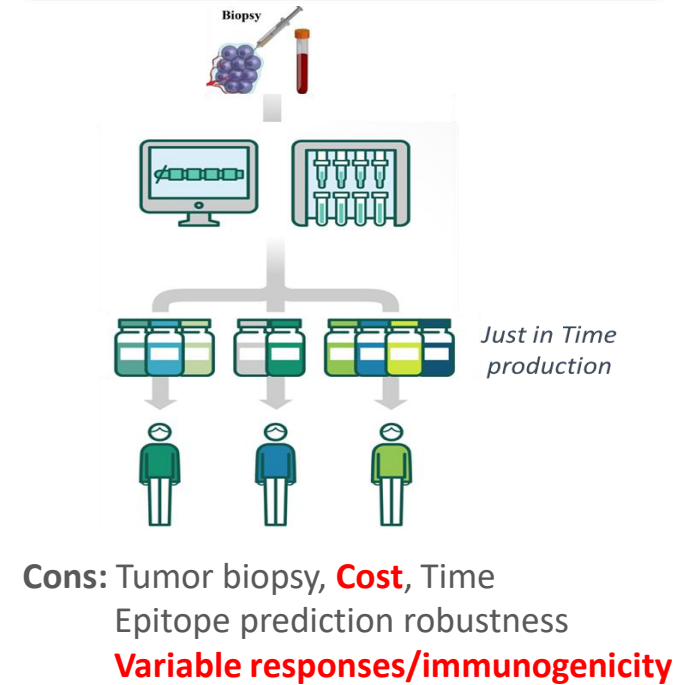
# Personalized vs *Off-the-Shelf* cancer vaccines

Neoepitope cancer vaccine  
= **Precision Medicine**  
-> *Off-the-Shelf*



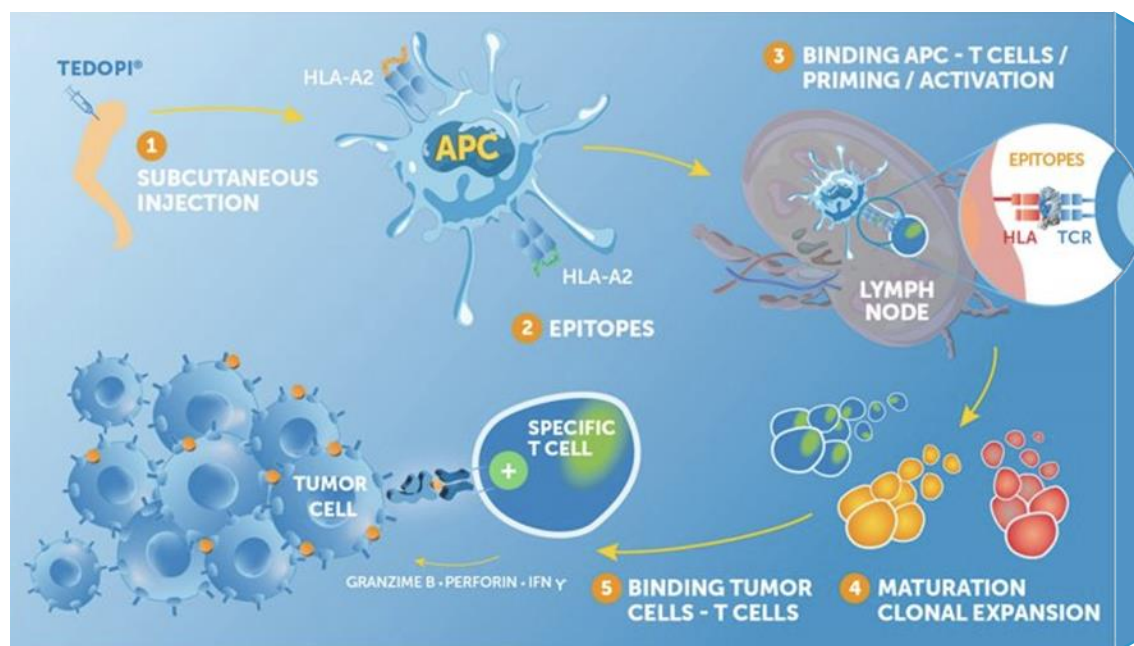
**Positive data to extend survival in metastatic disease**  
*(randomized Phase III NSCLC)*

Neoantigen cancer vaccine  
= **Personalized Medicine**  
-> *Custom*



**Adjuvant treatment at early stage to prevent tumor relapse**  
*(non-randomized phases I/II to date)*

# An immunotherapy activating specific T-cells to revive anti-tumor response



*Most advanced Cancer Vaccine in clinical development*

- **Unique** combination of **neopeptides**: small peptides deriving from **tumor specific** antigens\* expressed in various cancers
- Strong **binding to HLA-A2** receptor (45% population)
- **Direct activation of tumor specific T-cells differs from checkpoint inhibitors** releasing the break of immune response

Proprietary combination  
(9 **optimized neopeptides**  
+ 1 epitope giving universal  
T helper response)

Induces early T cell  
**memory** responses  
+  
**Migration** in tissues

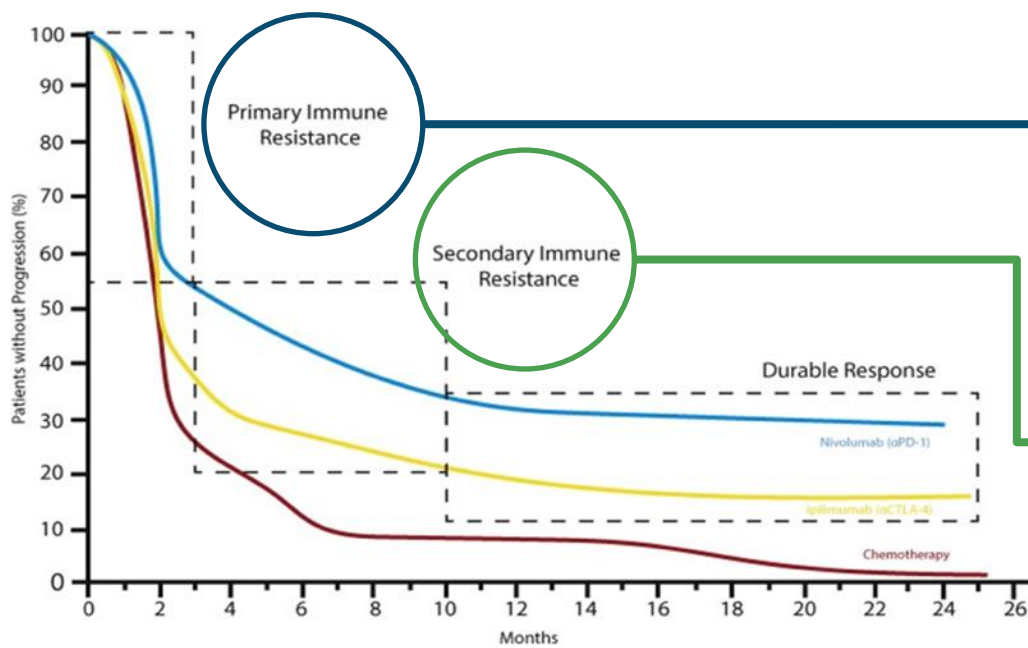
**Ready to Use**  
**subcutaneous** formulation  
with Q3W injection

**Orphan Drug**  
Designation (FDA)  
**>1,000 injection**  
in clinical trials

Strong IP position  
until **2038**<sup>1</sup>  
(US / EU / Asia)

# Tedopi® is a novel cancer vaccine with a strong biological rationale in post-ICI secondary resistance

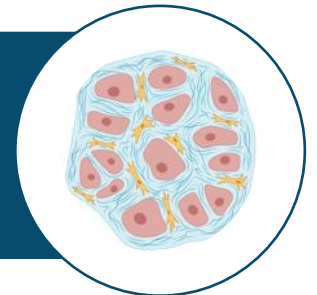
Shifting paradigms with cancer vaccine immunotherapy



### Primary (intrinsic) resistance

Patients who do not respond to ICIs with a rapid disease progression  
 → Immune refractory tumors

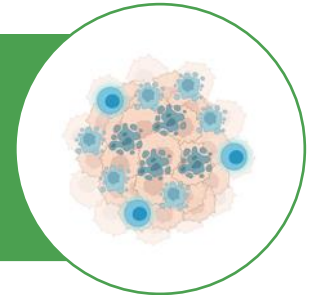
No T-cell refractory tumors



### Secondary (acquired) resistance<sup>1</sup>

Patients who have a period of initial ICI therapy benefit followed by disease progression  
 → Immuno-sensitive tumors

T-cell exhausted & dying



**Tedopi®** has the **potential to rejuvenate & refresh specific TILs** in immuno-sensitive tumors. Neopeptide-specific T cells have tumor killing potential and limited side effects.

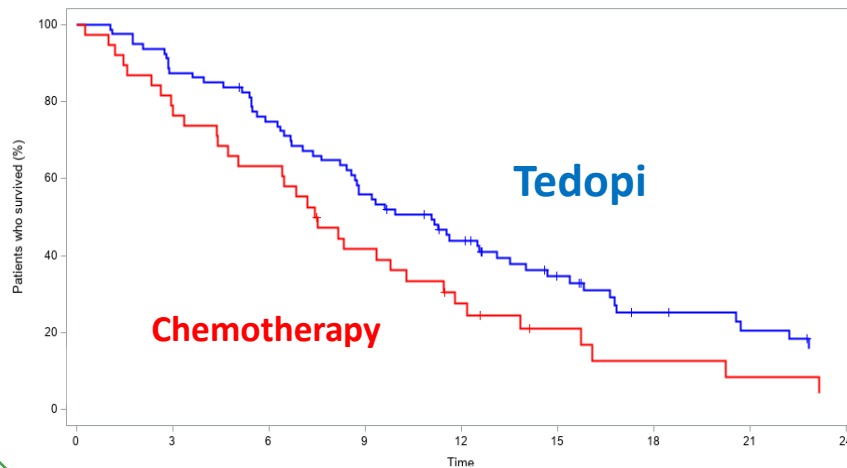


# Clinically meaningful benefit of Tedopi® in 3<sup>rd</sup> line NSCLC

Randomized Phase 3 with positive results vs. standard of care (SOC)

