



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

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October 2025

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# Investment highlights

## Compelling portfolio of late-stage, OSE-owned programs

**Tedopi®**, is a potential first-to-market oncology vaccine, currently in pivotal Phase 3 study  
**Lusvertikimab**, an anti-IL7R antibody, represents a first-in-class and best-in-class program across a range of I&I indications including IBD, with positive Phase 2 proof-of-concept data in UC

## Large market opportunities

### Focus on multi-billion \$ markets

- **I&I**: Ulcerative colitis (IBD), Cardiovascular-Renal-Metabolic diseases (MASH), Kidney Transplantation
- **I/O**: NSCLC (2L, 3L), PDAC, HNSCC (2L)

## Multiple near-term value inflection catalysts

### Multiple key clinical and regulatory milestones expected in near term

- **Tedopi®**: Confirmatory pivotal Phase 3 NSCLC 2L and combination Phase 2 readouts (OC, NSCLC)
- **Lusvertikimab**: Phase 2b initiation and subcutaneous formulation development
- **BI 770371**: Phase 1b results in solid tumors + Phase 2a results in MASH
- **Pegrizeprium (FR104)**: Phase 2 initiation in Kidney Transplantation
- **ABBV-230 (OSE-230)**: Phase 1 initiation

## Strong Pharma partnerships

### Sustainable business through multi-partnership strategy

> **€2.1bn milestones** (+€60m potential milestones over the next 4 years): AbbVie, Boehringer Ingelheim, Veloxis

## Long duration IP portfolio

### IP extends to 2040s

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

## Financial position

### Cash runway until the beginning of Q4 2026

Cash position at **€41.6 million** as of June 30, 2025, providing financial visibility until the beginning of Q4 2026\*

# An experienced executive leadership team



Marc Le Bozec  
**Interim Chief Executive Officer**

- Currently supports numerous biotech companies as an advisor, board member and investor
- Previously created and managed two biotech investment funds within Financière Arbevel
- Previously CEO of Cellectis
- Graduated from HEC
- Previous companies:



Nicolas Poirier, PhD  
**Chief Scientific Officer**

- 20+ years of experience in Immunotherapy
- Advanced 6 novel immunotherapies to clinic, ultimately leading to six pharma deals
- Global management & finance education (INSEAD, HEC)
- Previous companies:



Thomas Gidoïn  
**Chief Financial Officer**

- 15+ years in pharma / biotech
- 10+ years as CFO in both private and public biotechs, Euronext and Nasdaq IPOs
- Msc in international finance, Msc in international management
- Previous companies:



Sonya Montgomery, ND  
**Chief Development Officer**

- 20+ years of experience in pharma / biotech
- Global management, portfolio strategy, translational, clinical and regulatory leadership roles (CMO, Head of clinical development) from discovery through registration
- Previous companies:



Silvia Comis, MD  
**Chief Clinical Research Officer**

- 30+ years of pharma experience
- Previously held positions of Senior Medical Director and European Head of Early Products Medical Affairs in Oncology
- Certified pharmacologist and endocrinologist
- Previous companies:



Jean-Jacques Mention, PhD  
**Chief Business Officer**

- 15+ years of academic research in Immunology and virology at Necker-Enfants Malades Hospital, King's College of London & Institut Pasteur of Paris
- 10 years' experience in BD and innovation
- Achieved four major pharma business deals for OSE
- Previous companies:



Fiona Olivier  
**Chief Corporate Affairs & Investor Relations Officer**

- 30+ years in international communications, public affairs and patient engagement
- Degree in communications & Master in Public Affairs
- Previous companies:



Aurore Morello, PhD  
**Head of Research**





- 10+ years in Immunotherapy research (mAb, bispecific, CAR-T)
- International researcher fellowship (MSK, NY)
- Previous company :









# Clinical Pipeline

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

<div></div> <div>I&amp;I</div>	Product candidate	Target	Indication	Research	IND-enabling	Phase Ia/Ib	Phase II	Phase III	Upcoming Milestones
	OSE-127 <i>Lusvertikimab</i>	Anti-IL-7R	Ulcerative Colitis					Positive Results	Complete data <i>Strategic update</i>
	BI 770371	Anti-SIRPα 	MASH						Phase 2a update
	Pegrizepriumment (FR104)	Anti-CD28 	Kidney Transplantation						Phase 2 start
	ABBV-230	Anti-ChemR23 	Chronic Inflammation						Phase 1 start
	OSE-220 <i>Pro-Resolutive mAbs</i>	Undisclosed GPCR Agonist	Chronic Inflammation						Preclinical update


<div></div> <div>IO</div>	Product candidate	Target	Indication	Research	IND-enabling	Phase Ia/Ib	Phase II	Phase III	Upcoming Milestones
	Tedopi® (OSE-2101)	Neoepitopes immunotherapy	NSCLC Mono post-ICI 2L					Pivotal Phase 3 (EU/US) Positive Results	Phase 3 update
			Pancreas cancer Combo (IIS)						Phase 2 presentation
			Ovarian cancer combo (IIS)						Phase 2 readout H1-2026
			NSCLC Combo 2L (IIS)						Phase 2 readout H2-2026
			NSCLC 1L combo OSE-279						Phase 1b combo data
	BI 770371	Anti-SIRPα 	Solid tumors (HNSCC)						Phase 1b results
	IL-7R CAR-T	IL-7R CAR-T 	IL-7R+ tumors						IND
	Anti-PD1/cytokine	Undisclosed 	Solid tumors						Preclinical update

# Research platforms

Extra(not) Ordinary Research PowerHouse




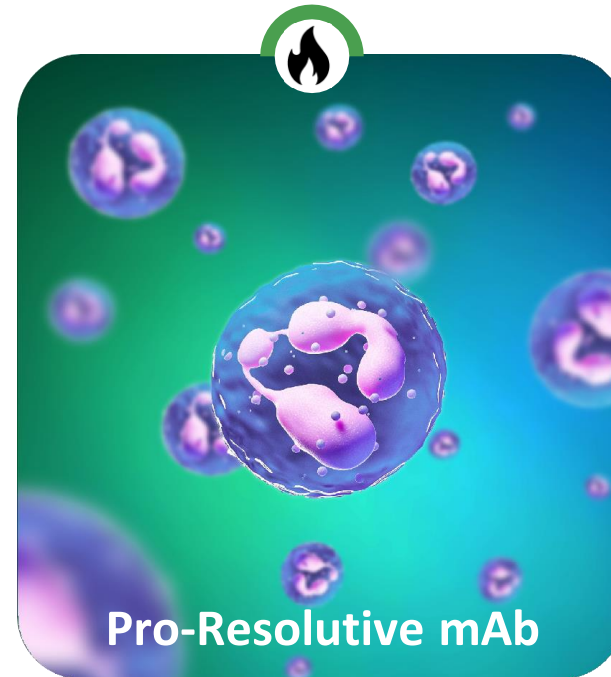
**Myeloid Checkpoint**

- ▶ 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**

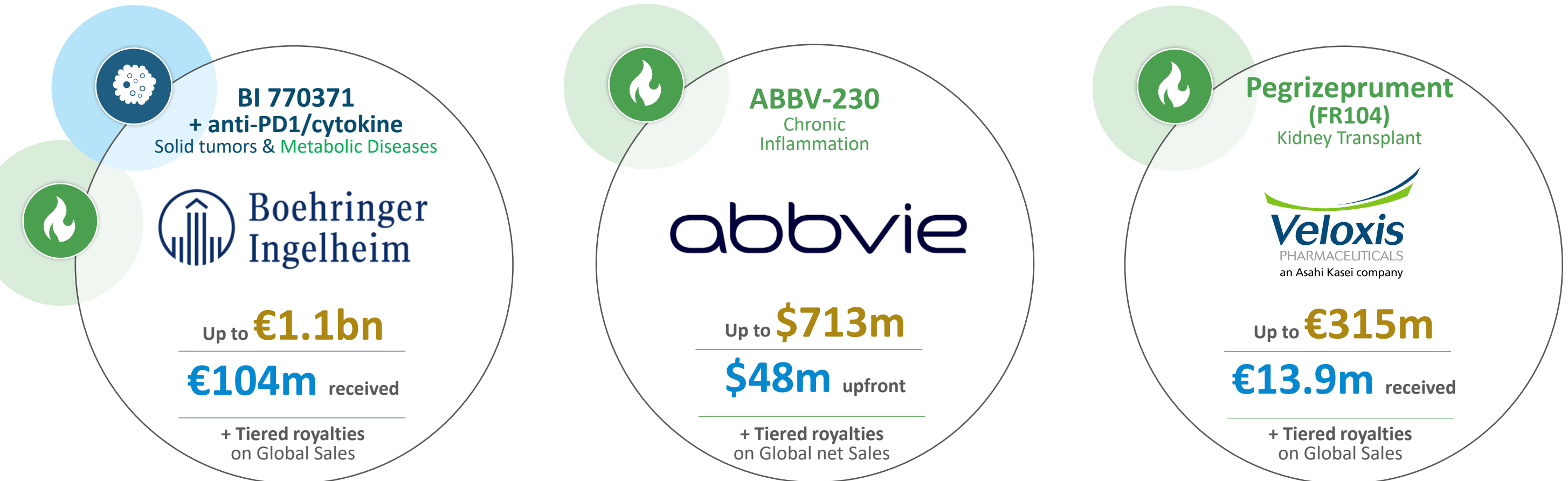
- ▶ IL-35 mRNA
- ▶ Undisclosed programs

 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



# Key potential catalysts\*



## Readouts

- **Lusvertikimab**
  - ✓ Full data set Phase 2 induction UC [results](#)
  - ✓ Extension period Phase 2 UC [results](#)
  - ✓ Biomarkers Phase 2 UC [results](#)
- **Tedopi®**
  - ✓ Phase 2 PDAC [results](#) presentation
- **BI 770371 (partnered)\***
  - ✓ Phase 1b [results](#) in solid tumors