## Overall Survival

secondary resistance post anti-PD(L)1



OS rate at 12 months  
**44%**  
 in Tedopi® vs.  
**27.5%**  
 in SoC

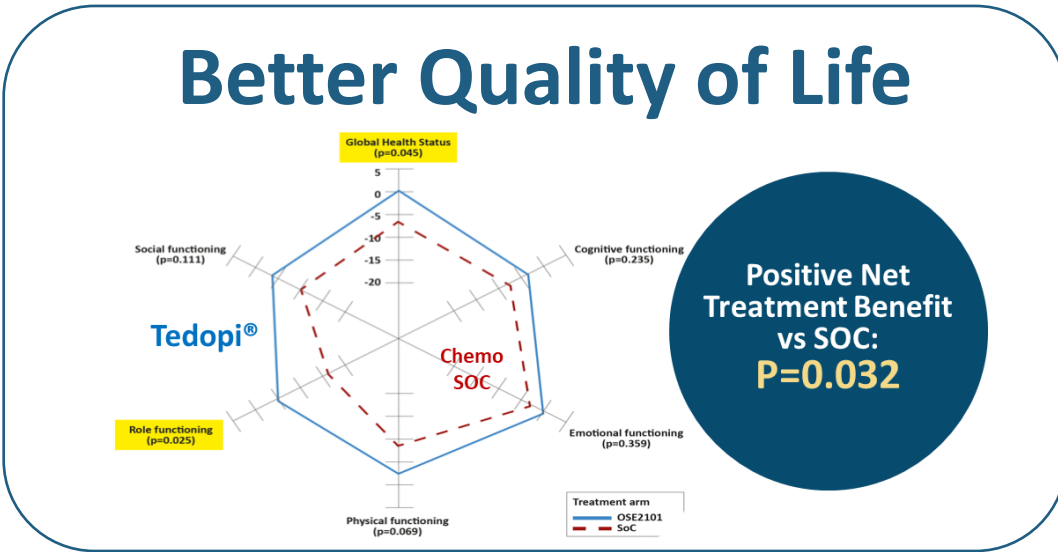
Delta OS: **3.6** months

**Tedopi® 11.1 months**  
 VS  
**SoC 7.5 months**

HR 0.59 /  
 p-value=0.017
















**Risk of Death reduced by 41% versus chemo.**

**Significantly safer than Chemo.**  
**11%** vs **35%** grade 3-5 AEs

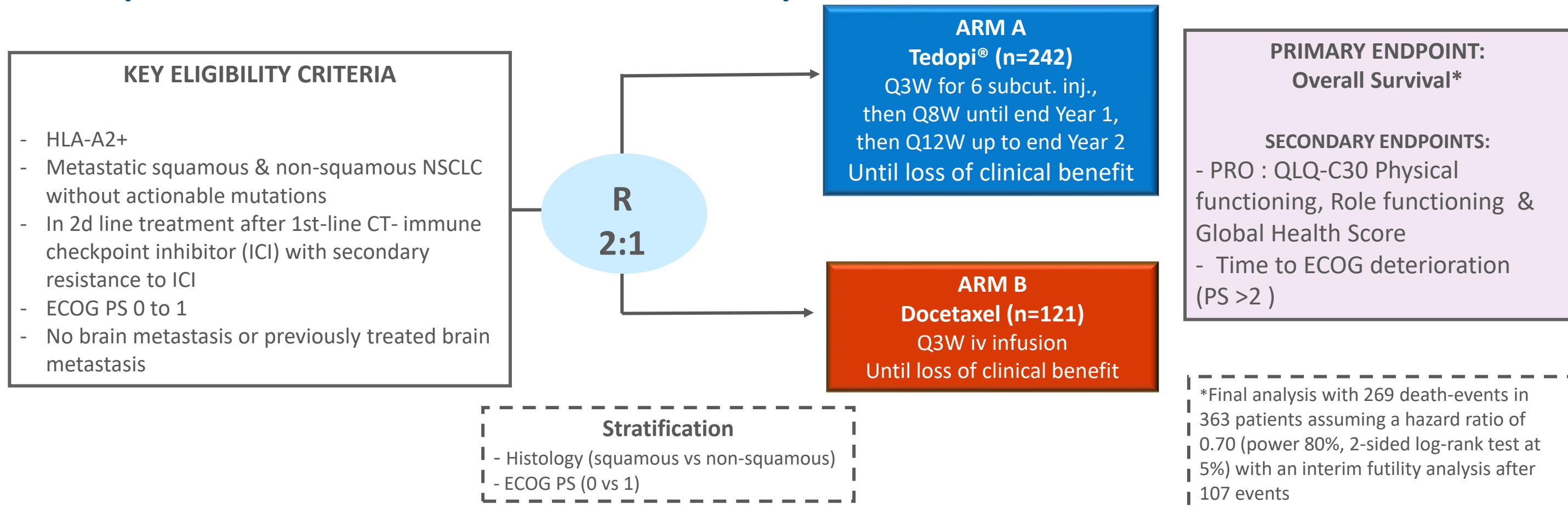


# Tedopi® delivers important clinical benefits vs competition

Better Safety profile and QoL in current landscape of late-stage drug development post CT-IO

Company			  	 		 	 			
Target	Multi-epitopes vaccine	TKIs (anti-angiogenic)			Checkpoint Inhibitors		ADCs			
Current Study	ATALANTE-1	SAPPHIRE	CONTACT-01	LEAP-008	COSTAR Lung	PRESERVE-003	Tropion-LUNG1	EVOKE-01	CARMEN-LC03	NCT04928846
n	219 118 (secondary resistant)	500	350	405	750	600	604	580	554	698
Therapy	Tedopi® vs docetaxel	Sitra + Opdivo vs. docetaxel	Cabo+Tecentriq vs. docetaxel	Lenva + Keytruda vs. docetaxel	Cobolimab + Jemperli vs. docetaxel	Gostistobart vs. docetaxel	datopotamab deruxtecan vs docetaxel	Sacituzumab Govitecan-hziy vs docetaxel	SAR408701 vs. docetaxel	Telisotuzumab Vedotin vs. Docetaxel
Primary endpoints	OS	OS	OS	PFS and OS	OS	OS	PFS and OS	OS	PFS and OS	PFS and OS
Initiation	2017	Q3 2019	Q3 2020	Q2 2019	Dec 2020	Q2 2023	Q4 2020	Q4 2021	Q1 2020	Q1 2022
Read-out	2022	Failed	Failed	Failed	Q2 2025	Q2 2026	Failed	Failed	Failed	Q1 2028
Safety data from early-stage trials in NSCLC post-ICI										
- TEAEs G3/4	11%	53%	39%	78%	n.a.	43%	25-30%	> 50%	36%	36%
Source	Besse et al. 2023	Borghaei et al, Annals Oncol 2023	Neal et al, ASCO 2022	Taylor et al, J. Clin. Oncol. 38, 1154–1163.	Davar et al, SITC 2018	He et al, ASCO 2023	ESMO 2023 WCLC 2024	ASCO 2024	Gazzah et al, ASCO 2020	Camidge DR, et al. WCLC 2021

# Tedopi® in NSCLC : ARTEMIA study



HLA: Human leukocyte antigen; NSCLC: Non-small cell lung cancer; SoC: Standard of care; CT: chemotherapy; ICI=Immune checkpoint inhibitors; ECOG PS: Eastern Cooperative Oncology Group Performance Status; PD: Progressive disease; subcut: subcutaneous; inj: injection; iv: intravenous, QLQ-C30: Quality of life questionnaire-core30

Protocol V2.0 on 14-MAR-24 (US, Canada) , 2.1 on 11-JUN-24 (UK), 2.3 on 23-AUG-24 (EU)

# Tedopi® answers to real medical need in NSCLC

Tedopi® has the potential to become the new standard for recurrent patients in 2L NSCLC presenting HLA-A2 phenotype

## LUNG CANCER :

High prevalence, mortality and unmet need - worldwide

- Highest mortality among 36 cancer types and 2<sup>nd</sup> most frequently diagnosed cancer type (based on data collected from 185 countries)\*
- About 2,206,771 new cases of lung cancer diagnosed (11,4% of all cancers) and 1,796,144 deaths from lung cancer (18%)\*
- The mortality is associated with a high degree of malignancy and late diagnosis. More than 65.33% of men diagnosed with lung cancer are in stage III-IV
- Majority of NSCLC patients without actionable mutation are treated with immune checkpoint inhibitors (ICI) as 1<sup>st</sup> line of treatment.

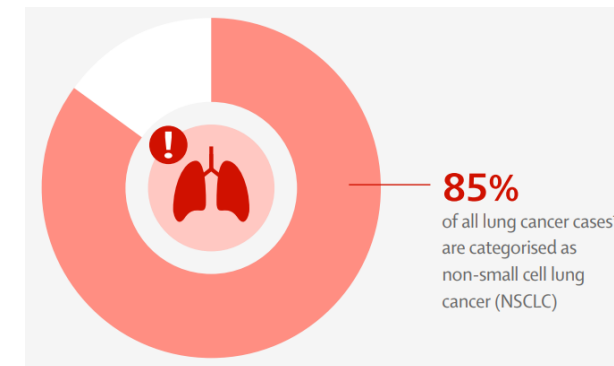
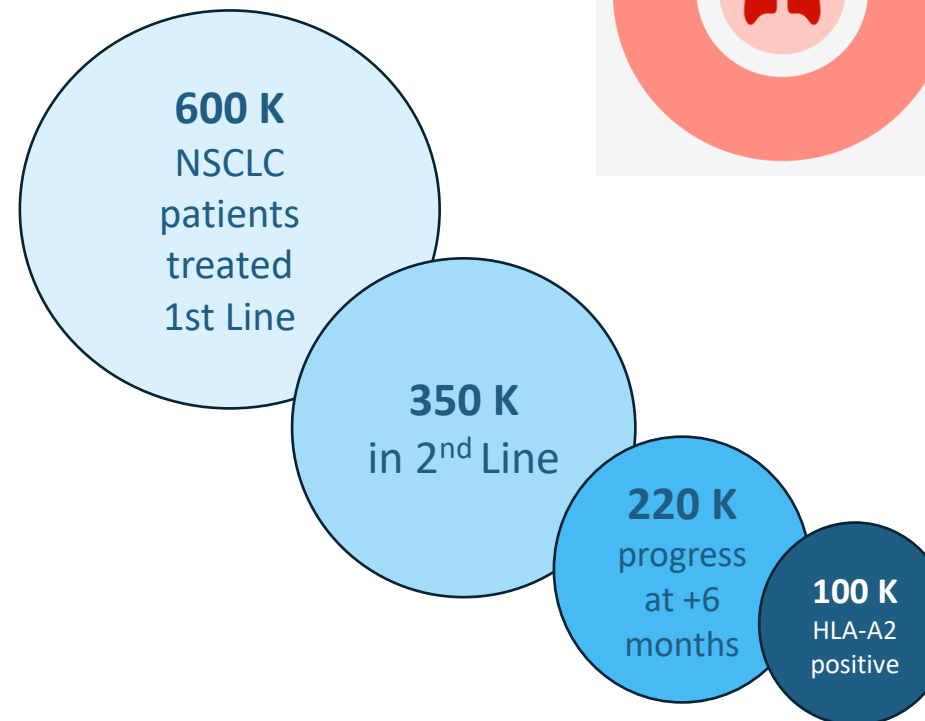
## Treatment paradigm in NSCLC with no driver mutation

- L1 : treatment anti-PD(L)1 based with/w/out chemotherapy
- L2 : docetaxel remains standard with its limited efficacy and toxicity

## Opportunity for Tedopi®

- Great opportunity for new standard without chemotherapy in a remaining high medical need after 1<sup>st</sup> line of treatment
- HLA-A2 patients represent about 45% of the patients

## Incidence of advanced NSCLC in the US/EU5/Japan\*\* + China





# Further additional potential clinical value in combination NSCLC, PDAC and OC

Phase 2 ISS trials in combination with immunotherapy or chemotherapy treatments

## 2<sup>nd</sup> line post 1<sup>st</sup> line chemo IO

**CombiTED - NSCLC**  
In combination with nivolumab



Tedopi® Plus Docetaxel or Tedopi Plus Nivolumab as 2nd line Therapy in Metastatic NSCLC failing standard 1st line Chemo-immunotherapy<sup>1</sup>

*Sponsored by FoRT*  
*PI: Federico CAPPUZZO*  
*(Roma Cancer Institute)*  
*Italy /Spain/ France*



*Readout expected H2 2026*

## Maintenance setting post standard of care

**TEDOVA - Ovarian Cancer**  
In combination with pembrolizumab



Tedopi® Alone or in Combination With Pembrolizumab vs Best Supportive Care as Maintenance in Patients with Platinum-Sensitive Recurrent Ovarian Cancer<sup>2</sup>

*Sponsored by ARCAGY-GINECO*  
*PI: Alexandra LEARY*  
*(Gustave Roussy Institute)*  
*France/ Germany/ Belgium*



*Recruitment completed Q4 2024*

*Readout expected in Q2 2026*

**TEDOPaM - Pancreatic Cancer**  
In combination with FOLFIRI



Tedopi® plus FOLFIRI vs FOLFIRI as Maintenance Treatment in Controlled Advanced or Metastatic Pancreatic Ductal Adenocarcinoma after 8 Cycles of Folfirinox<sup>3</sup>

*Sponsored by GERCOR PRODIGE*  
*PI: Cindy NEUZILLET*  
*(Curie Institute)*  
*France*



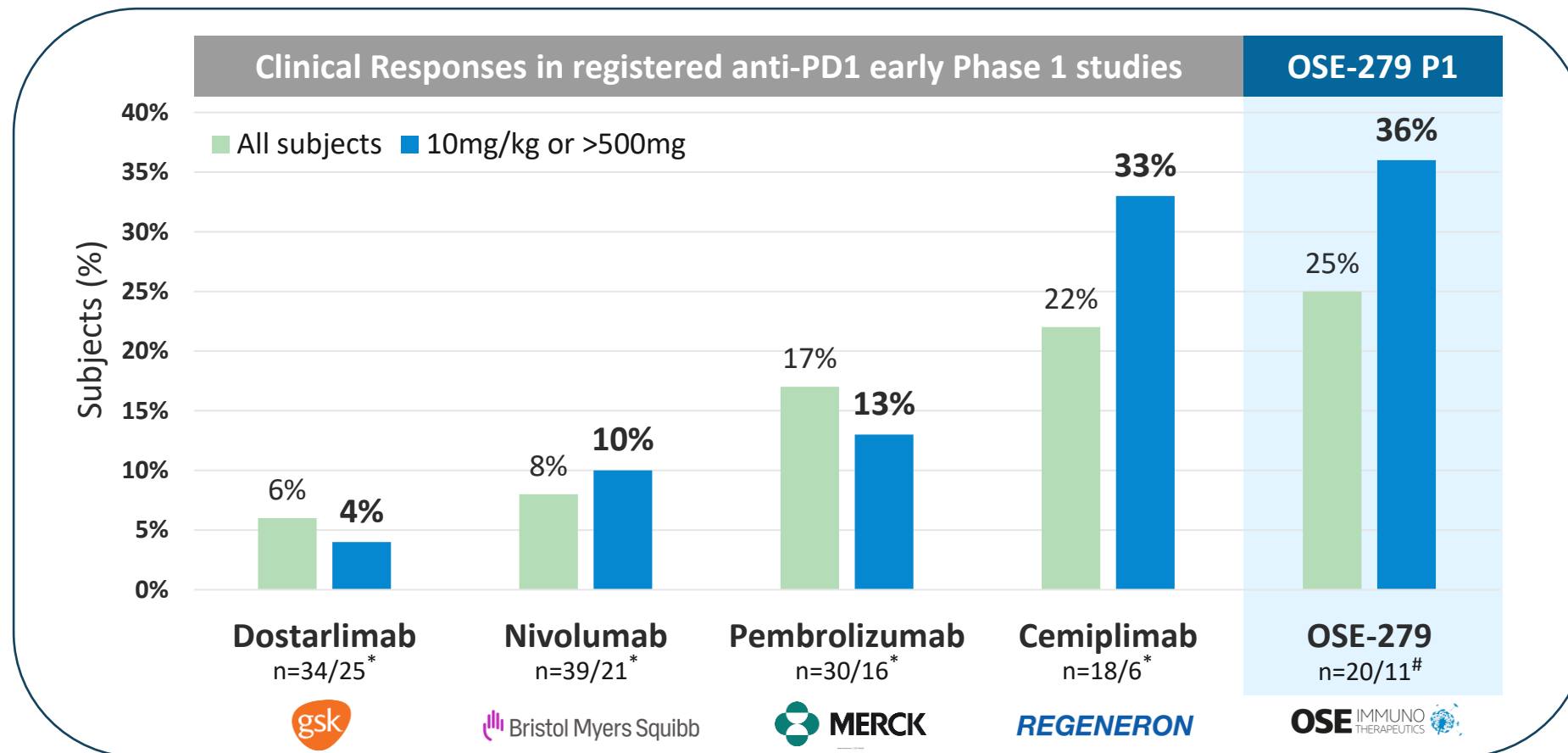
*Recruitment completed Q2 2023*

*Readout expected in H1 2025*

# OSE-279: Proprietary anti-PD1 mAb

High affinity PD-1 antibody, recent patent granted in US, Europe, China, Japan

- ❖ Potential of combo with internal asset
- ❖ Potential for partnership with biotech/biopharma in combo with external assets
- ❖ Potential future marketing approvals in orphan indications with strong unmet medical needs



Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials. For illustrative purposes only.

A silhouette of a diverse group of people of various ages and ethnicities holding hands in a line, set against a sunset or sunrise sky. The silhouettes are dark against the lighter, colorful background of the sky. The group includes men, women, and children of different heights and builds, representing a multicultural community.