## Progress

- **Tedopi®**
  - Phase 3 NSCLC 2L update
  - ✓ Phase 2 combination completion
- **Lusvertikimab**
  - Development update
- **Pegrizеprument (FR104) (partnered)\***
  - Phase 2 start in Kidney Tx
- **ABBV-230 (partnered)\***
  - Phase 1 initiation



## 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](#)
- **Pegrizеprument (FR104) (partnered)**
  - Phase 2 [results](#) in Kidney Transplantation
- **ABBV-230 (partnered)**
  - Phase 1 [results](#) + Phase 2 [results](#)



## Progress

- **Undisclosed internal Programs**
  - IND/Phase 1
- **New Research programs/platforms**
  - New partnering opportunities

2025

2026-2027



The background image is a composite. On the left, there are three clusters of white, fluffy bacterial colonies on a dark surface. On the right, a gloved hand in a light green nitrile glove is visible, holding a petri dish. The petri dish is tilted, showing a white agar surface with a streaked bacterial culture. The entire image is overlaid with a semi-transparent blue gradient that is darker on the left and fades to a lighter blue on the right.

Proprietary clinical programs

A background image showing the silhouettes of a diverse group of people of various ages and ethnicities holding hands in a line, standing on a grassy field against a sunset sky. The silhouettes are dark against the lighter, orange and blue gradient of the sky.

# Lusvertikimab

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

**Strong biological rational in refractory IBD patients**

# IL-7 fuels chronic inflammation in tissues

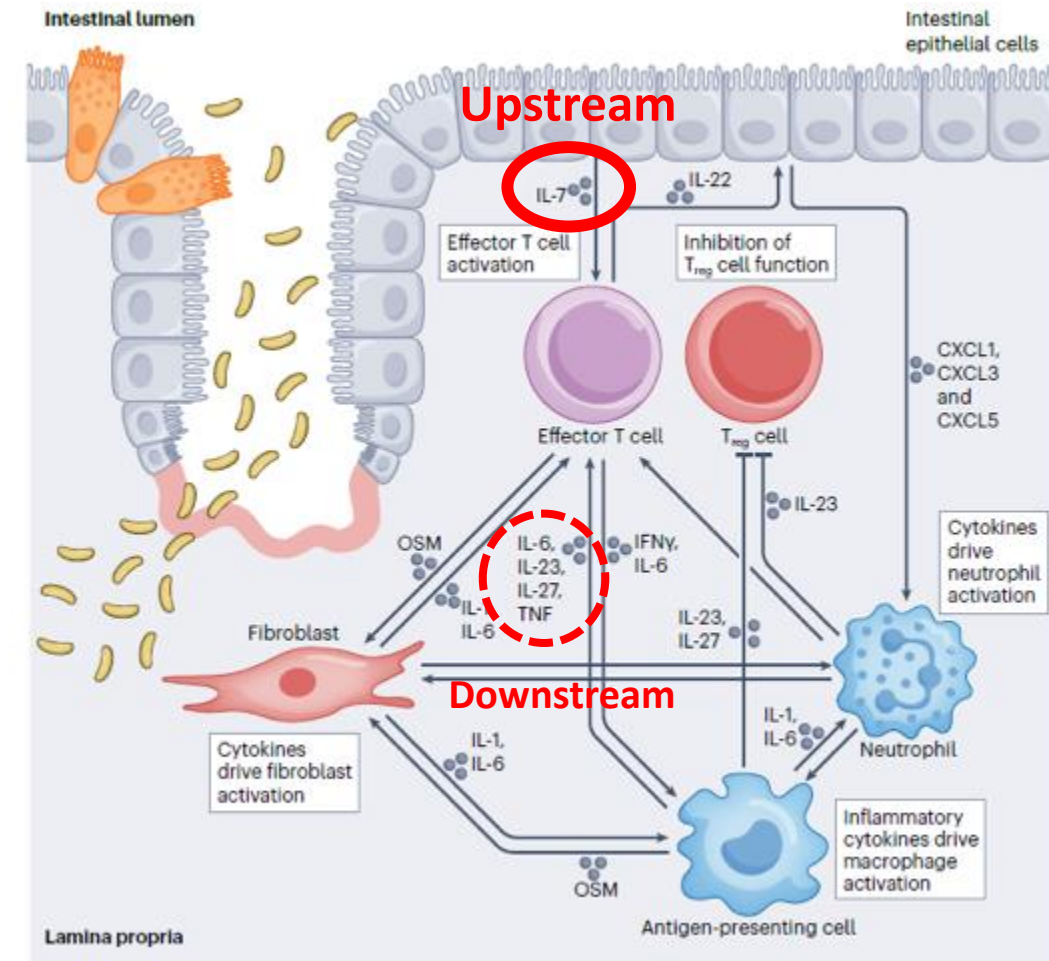
## Upstream mechanism of resistance in hyper-inflammation

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-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.’

Pr. Neurath, *Nature Review Immunology* 2024

Intervening upstream at the IL-7 receptor will prevent molecular signalling transmission by IL-7 through the JAK/STAT5 pathway, while sparing Tregs



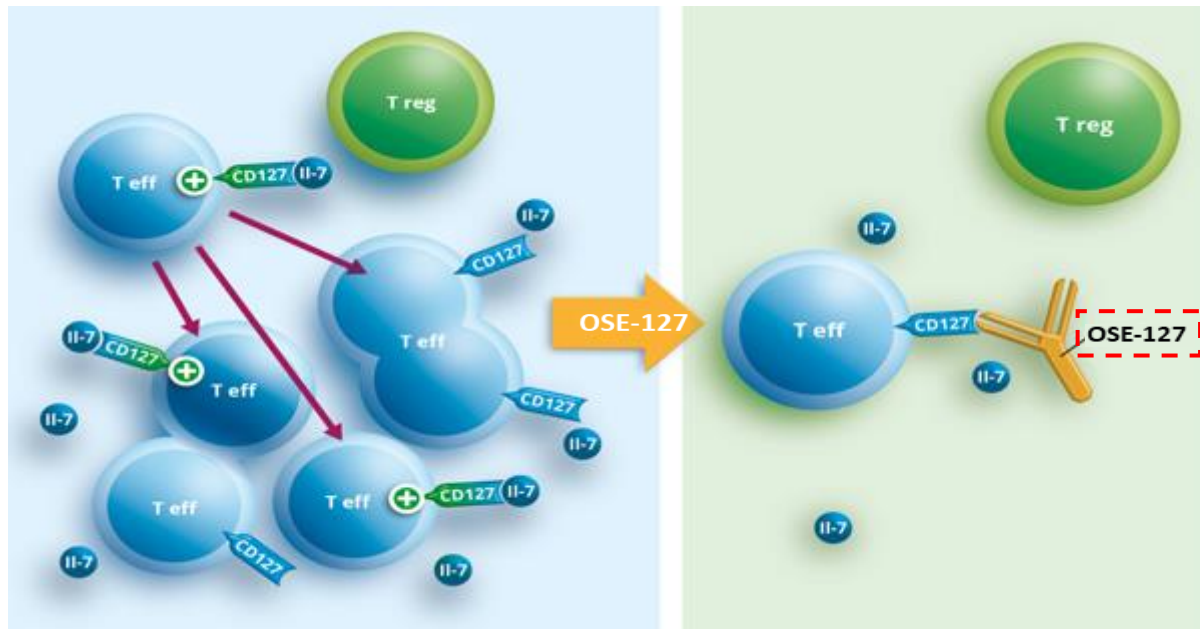
Neurath M. *Nature Review Immunology* 2024