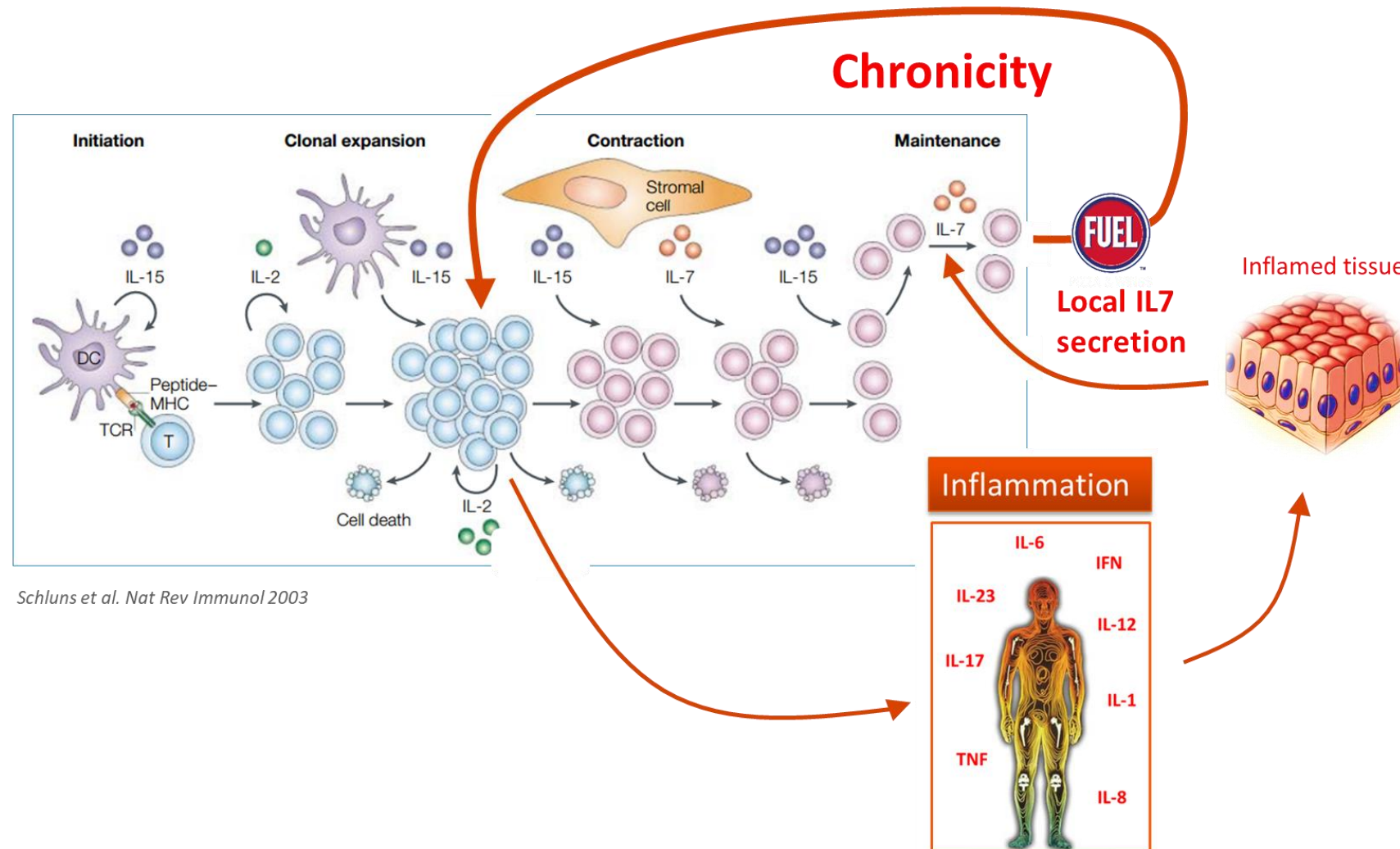
# Lusvertikimab

**Most advanced anti-IL-7R mAb**

**Strong biological rationale in refractory IBD patients**

# IL-7 fuels chronic inflammation in tissues

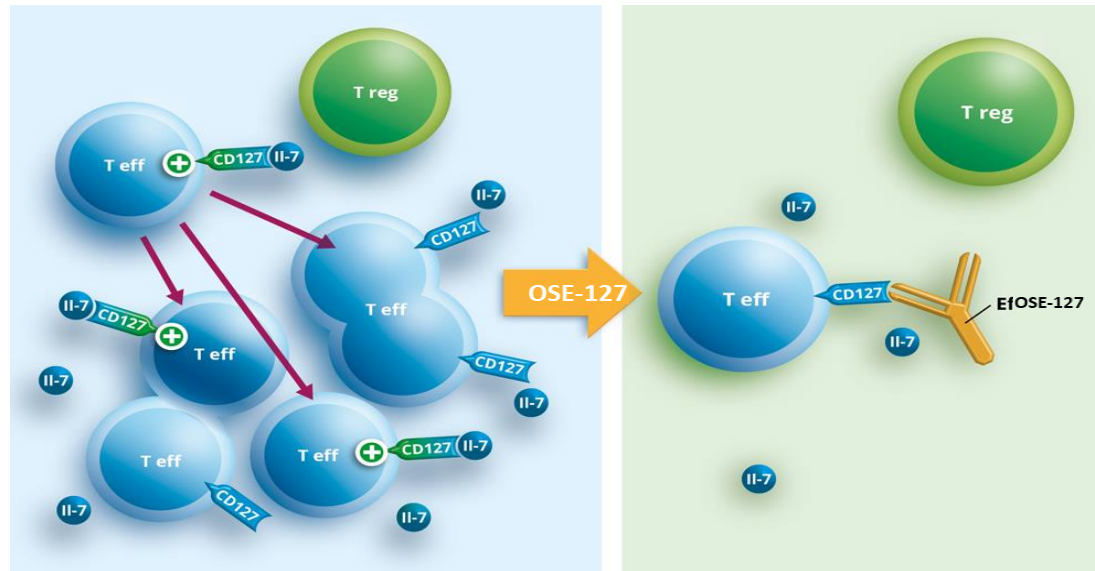
Lusvertikimab controls pathogenic memory T-cell persistence



# Lusvertikimab/OSE-127

## Pure IL-7 receptor antagonist mAb

Tackling the fuel of memory T-lymphocytes while sparing Tregs



### A differentiated and highly qualified candidate

- IL-7 produced by inflamed tissues sustain T-cell survival and chronicity, drives Th1 and Th17 T cell differentiation
- IL-7R pathway overexpression in anti-TNF IBD non-responders<sup>1</sup>
- Lusvertikimab, first non-internalizing (fully antagonist) acting as pure antagonist anti-IL-7R mAb<sup>2</sup> – no antagonist activity on TSLP
- **Good safety, PK/PD profile in Phase 1<sup>3</sup>, no cytokine release, confirmed target-engagement**
- **Positive Phase-2 study in UC Top-line Results Q3 2024**
- High preclinical activity in acute leukemia (T and B-ALL)<sup>4</sup>  
**ASH Merit Award- ALL**

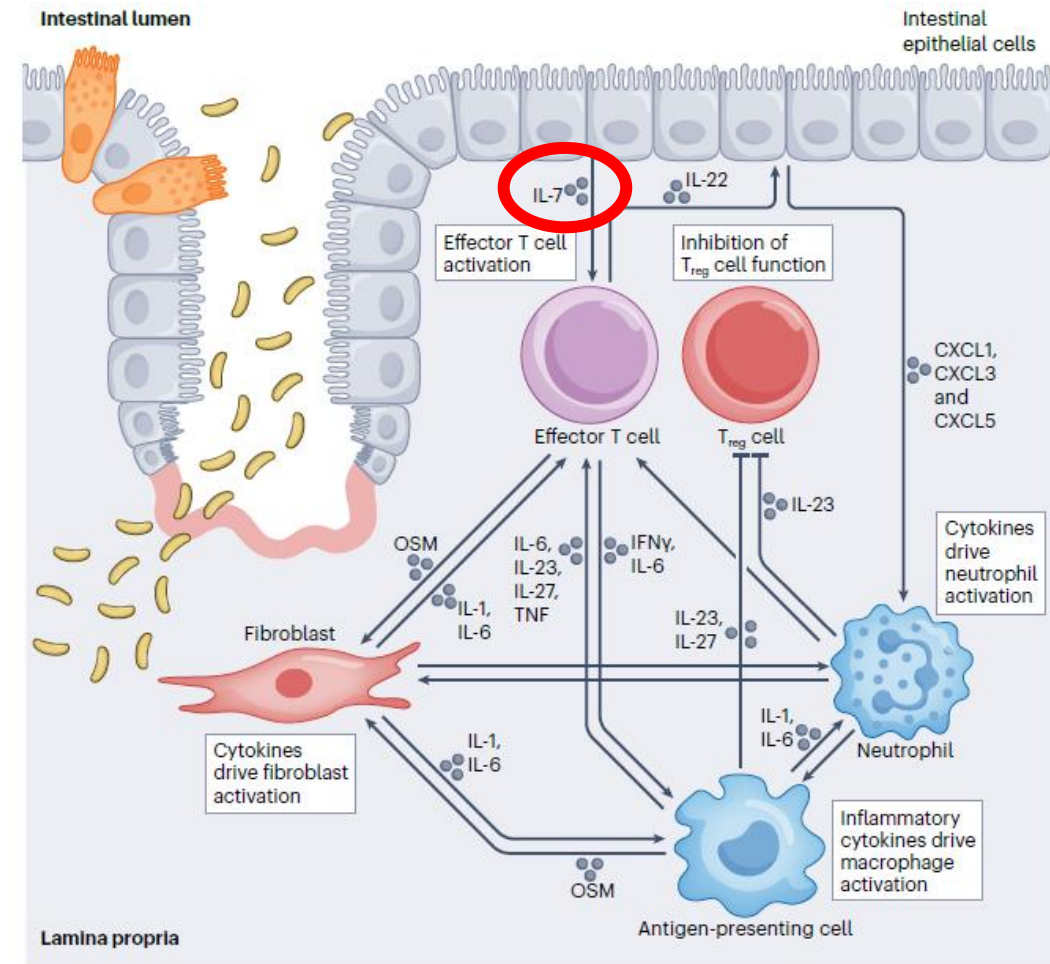


# IL-7 downstreams mechanism of resistance in hyper-inflammatory IBD

The ‘angry’ cell concept and resistance to anti-cytokine therapies.

“Recent evidence suggests the presence of highly pro-inflammatory — or ‘angry’ — cells in the intestinal mucosa in inflammatory bowel disease (IBD) that drive molecular resistance to anti-cytokine therapy (such as anti-tumour necrosis factor (anti-TNF) and anti-IL-12/IL-23 therapies). »

« Intestinal epithelial cells (IECs) produce cytokines such as **IL-7** to activate effector T cells and can produce chemokines such as CXCL1, CXCL3 and CXCL5 to induce neutrophil recruitment and activation.”

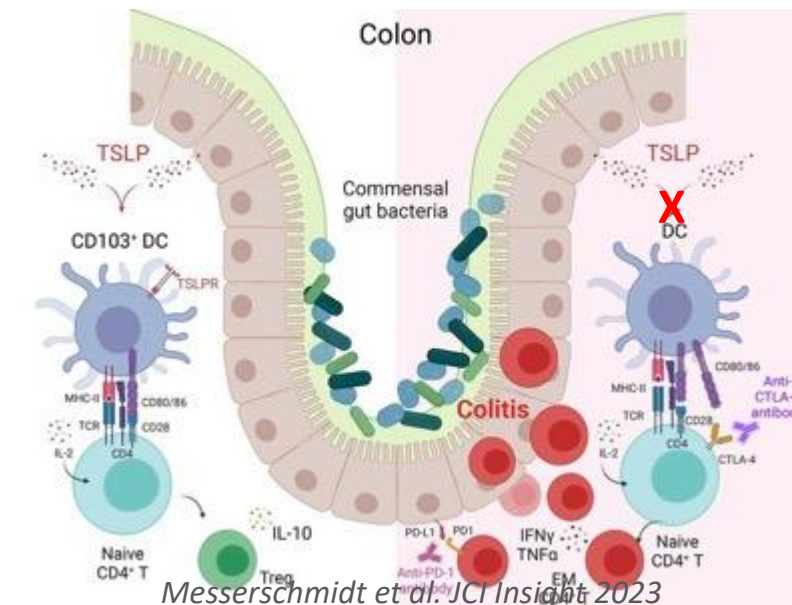
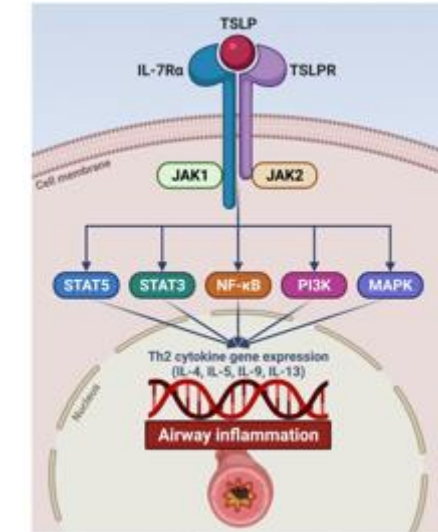