# Lusvertikimab / OSE-127

Pure IL-7 receptor antagonist mAb

Tackling the fuel of memory T-lymphocytes while sparing Tregs



A differentiated IL7R antagonist with positive Phase 2 data in hand

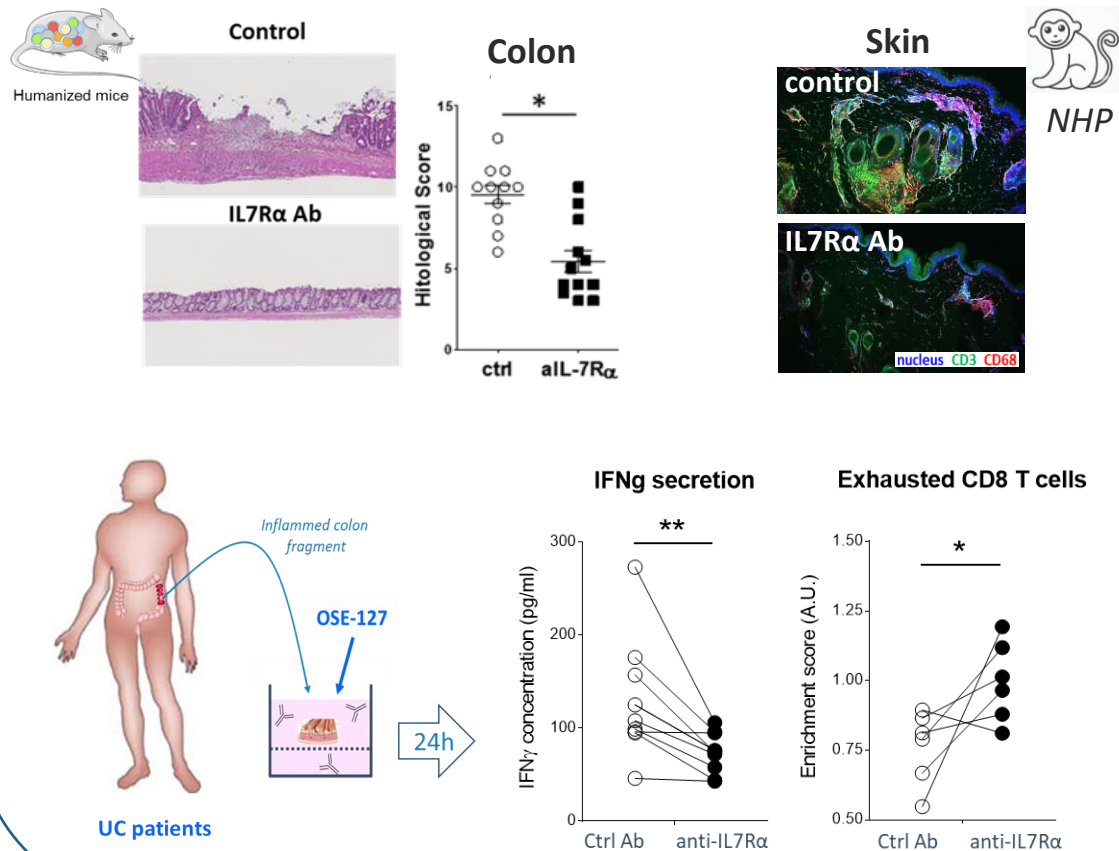
- IL-7 produced by inflamed tissues sustains **T-cell survival and chronicity, drives Th1 and Th17** T cell differentiation
- IL-7R pathway is overexpressed in bio-refractory IBD patients<sup>1,2</sup>
- High preclinical efficacy in combination<sup>2</sup>
- Lusvertikimab, first non-internalizing pure antagonist anti-IL-7R mAb<sup>3</sup> – no antagonist activity on TSLP
- Good safety, PK/PD profile in Phase 1<sup>4</sup>, no cytokine release, confirmed target-engagement
- **Positive Phase 2 study in UC results released in Q1 & Q2 2025<sup>5</sup>**



# Preclinical & translational research of IL-7 in IBD

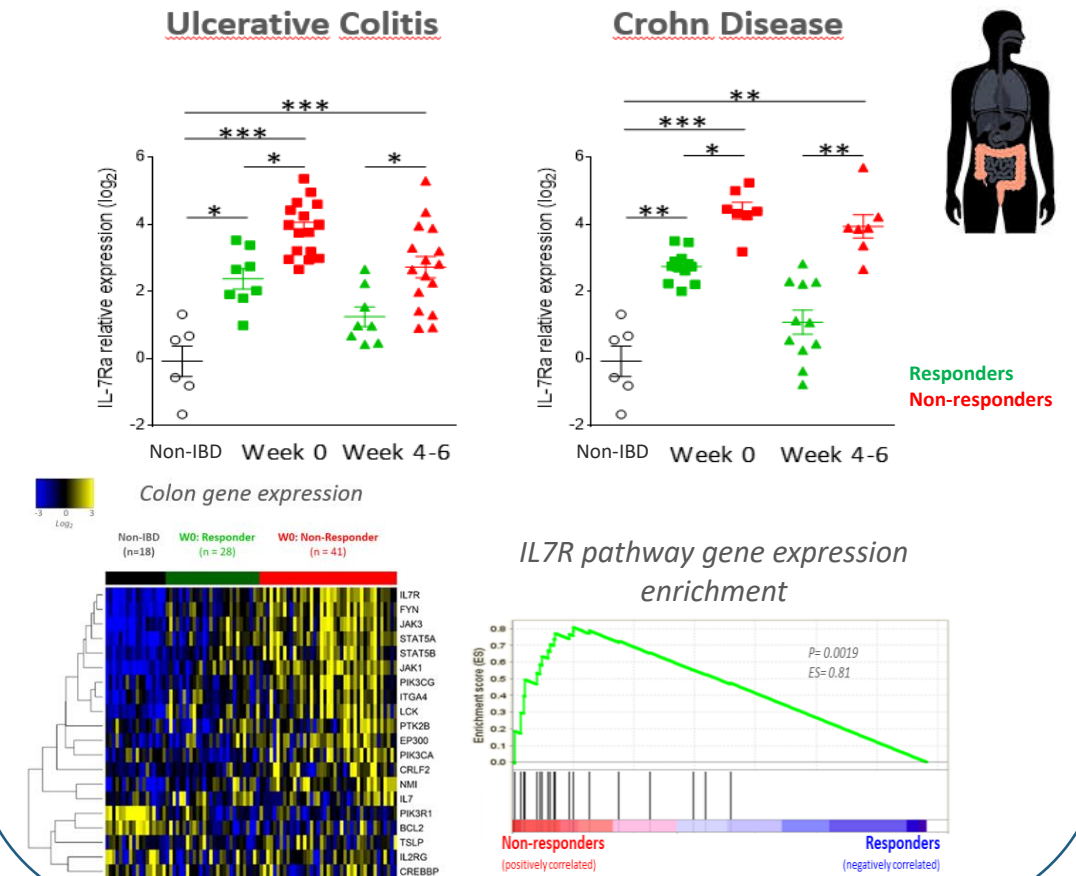
High preclinical efficacy *in-vivo* and *ex-vivo* + high target expression in diseased tissues

## High preclinical efficacy in different models



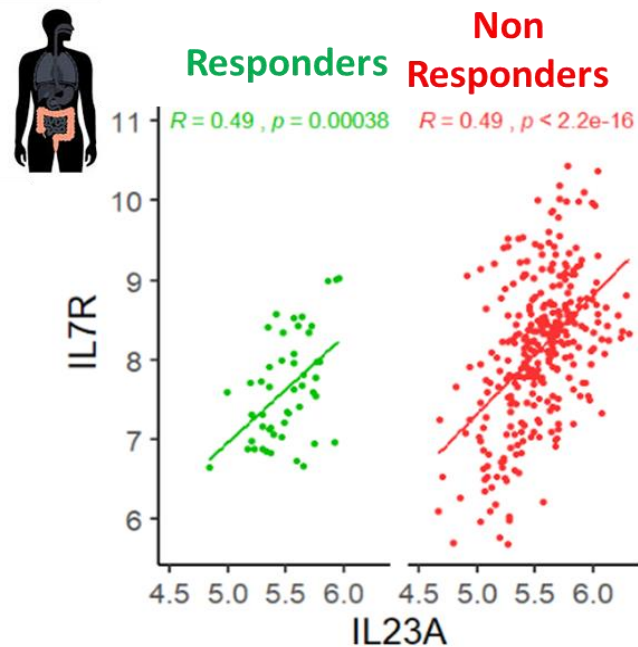
## Mucosal IL7R pathway over-expression in IBD