Neurath M. Nature Review Immunology 2024

# Protective role of TSLP in intestinal immunity

## Lusvertikimab selectively blocks IL-7 but not TSLP axis

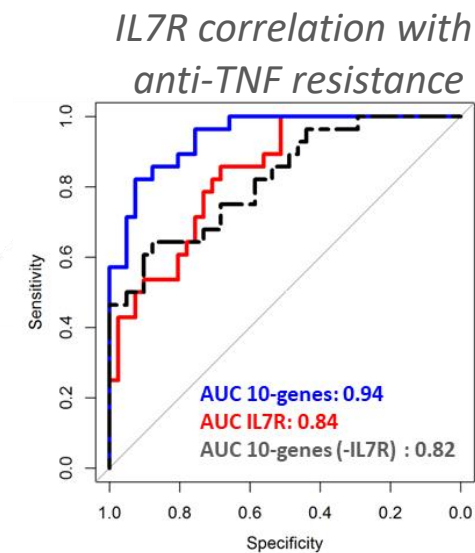
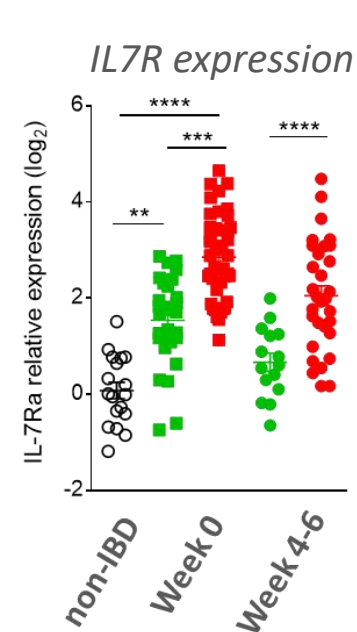
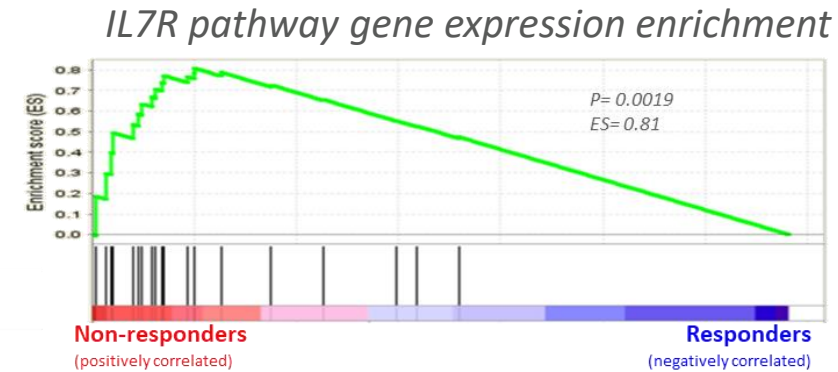
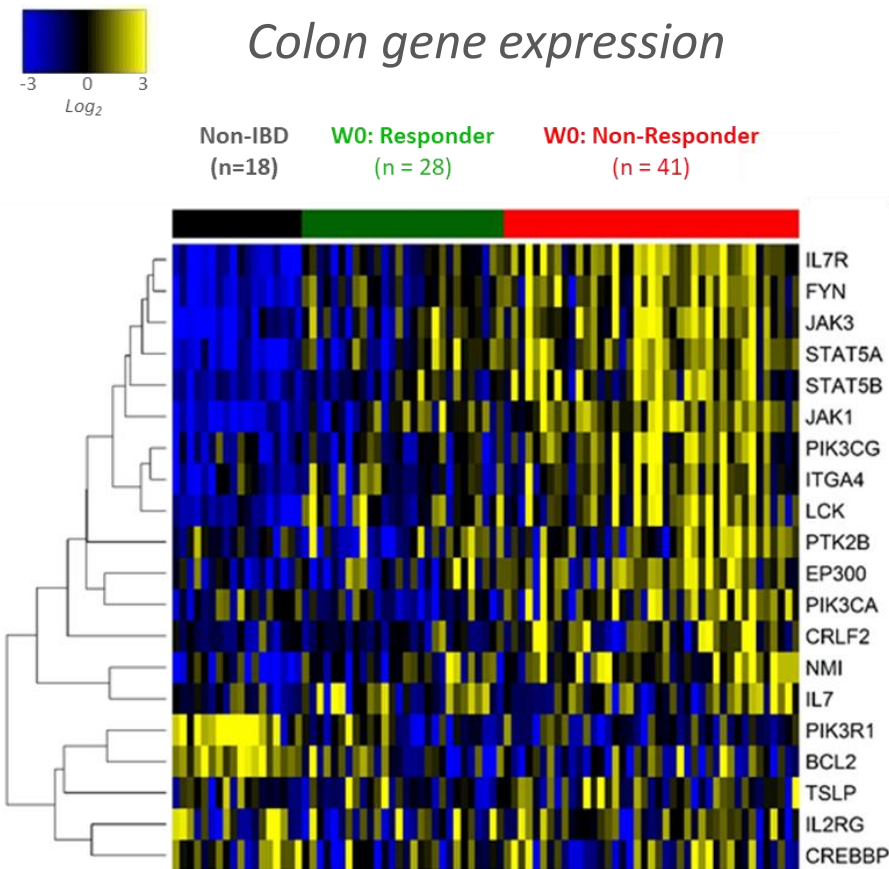
- TSLP drives Th2 responses → Pathogenic role in allergic diseases & atopic responses
- TSLP drives Foxp3+ Treg induction by DCs against commensal bacteria  
(Spadoni et al. *Mucosal Immunology* 2012; Jiang et al. *Bio Med Central Immunology* 2006)
- TSLP protects against colitis & intestinal disorders (∇ intestinal cytokine)  
(Aubry et al. *Microbial Cell Factories* 2015; Ziegler et al., *Adv Pharmacol* 2013; Spadoni et al. *Mucosal Immunology* 2012; Ordonez et al. *Inflamm Bowel Dis* 2012; Abraham et al *Gastroenterology* 2011)
- TSLP blockades or TSLP deficient mice exacerbates severe colon inflammation & gut inflammatory cytokines (IFN $\gamma$ , IL23, IL12p40...)  
(Messerschmidt et al. *JCI Insight* 2023; Reardon et al. *Immunity* 2011; Taylor et al. *J Exp Med* 2009)
- Decreased TSLP gene expression in IBD associated with severity  
(Messerschmidt et al. *JCI Insight* 2023; Tahaghoghi-Hajghorbani et al. *Auto Immu Highlights* 2019; Noble et al *Infl Bow Dis* 2010; Middel et al. *Gastroenterology* 2006; Rimoldi et al. *Nature Immunol* 2005)



Messerschmidt et al. *JCI Insight* 2023

# Mucosal IL-7R pathway over-expression in IBD tissues

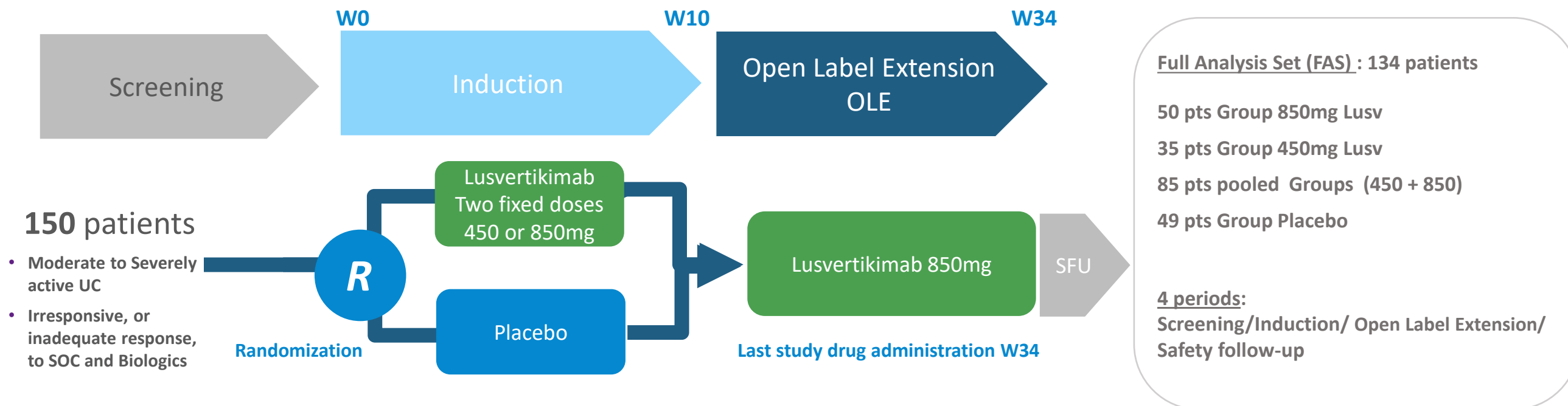
High IL-7R expression in anti-TNF refractory patients



Anti-TNF Responder patients  
Anti-TNF Refractory patients

# CoTikiS Phase 2 randomized study of Lusvertikimab

## Moderate-to-severe Ulcerative Colitis



Multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase 2 study in patients with moderate to severe active UC

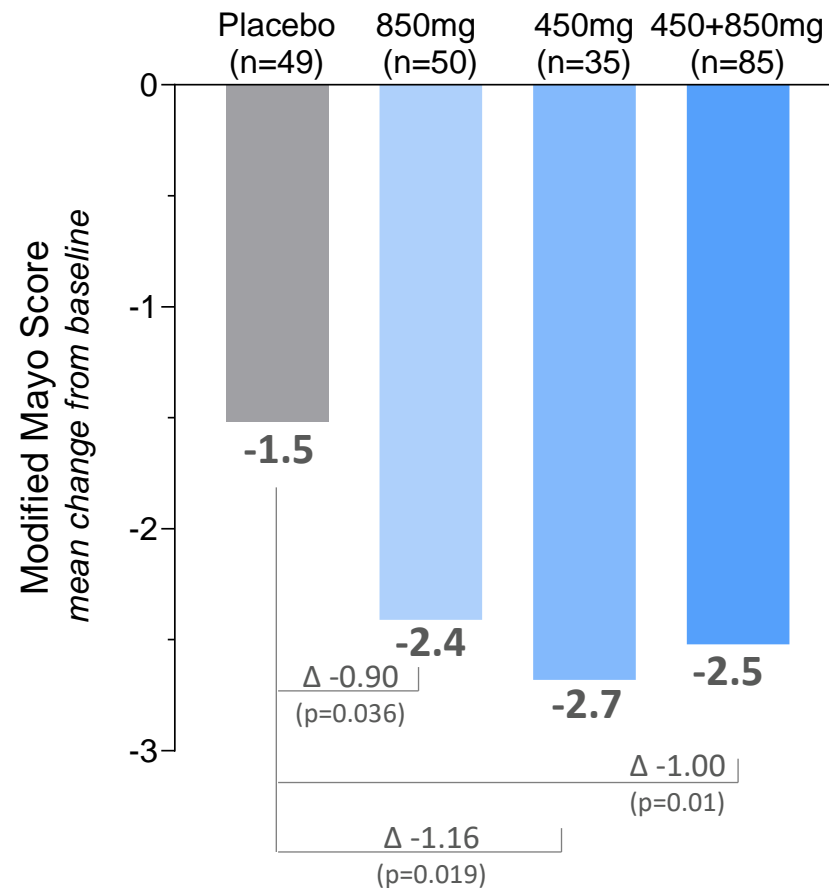
**Induction:** Lusv group 450mg/ Lusv group 850mg/ Placebo: IV infusions at Week 0, Week 2, Week 6. Analysis at W10