High correlation with SOC unresponsiveness



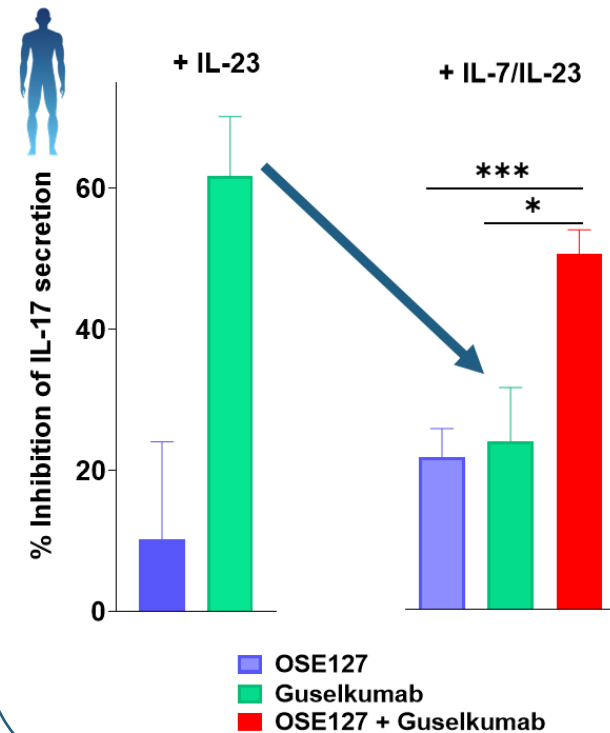
# Anti-IL-7R + IL-12/23 combination preclinical & translational rationale

## IL-7R and IL-23 cytokine mucosal over-expression in Ustekinumab UC patients



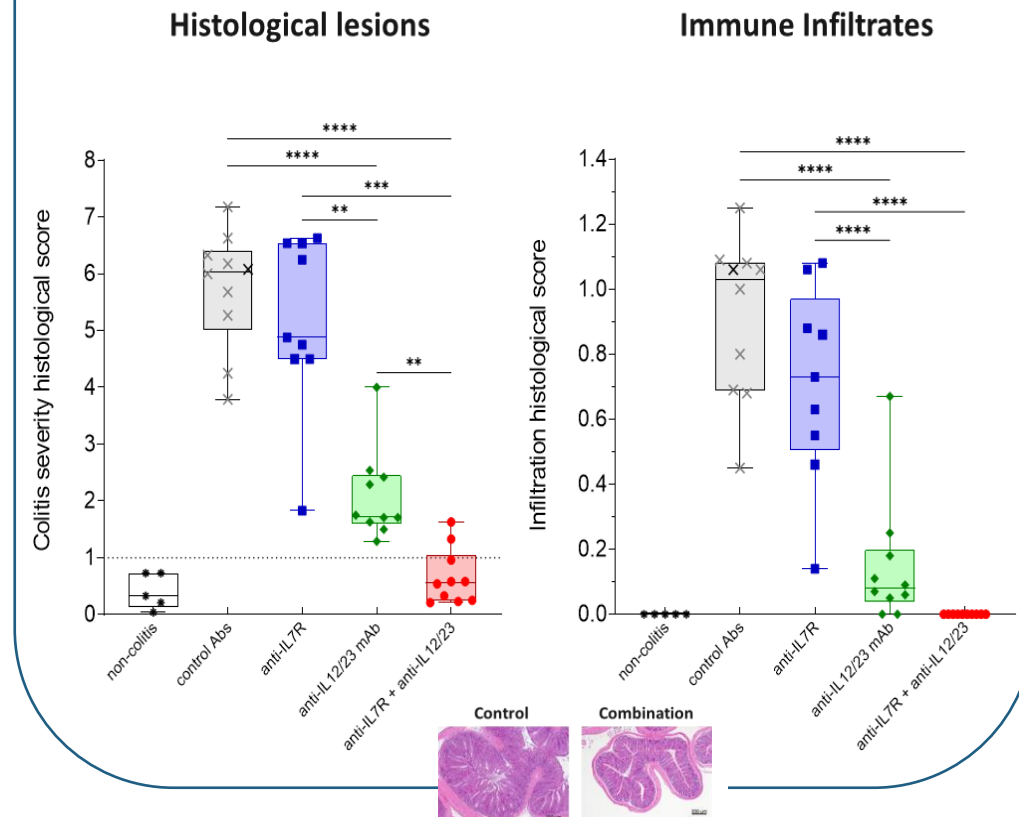
UC colon transcriptomic analysis (GSE206285)

## IL-7 drives IL-23 antagonist resistance



In-vitro model: naïve human primary Th17 cells differentiation

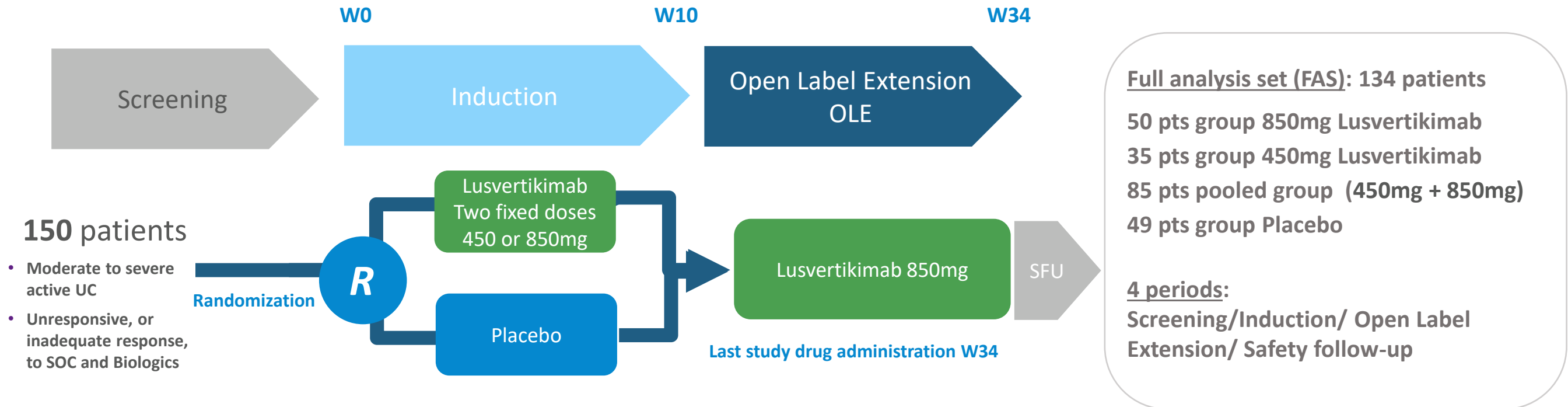
## IL-7R + IL-12/23 blockade synergizes to induce complete mucosal healing in chronic colitis



In-vivo model: mouse chronic colitis T-cell transfer model (Epistem)

# CoTikiS phase 2 randomized study of Lusvertikimab

Moderate-to-severe ulcerative colitis



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

**Induction:** Lusvertikimab 450 mg/ Lusvertikimab 850 mg/ Placebo: IV infusions at Week 0, Week 2, Week 6. **Analysis at Week 10**

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

# IBD clinical Advisory Board, and what they say

*"These data suggest that Lusvertikimab has the potential to be a game-changer, either as a monotherapy or in combination. Some additional exploration to understand best dosing will be valuable."*

**Vipul Jairath**  
London, Canada



*"The trial was well-conducted, with robust data and a low placebo rate. This is very encouraging endoscopic data for such an early stage of development. The potential for Lusvertikimab in the treatment landscape is therefore very promising. Further studies and strategic planning are needed to realize its full potential."*

**Laurent Peyrin-Biroulet**  
Nancy, France



*"We have a new mode of action in UC with a strong safety profile. These full Phase 2 clinical induction results provide strong efficacy data for Lusvertikimab in UC, particularly highlighting the meaningful achievement in the key endpoints of endoscopic remission and histological improvement after only 10 weeks of treatment. The latest data showing high histo-endoscopic mucosal improvement (HEMI) and mucosal healing rates represent a strong signal of efficacy"*

**Arnaud Bourreille**  
Nantes, France



*"There is little true innovation in our field. Given the promising results, Lusvertikimab could play a significant role, particularly in treating refractory patients."*

**Silvio Danese**  
Milan, Italy



*"Lusvertikimab has been shown to significantly decrease FCP, an objective inflammatory biomarker most commonly used in clinical practice to monitor treatment response in patients with ulcerative colitis. These data confirm the overall results of the primary and secondary endpoints from the CoTikiS study, highlighting the potential of Lusvertikimab as an efficacious therapy for all UC patients, also by normalising increased baseline FCP values."*