**Open Label Extension OLE:** At Week 10, additional infusions proposed for all patients at 850mg every 4 weeks for 6 months (W10, 14, 18, 22, 26, 30, 34)

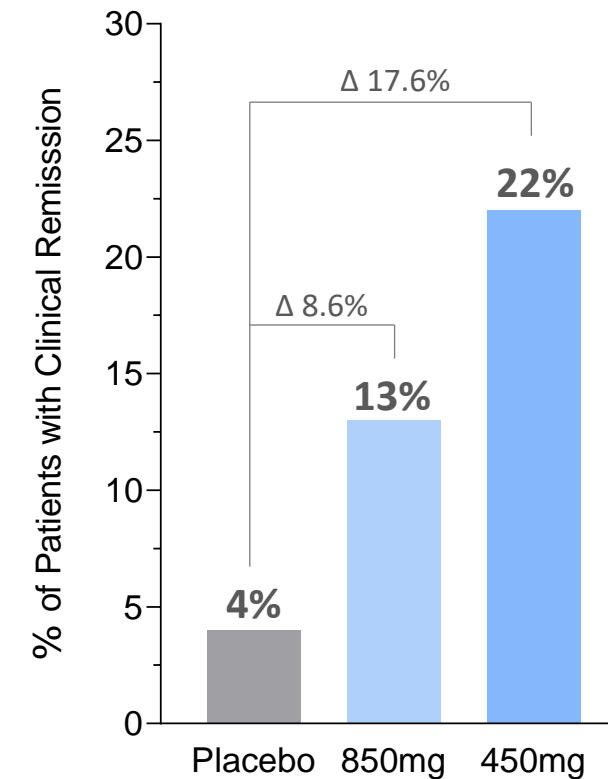
# Clinical induction results at week-10

Clinically and statistically relevant clinical improvement in the Lusvertikimab groups

## Primary Endpoint: Modified Mayo Score Improvement (MMS)\*



## Clinical Remission\*\*



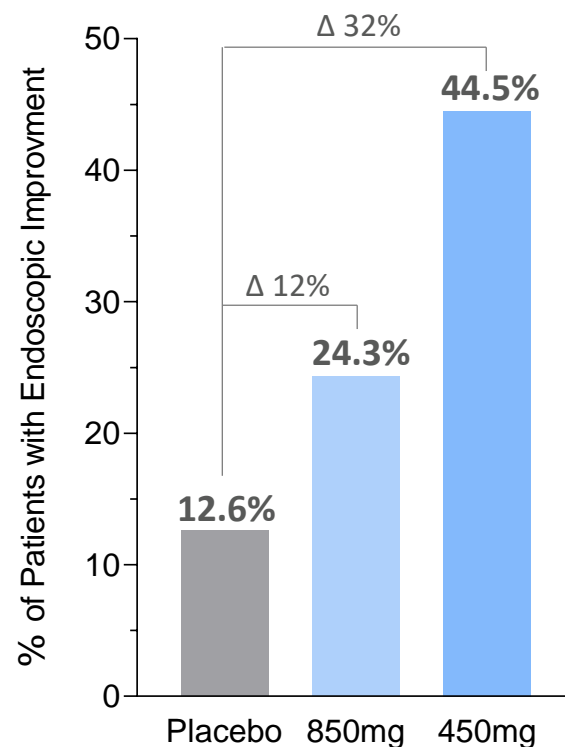
\* Least Square Mean Difference between Lusvertikimab and placebo= difference between groups of the Mean change in MMS between baseline and W10



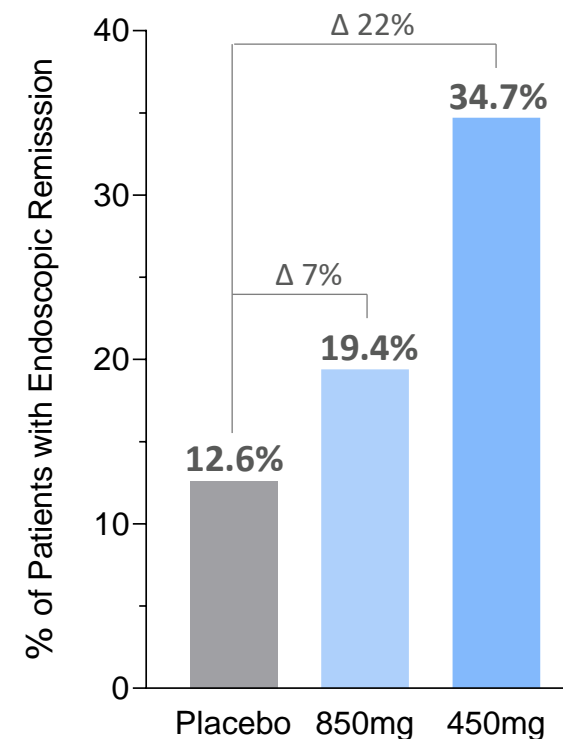
# Clinical induction results at week-10

Clinically meaningful and significant endoscopic improvement and remission

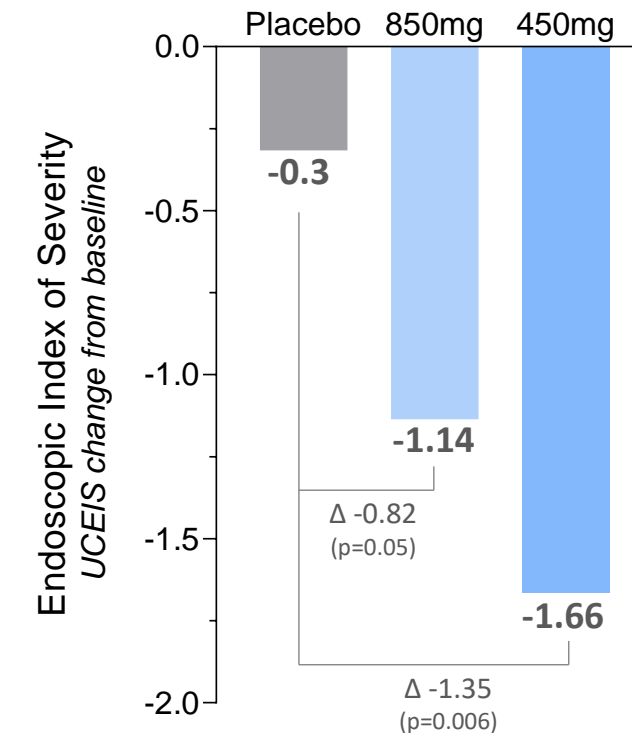
## Endoscopic Improvement\*



## Endoscopic Remission\*\*



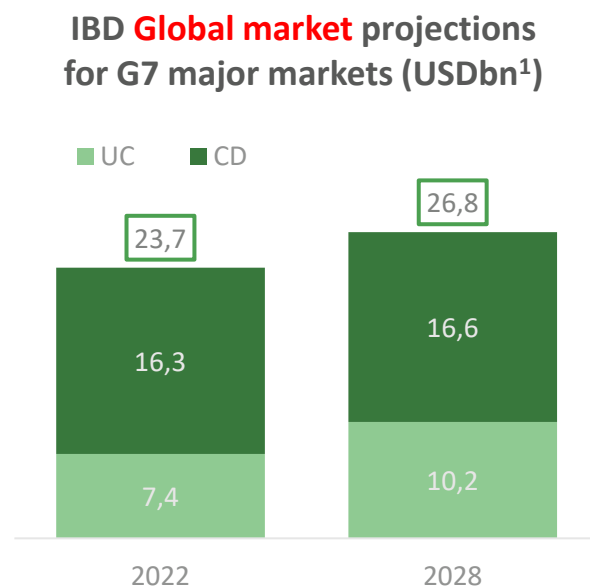
## UC Endoscopic Index of Severity UCEIS\*\*\*



# Significant opportunity in Ulcerative Colitis & Acute Lymphoblastic Leukemia targeted markets

## Ulcerative Colitis (UC)

- UC affects **3.3 million patients** in US, Europe and Japan
- ~50% UC patients “moderate to severe”, requiring methotrexate, corticosteroids, anti-TNFa, JAK etc.
- Despite broad options, remission rates are of only 25-30% leaving most patients without satisfactory treatment



## Acute Lymphoblastic Leukemia (ALL)

- ALL is a rare disease with a diagnosed incident cases in EU, US, China, Japan estimated to achieve 26,482 in 2029<sup>2</sup>.
- 40% cases of ALL diagnosed are in adults and among them about 50% present refractory disease or undergo relapse under current conventional therapies<sup>3</sup>.
- IL-7R expression in >84% of B-ALL and T-ALL samples<sup>4</sup>

**ALL Global market projections for G7 major markets (USDbn<sup>5</sup>)**





Partnered clinical programs

# Resolution of inflammation

Pr. C. Serhan, Harvard  
seminal works  
(OSE SAB member)



NEWS | FEATURES



## Inflammation's **STOP SIGNALS**

Inflammation doesn't just peter out. The body actively shuts it down, using signals that researchers hope to transform into therapies *By Mitch Leslie*

### Players in the endgame

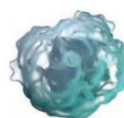
An assortment of molecules shut down inflammation and promote tissue healing by targeting different cells.



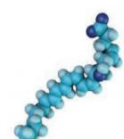
**Lipoxins**  
Lipids whose jobs include stimulating macrophages and preventing neutrophils from slipping between endothelial cells to enter damaged tissue.