**Walter Reinisch**  
Vienna, Austria



**Bruce Sands**  
New-York, USA





# CoTikiS - demographics and disease characteristics

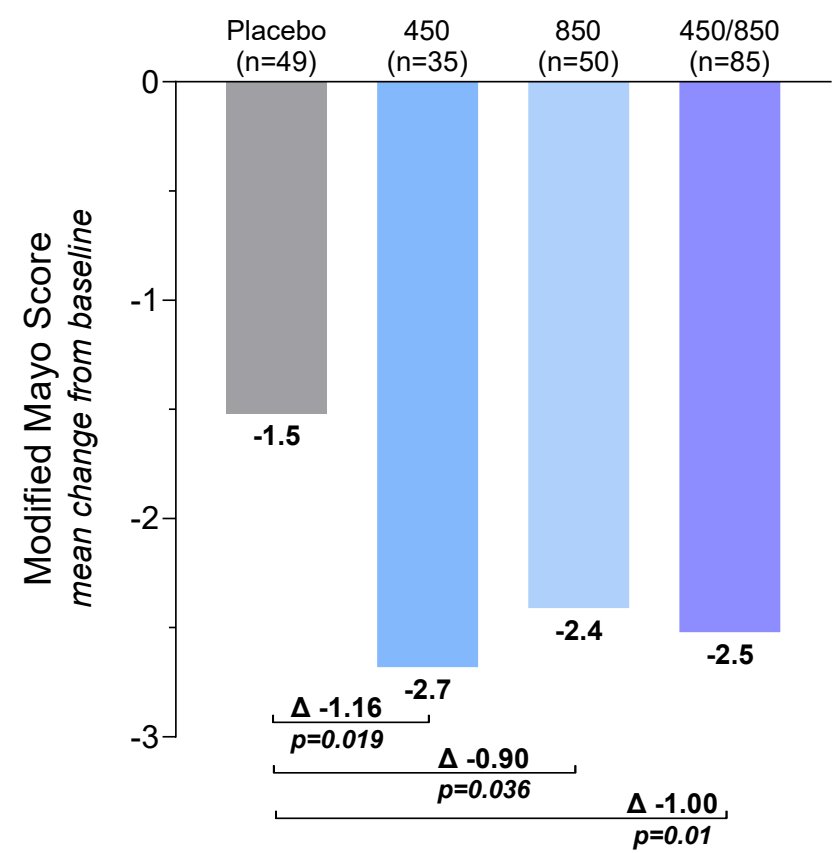
850 mg group slightly more severe disease than 450 mg and/or placebo groups

	Placebo (n=49)	450 mg (n=35)	850 mg (n=50)	Total (n=134)
Age: mean (SD)	42.7 (15.9)	38.8 (10.5)	42.5 (15.1)	41.6 (14.4)
Sex: male	28 (57.1%)	22 (62.9%)	27 (54.0%)	77 (57.5%)
Weight (kg) mean (SD)	75.3 (15.2)	72.8 (16.2)	71.5 (18.0)	73.2 (16.5)
Never smoker	39 (79.6%)	25 (71.4%)	43 (86.0%)	107 (79.9%)
Never alcohol consumption	34 (69.4%)	25 (71.4%)	40 (80.0%)	99 (73.9%)
Region: EU Country	22 (44.9%)	8 (22.9%)	22 (44.0%)	52 (38.8%)
UC duration (years) mean (SD)	8.2 (7.5)	7.2 (6.5)	9.3 (8.6)	8.4 (7.7)
<b>Previous exposure to biologics</b>	<b>19 (38.8%)</b>	<b>5 (14.3%)</b>	<b>19 (38.0%)</b>	<b>43 (32.1%)</b>
<i>Previous biologics: 2+</i>	11 (57.9%)	2 (40%)	13 (68.8%)	26 (60.4%)
<i>Previous biologics: 3+</i>	5 (26.3%)	0 (0%)	6 (31.5%)	11 (25.6%)
Concomitant use of steroids	23 (46.9%)	18 (51.4%)	25 (50.0%)	66 (49.3%)
Modified mayo score (mMS) Mean (SD)	6.6 (1.2)	6.0 (1.4)	6.5 (1.0)	6.4 (1.2)
<b>Category of mMS</b>				
5-6	21 (42.9%)	17 (48.6%)	25 (50.0%)	63 (47.0%)
<b>7-9</b>	<b>26 (53.1%)</b>	<b>13 (37.1%)</b>	<b>25 (50.0%)</b>	<b>64 (47.8%)</b>
Endoscopic subscore mean (SD)	2.5 (0.5)	2.4 (0.5)	2.6 (0.5)	2.5 (0.5)
<b>Category of endoscopic subscore: 3</b>	<b>26 (53.1%)</b>	<b>15 (42.9%)</b>	<b>32 (64.0%)</b>	<b>73 (54.5%)</b>
C-Reactive protein (mg/L) Mean (SD)	8.6 (13.6)	9.4 (16.7)	11.2 (18.1)	9.8 (16.1)
Serum albumin (g/L) Mean (SD)	42.3 (4.4)	42.6 (4.5)	40.8 (5.4)	41.8 (4.9)
FCP (µg/g) mean (SD)	1459.5 (1865.0)	1088.0 (1600.5)	1191.8 (1603.3)	1261.6 (1696.7)

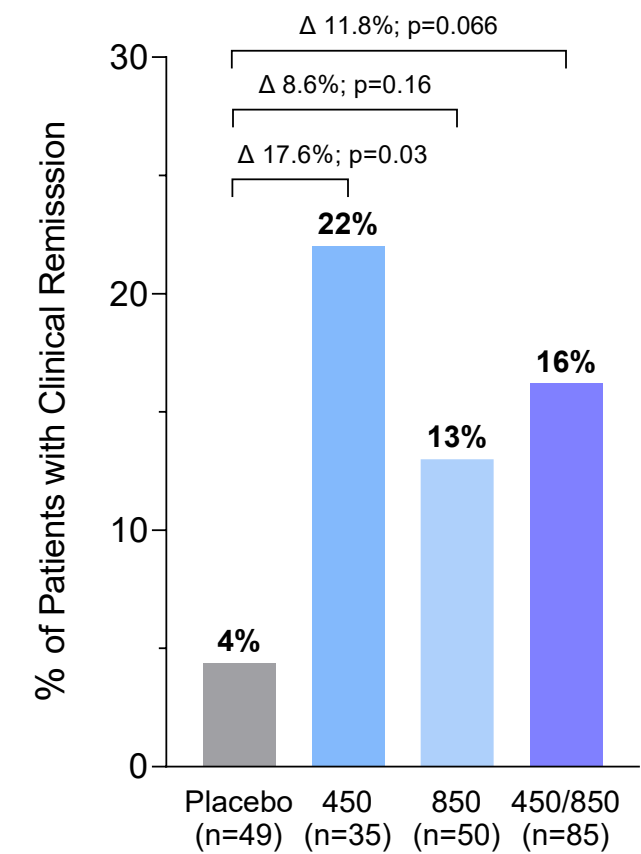
# Clinical induction results at week 10

Clinically and statistically meaningful outcomes in the Lusvertikimab-treated groups

**Primary Endpoint: Modified Mayo Score Improvement (MMS)\*<sup>μ</sup> at W10**



**Clinical Remission at W10**



clinical remission: MMS ≤2 with no subscore >1 and a RB 0, SF ≤ 1, MES 0 or 1

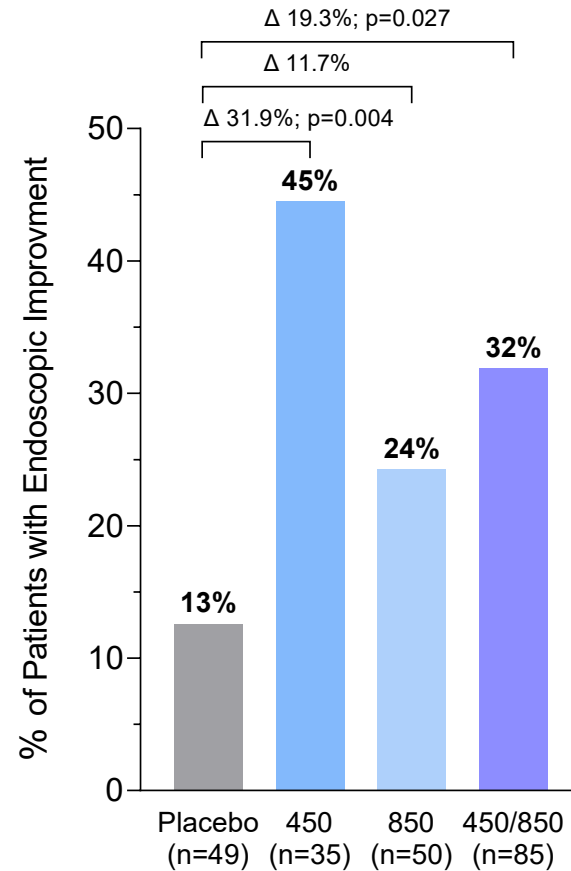
\*MMS Improvement defined on mean change at Wk 10 from baseline on the 3 subscores: rectal bleeding, stool frequency, endoscopic (central reading)

<sup>μ</sup> Least Square Mean Difference between Lusvertikimab and placebo= difference between groups of the Mean change in MMS between baseline and W10

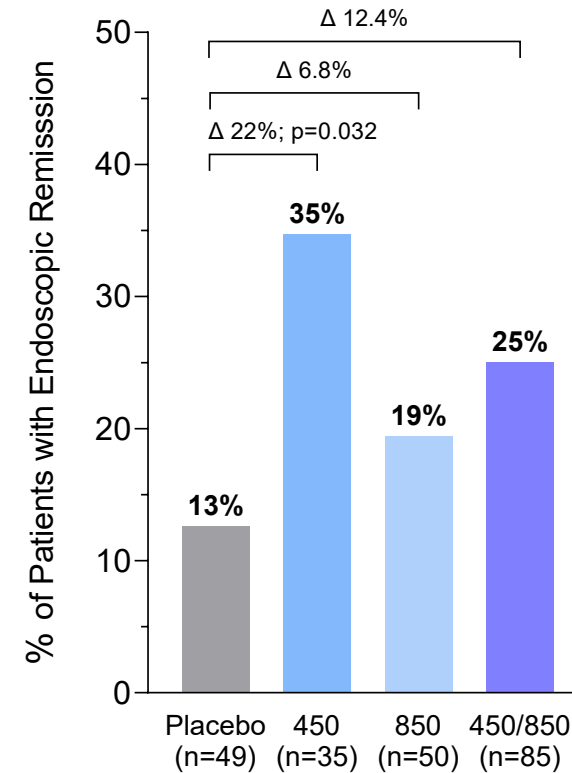
# Clinical induction results at week 10

Clinically meaningful and significant endoscopic improvement and remission

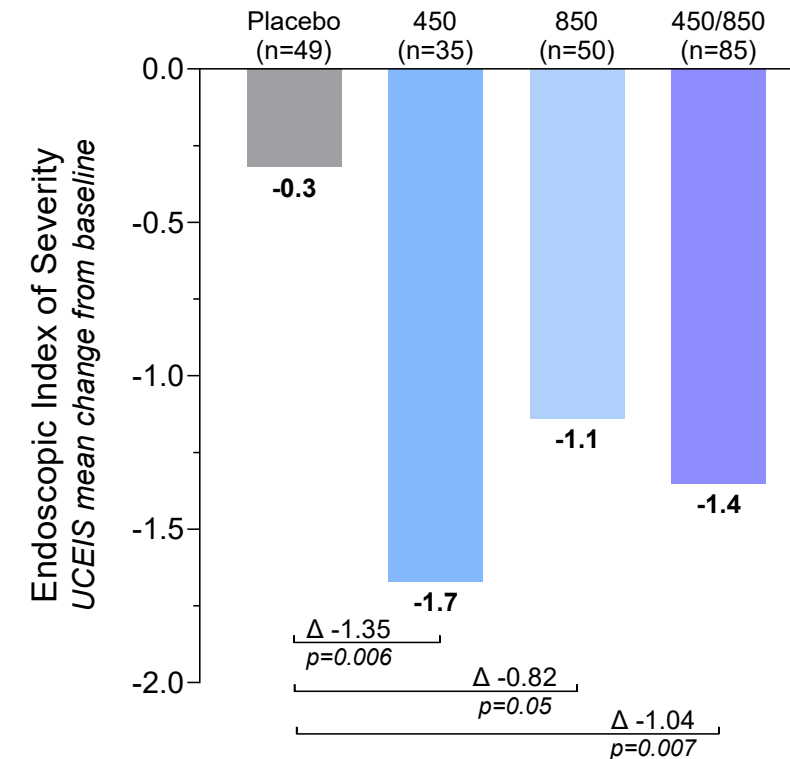
## Endoscopic Improvement\* at W10



## Endoscopic Remission\*\* at W10



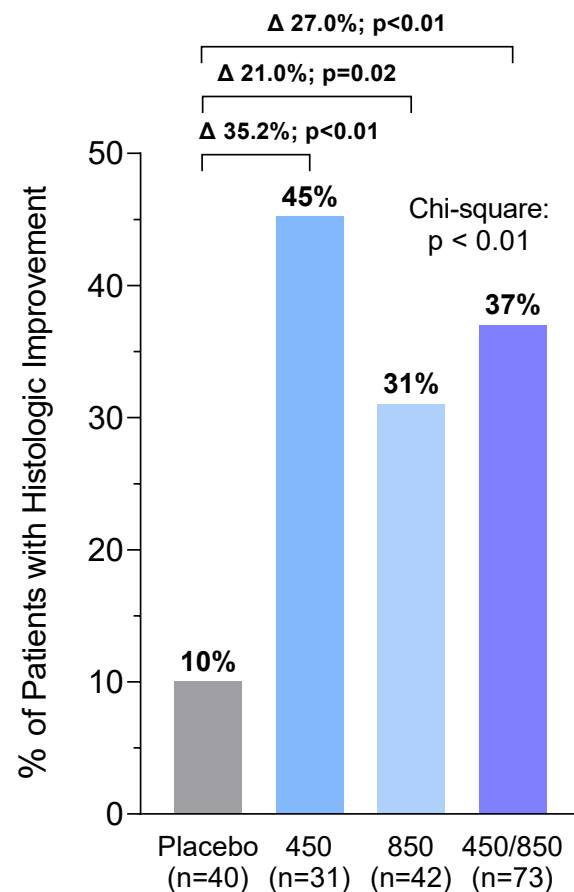
## UC Endoscopic Index of Severity UCEIS\*\*\* change from baseline at W10



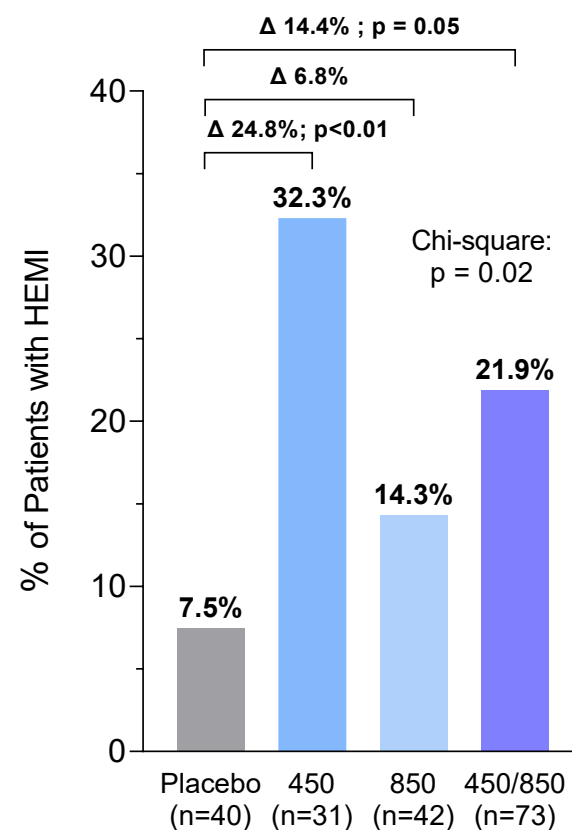
# Clinical induction results at week 10

Clinically meaningful and significant histological and histo-endoscopic mucosal improvement