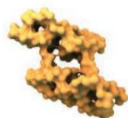
**Protectins**  
Lipids that curtail release of inflammation-promoting molecules and are protective in the nervous system.



**Macrophages**  
After clearing an infection, these immune cells consume proinflammatory cellular remains.



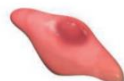
**Resolvins**  
Family of lipids that block neutrophils' exit from the bloodstream and prod macrophages to eat cellular debris.



**Annexin A1**  
A protein released by dying neutrophils, its functions include preventing other neutrophils from entering the injured site.



**Neutrophils**  
First responders to wounds and infections, they release inflammatory cytokines.



**Endothelial cells**  
These cells form the walls of blood vessels and make H<sub>2</sub>S.



**Maresins**  
Made by macrophages, lipids that spur tissue repair and act on nerves to ease pain.



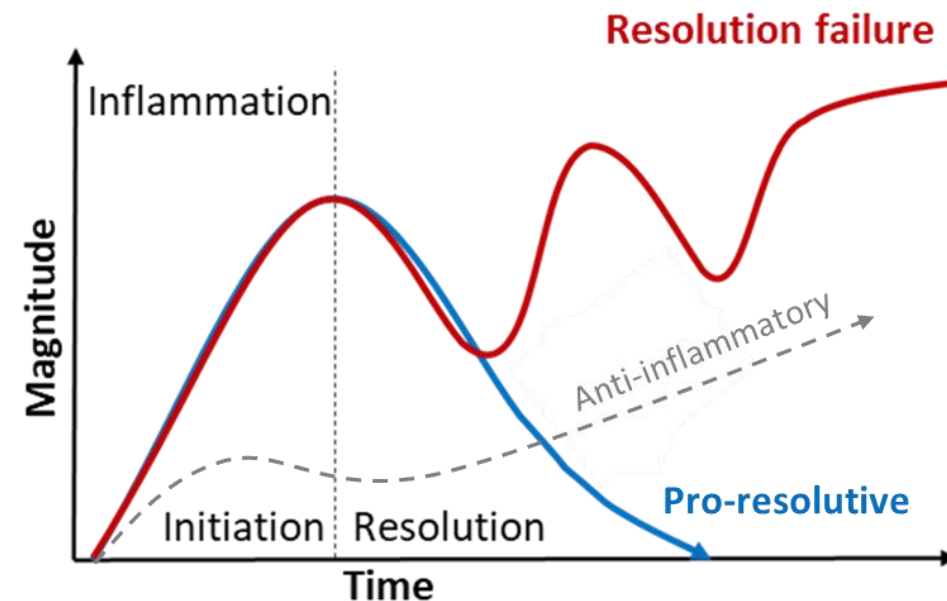
**Hydrogen sulfide**  
Message-carrying gas that reduces pain and stimulates neutrophils to commit suicide.



**Nerves**  
Inflammatory molecules trigger nerve cells, creating pain and itchiness.

SCIENCE sciencemag.org

2 JANUARY 2015 • VOL 347 ISSUE 6217 19



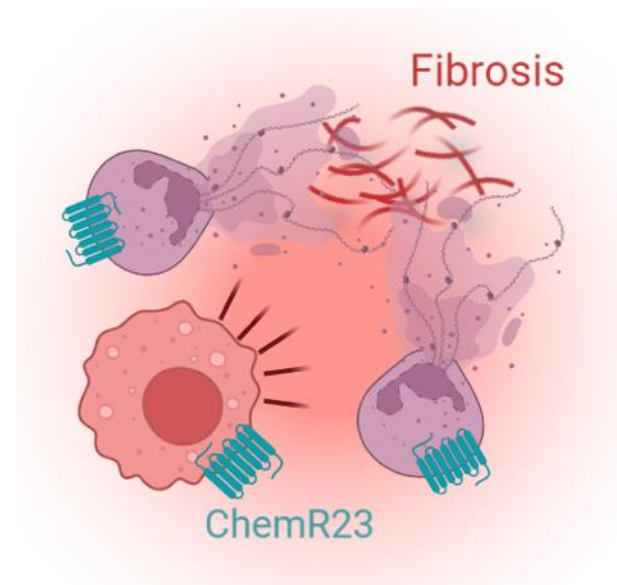


# ABBV-230 - Resolving inflammation is an active immune process



## During chronic inflammation

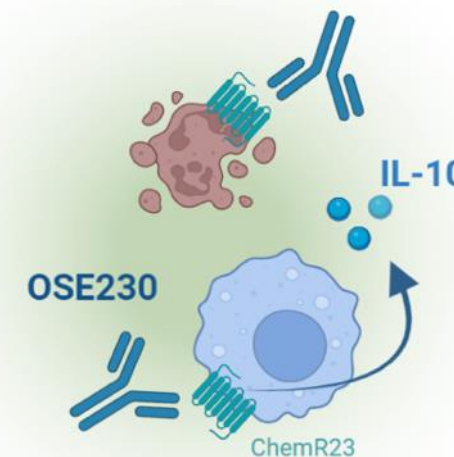
Dying neutrophils **send out inflammatory signals (e.g. NETosis)** that are important in maintaining chronic inflammation & fibrosis



## With ChemR23 agonistic mAbs

ABBV-230 limits recruitment, survival & NETosis of inflammatory neutrophils & reprograms macrophages, **removing further chronic inflammatory signals**

### Restoration of homeostasis



Potential First-in-class pre-IND candidate

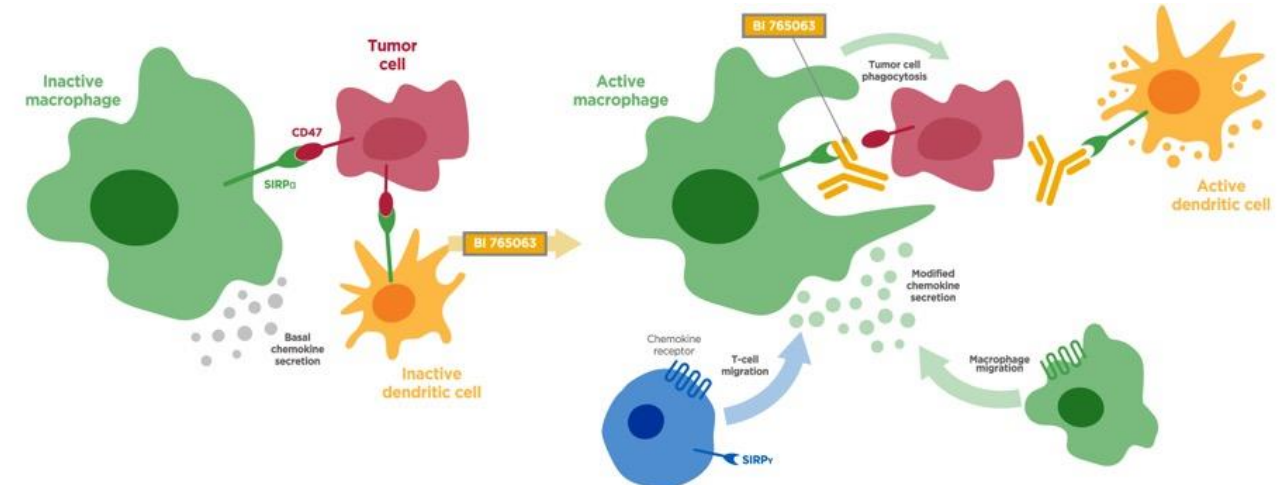
Published in **ScienceAdvances**  
MAAS



# SIRP $\alpha$ inhibition may have a synergistic antitumour effect when combined with ICIs

- Infiltrating **myeloid cells promotes immune evasion**, and this has generated interest in **myeloid-immune targets**<sup>1,2</sup>
  - The CD47–SIRP $\alpha$  interaction transduces inhibitory signals on macrophages and other myeloid cells<sup>2</sup>
- Preclinical studies have indicated that **CD47 or SIRP $\alpha$  blockade in combination with ICIs** may have a synergistic antitumour effect<sup>3</sup>

The use of SIRP $\alpha$  antagonists to enhance antitumour immunity is currently being explored<sup>4</sup>



	Anti-CD47	Anti-SIRP $\alpha$
Broad/restricted expression	Broad	Restricted to cells of the myeloid lineage
Safety signals	Acute anemia, Thrombocytopenia	<b>No hematotoxicity</b>
Interaction CD47/SIRP $\gamma$	<b>Inhibit human T cells</b>	OSE-172 is SIRP $\alpha$ specific

Limited **side effects** expected and less frequent dosing

Higher therapeutic window expected

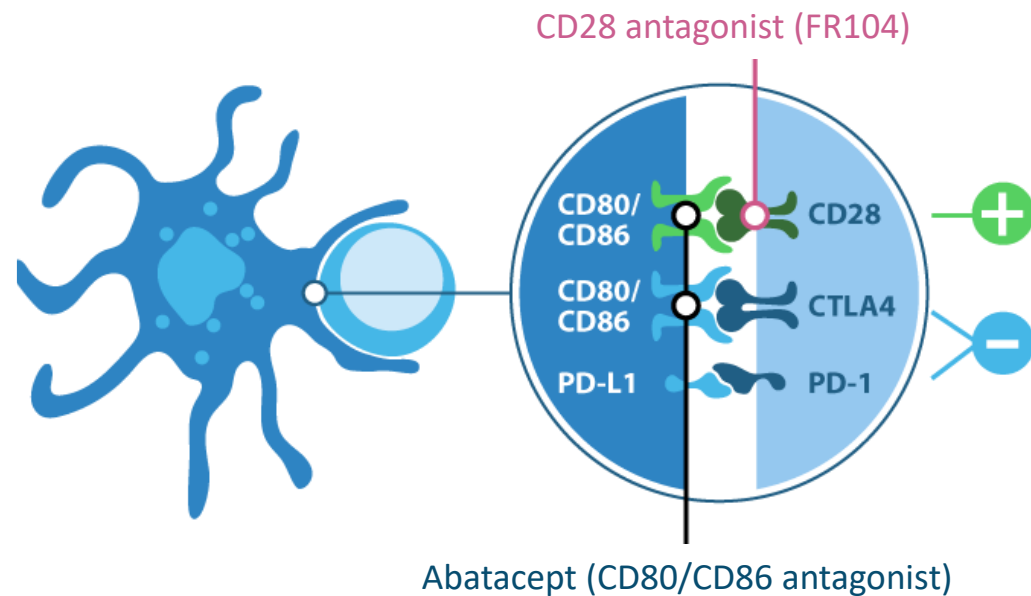
Favors T cell responses in solid tumors

CD: cluster of differentiation; ICI: immune checkpoint inhibitor; SIRP $\alpha$ : signal regulatory protein- $\alpha$ .