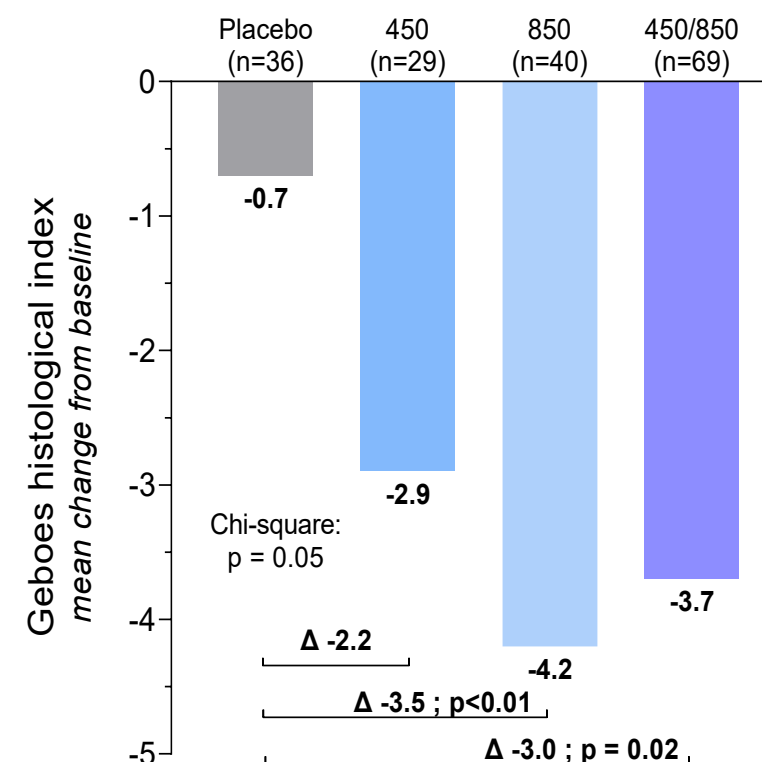
## Histological Improvement at W10\*



## Histo-Endoscopic Mucosal Improvement (HEMI) at W10\*\*



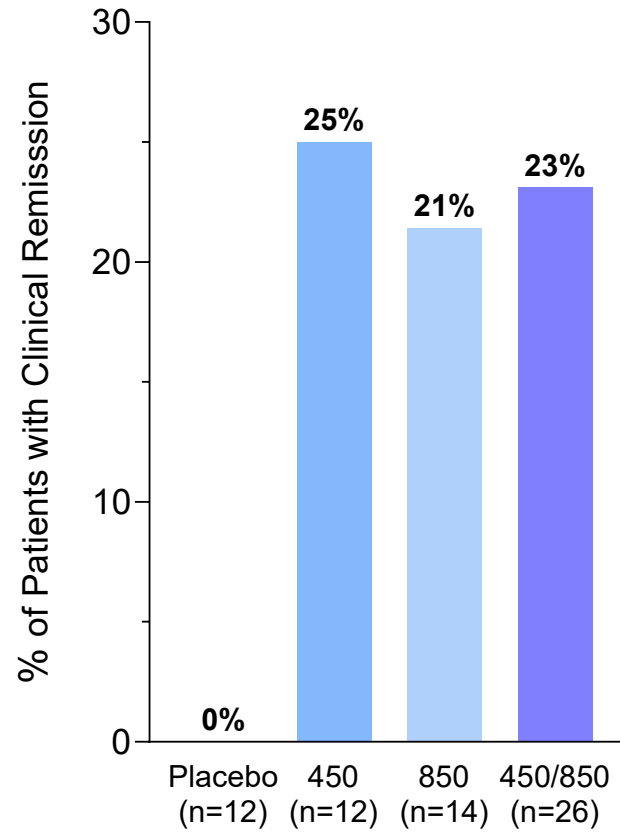
## Histological Geboes index change from baseline at W10



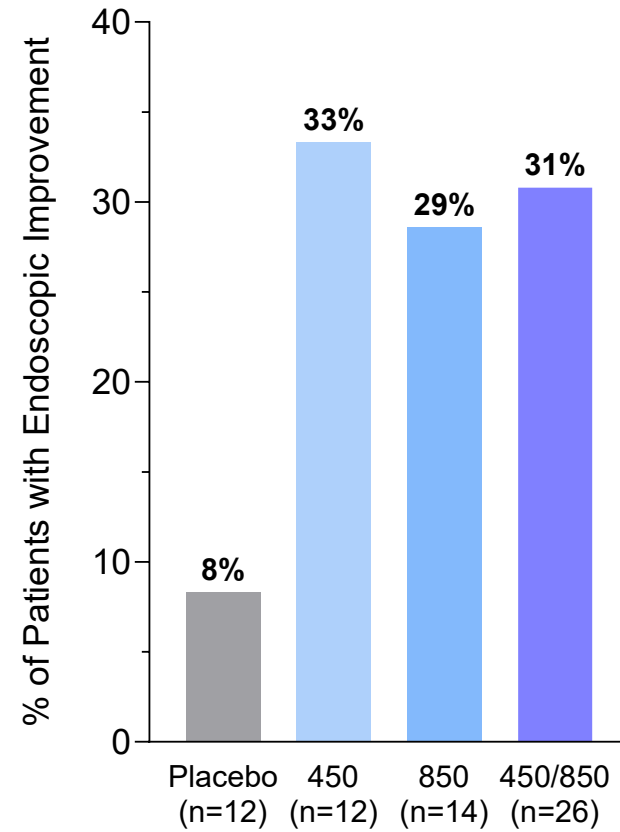


# Subgroup analysis: bio-naïve, baseline endoscopic score = 3

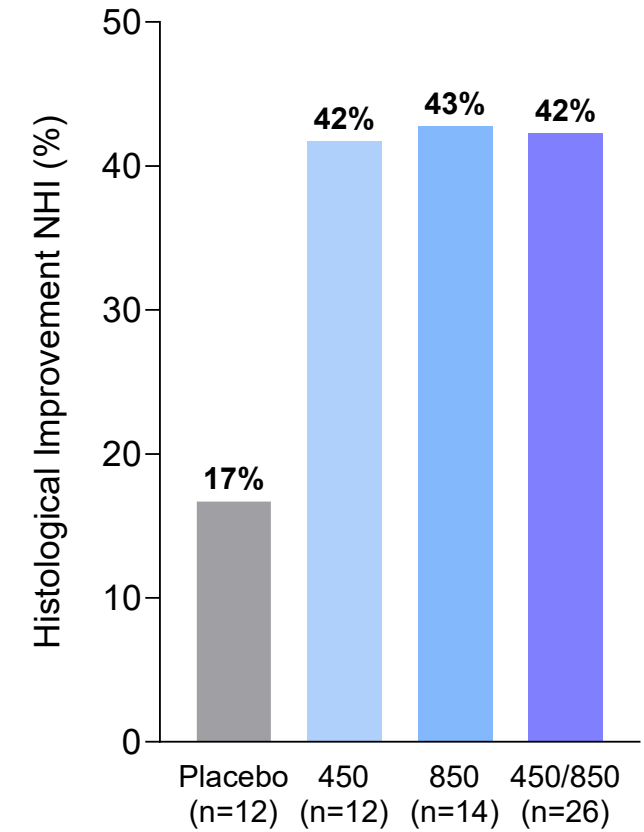
### Clinical Remission at W10



### Endoscopic Improvement at W10



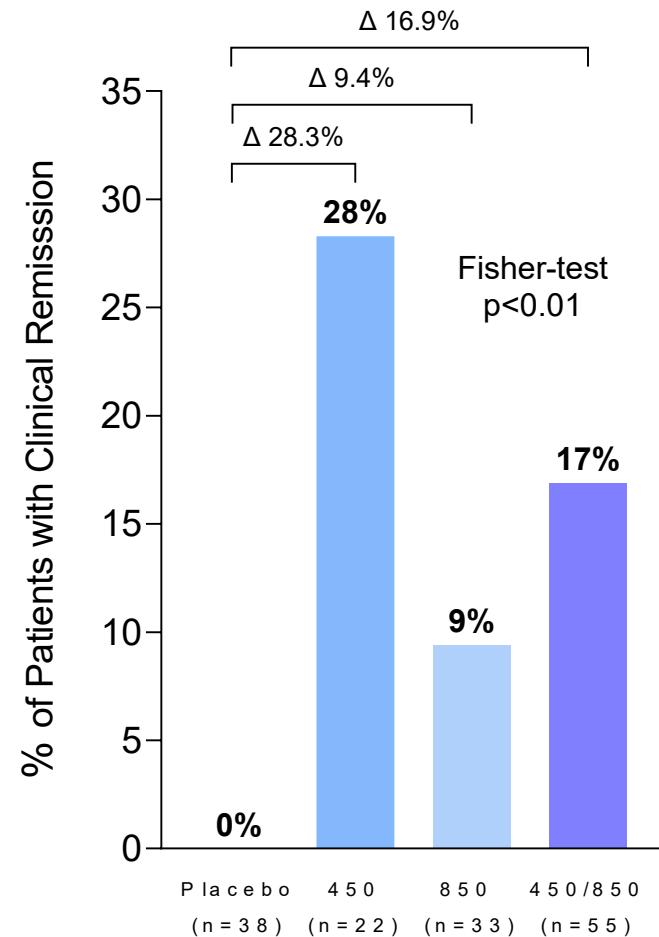
### Histological Improvement at W10



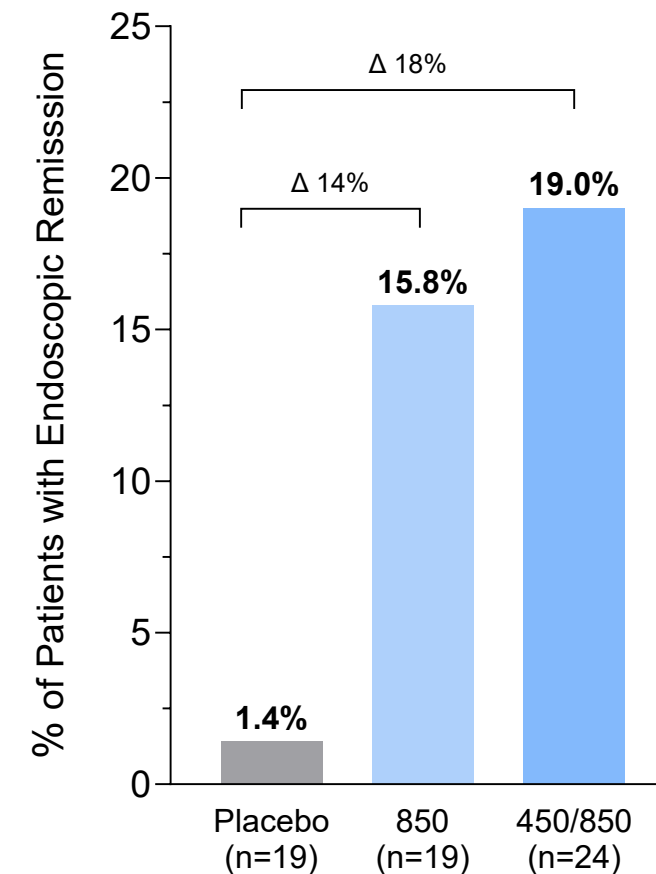
# Subgroup analysis: clinical induction at week 10