# FR104/VEL-101

## CD28 antagonist in organ transplantation

### Selective CD28 antagonist mAb in Kidney Transplantation



### Ambitious Partnership & Development Plan with Veloxis

- **Veloxis** is a global leader in transplantation with leading product Envarsus XR (tacrolimus) realizing c. **USD 140m<sup>1</sup>** turnover; Joined **Asahi Kasei** in FY2019<sup>2</sup>, a **USD 17bn** annual turnover conglomerate with healthcare representing 17% of sales
- **Strong Preclinical data in Kidney & Cardiac transplantation + GVHD<sup>3,4,5</sup>**
- **Positive Phase 1/2 in kidney transplantation (intravenous)<sup>6</sup>**
- **Positive Phase 1 subcutaneous<sup>7</sup>**

*Phase 2 in kidney transplantation (subcutaneous) under preparation by Veloxis*

# FR104/VEL-101 - Transforming kidney transplant management



## Positive results of the FIRsT phase I/II clinical evaluation in kidney transplantation<sup>1</sup>

Good Safety profile and early sign of efficacy:

- *Drug exposure allow high receptor occupancy maintenance during the one-year follow-up.*
- *No acute rejection under FR104/VEL-101 treatment, including after calcineurin-inhibitor (CNI) discontinuation.*
- *No biopsy-proven acute rejection (BPAR) observed at 1-year*
- *No donor-specific antibodies (DSA) detected at 1-year*

## Kidney Transplant Market: A multi-billion-dollar commercial opportunity

- **45k+** new kidney transplant annually for an estimated **500k+** people living with a functioning kidney graft in G7 countries
- 90k+ Americans in transplant waiting list, many transplanted patients require repeat transplants
- Chronic exposure to **CNIs** is associated with **renal toxicity**, cardio-metabolic complications, **insufficient** graft protection as well as **cancer** and **infections**
- FR104/VEL-101 seeks to address challenges associated with current immunosuppressive transplantation regimens using CNI-based therapies

# The OSE team



# An experienced executive leadership team



Nicolas Poirier, PhD  
CEO

- 20 years of experience in biotech/immunotherapy
- Advanced 6 novel immunotherapies to clinic
- Leading to 6 pharma deals
- Global Management & Finance (INSEAD, HEC)



Sonya Montgomery, MD  
CHIEF DEVELOPMENT OFFICER

- 20+ years in Pharma / Biotech
- Global management, portfolio strategy, development plans, regulatory, from discovery through registration (Pfizer, Gyroscope Tx, Evox Tx, Transition Tx, Relypsa, ProQR, Vasogen ...)



Anne-Laure Autret-Cornet  
CHIEF FINANCIAL OFFICER

- 15+ years in Finance / Biotech
- Graduated from ESSCA Management school
- Corporate Finance, HEC



Fiona Olivier  
CHIEF CORPORATE AFFAIRS &  
INVESTOR RELATIONS OFFICER

- 30+ years in international communications, public affairs and patient engagement at global companies (Sanofi, AbbVie, Abbott, GSK)
- Degree in Communications (DCU) & Master in Public Affairs (Sciences Po)



Jean-Jacques Mention, PhD  
CHIEF BUSINESS OFFICER

- 15+ years of Research in Immunology at King's College London & Institut Pasteur
- 10 years experience in Business Development



Silvia Comis, MD  
HEAD OF CLINICAL

- 30+ years in Pharma
- Previously Senior Medical Director IQVIA, and European Head of Early Products Medical Affairs in oncology at Novartis



Aurore Morello, PhD  
HEAD OF RESEARCH

- 13+ years in Immunotherapy (mAb, bispecific, CAR-T)
- International Post-doctoral Fellowship (MSKCC, NYC)



# A Board of Directors combining international expertise in medicines development, industry & finance, and experience in listed biotech companies



**Didier Hoch, MD**  
Chairman



25+ years in pharma and vaccine industry (Sanofi-Pasteur MSD, Rhone-Poulenc)

Several functions incl. commercial, marketing, general management



**Maryvonne Hiance**  
Vice Chairwoman



Founder and CEO of Effimune

General Manager SangStat Atlantic, DrugAbuse Sc.

Former President & Vice President of France Biotech



**Nicolas Poirier, PhD**  
Director, CEO & Chief Scientific Officer



20 years in biotech/immunotherapy  
Advanced 6 novel therapies to clinic leading to 6 pharma deals

Global Management (INSEAD,HEC)



**Anne-Laure Autret-Cornet**  
Chief Financial Officer



15+ years in Finance & Biotech  
ESSCA Management School  
Finance Corporate, HEC



**Marc Dechamps**  
Independent Director



35+ years in pharma industry (GSK, ViiV Healthcare)  
Expertise in market development for new products, I&I, I/O, vaccines  
CEO of Bioxodes



**Markus Goebel, MD, PhD, MBA**  
Independent Director



30+ years in the Life Science industry (Novartis, Roche)

Positions in BD&L, Corporate M&A, Corporate Venture Funds

Founder & CEO of M&G Advisor

Certified MD in oncology/hematology, MBA



**Martine George, MD**  
Independent Director



30+ years in pharma & academic in the US (Pfizer, J&J, Sanofi, Sandoz-Novartis)  
Service Chief Gustave Roussy, Cancer center

Expertise in clinical research, drug development, medical and regulatory affairs specializing in oncology



**Eric Leire, MD**  
Independent Director



Genflow Bioscience CEO  
Previously chairman & CEO of several biotech companies listed in US  
Previous Marketing Director position in Pharma US & EU



**Cécile Nuyen-Cluzel**  
Independent Director



Extensive experience in financial engineering & healthcare private equity. Senior advisor in healthcare for France & Europe at Apposite Capital. Master 2 « Ingénierie financière & « Leading the digital transformation in healthcare »certification from Harvard Medical School



**Brigitte Dréno, MD**  
Independent Director



25+ years in pharma and vaccine industry (Sanofi-Pasteur MSD, Rhone-Poulenc)  
Several functions incl. commercial, marketing, general management

# International Scientific Advisory Board (SAB) - renowned experts in IO and I&I



**Wolf-Hervé Fridman, MD**

Chairman of the SAB, Professor Emeritus of Immunology at the Université de Paris, France



**Myriam Merad, MD, PhD**

Director of the Precision Immunology Institute at Mount Sinai School of Medicine in New York and Director of the Mount Sinai Human Immune Monitoring Center (HIMC)



**Charles N. Serhan, PhD, DSc**

Professor of Anaesthesia (Biochemistry and Molecular Pharmacology) at Harvard Medical School, Professor of Oral Medicine, Infection and Immunity at Harvard School of Dental Medicine



**Jennifer Wargo, MD, M.M.Sc**

Professor of Genomic Medicine & Surgical Oncology, UT MD Anderson Cancer Center



**Bernard Malissen, PhD**

Group Leader at Centre d'Immunologie de Marseille-Luminy and Founding-Director of Center for Immunophenomics, Marseille, France



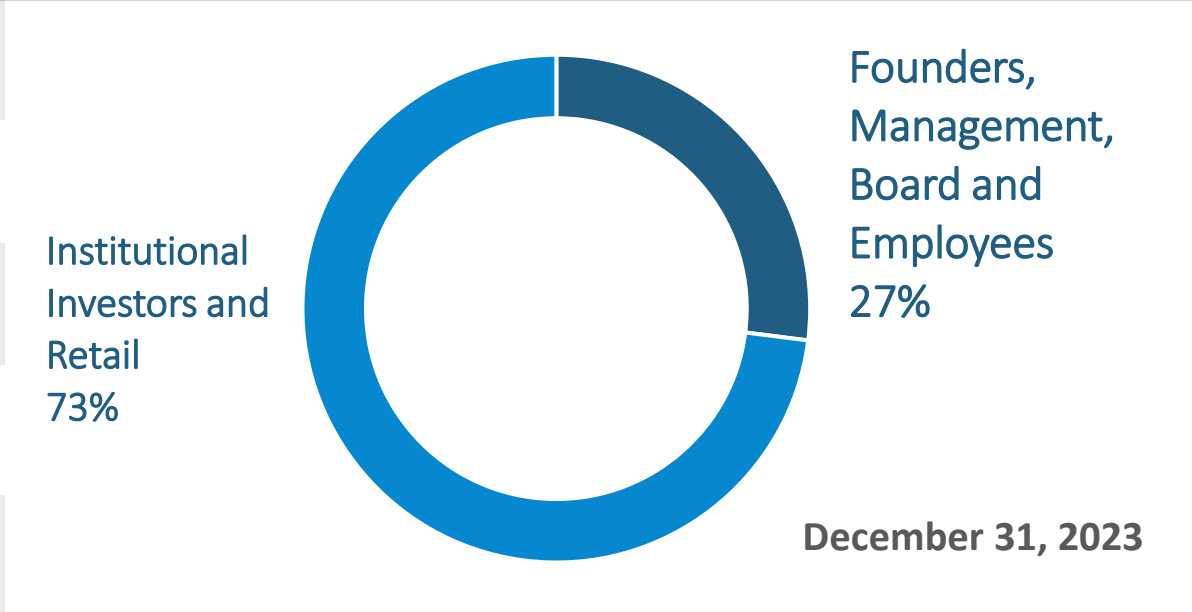
**Sophie Brouard, PhD**

Immunologist and Director in Veterinary Sciences, Director of Research at the Institut National de la Santé et Recherche Médicale (Inserm, National Institute for Health and Medical Research) in Nantes

# Key financial and shareholding structure

Key financials		Shareholding structure	
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ISIN code	FR0012127173
Market	Euronext Paris
Shares outstanding	21 817 777
Market cap <i>(Sept 5, 2024)</i>	€193 m
Level of Cash <i>(June 30, 2024)</i>	€80.7 m (of which €75.7 m classified in financial assets)
Financial visibility	2027



### Analyst coverage



**OSE** IMMUNO  
THERAPEUTICS



Breaking through the  
therapeutic ceiling with  
first-in-class immunotherapies

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Immuno-Oncology & Immuno-Inflammation

**Head Office**  
22, boulevard Bénoni Goullin  
44200 Nantes, France

**Paris Office**  
10, Place de Catalogne  
75014 Paris, France

Company Information: <http://ose-immuno.com/en/>