Lusvertikimab induced clinical and endoscopic remission in high disease activity & biologics-experienced populations

**Patients with high baseline FCP**  
(Fecal Calprotectin >250µg/g)

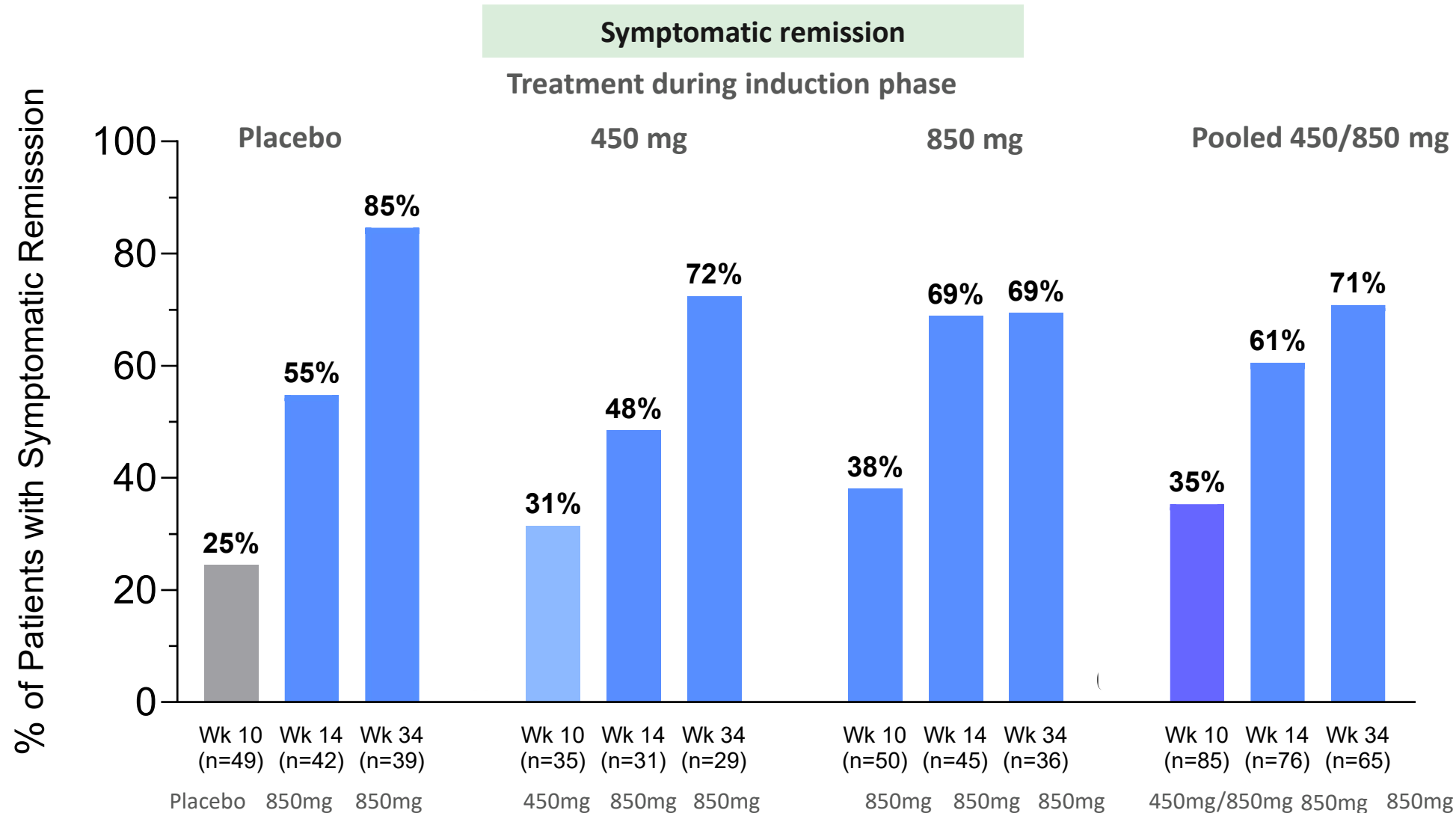


**Patients with previous exposure to biologics**



# PRO2 results in the open label extension (OLE)

Symptomatic remission rates improved for all groups, with 850 mg induction dose group plateauing earlier in the OLE



**All patients received 850 mg every 4 weeks from week 10 through 34**

\*Symptomatic remission defined as patients with PRO2  $\leq 1$  and RBS=0

# Safety in induction phase

	Placebo (N=49) N(%) [E]	450 mg (N=36) N(%) [E]	850 mg (N=51) N(%) [E]	Total (N=136) N(%) [E]
At least one TEAE	16 (32.7) [29]	17 (47.2) [33]	20 (39.2) [42]	53 (39.0) [104]
At least one TEAE related to study treatment	1 (2.0) [1]	3 (8.3) [4]	4 (7.8) [14]	8 (5.9) [19]
At least one serious TEAE	3 (6.1) [3]	2 (5.6) [3]	2 (3.9) [3]	7 (5.1) [9]
At least one serious TEAE related to study treatment	—	1 (2.8) [1]	—	1 (0.7) [1]
At least one severe TEAE	2 (4.1) [2]	1 (2.8) [2]	—	3 (2.2) [4]
At least one severe TEAE related to study treatment	—	1 (2.8) [1]	—	1 (0.7) [1]
At least one related TEAE leading to death	—	—	—	—
At least one TEAE leading to drug withdrawal	3 (6.1) [3]	2 (5.6) [3]	—	5 (3.7) [6]
At least one TEAE leading to drug interruption	2 (4.1) [2]	1 (2.8) [1]	—	3 (2.2) [3]
At least one TEAE leading to study discontinuation	3 (6.1) [3]	2 (5.6) [3]	—	5 (3.7) [6]
At least one AESI	6 (12.2) [7]	7 (19.4) [7]	9 (17.6) [10]	22 (16.2) [24]
At least one infection	6 (12.2) [7]	5 (13.9) [5]	7 (13.7) [8]	18 (13.2) [20]
At least one lymphopenia < 500 10 <sup>6</sup> /L	—	2 (5.6) [2]	2 (3.9) [2]	4 (2.9) [4]

Lusvertikimab was well tolerated with an acceptable safety profile

Lymphopenia was transient, not associated with a higher rate or severity of infection, was more frequent in patients treated with corticosteroids or with baseline values <1\*10<sup>9</sup>/L and did not lead to treatment discontinuation



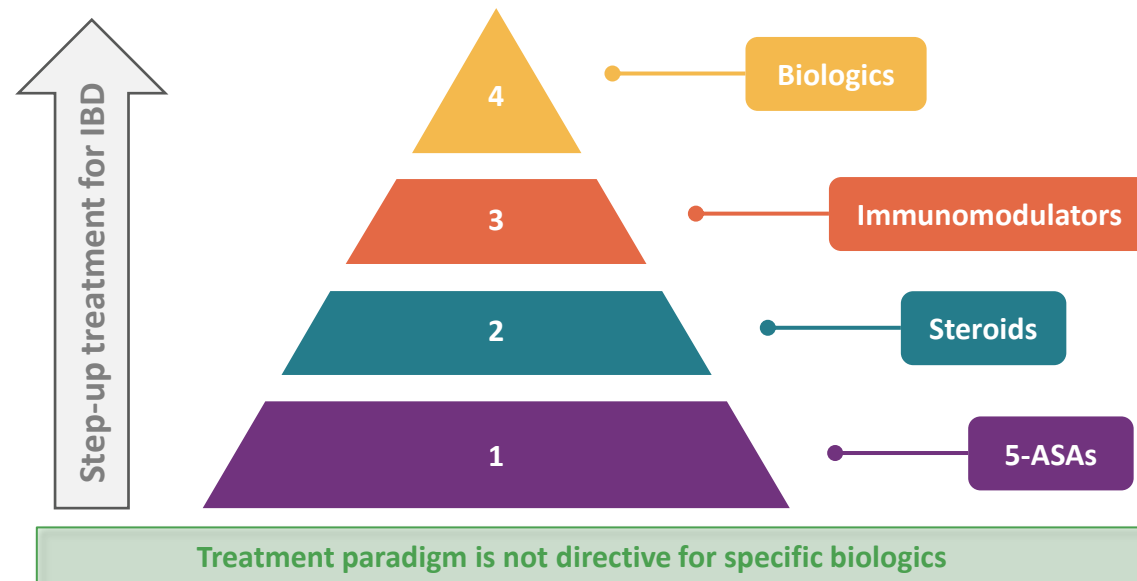
# CoTikiS Phase 2 study of Lusvertikimab highlights

- Lusvertikimab demonstrated high clinical, endoscopic, and histological efficacy vs placebo at week 10 at both 450 and 850mg doses in moderate to severe UC patients
- 89% of the CoTikiS patients entered the open label extension phase and 87% of them completed
- UC symptoms continued to improve in both the 450 mg and 850 mg dose groups through week 14
- Symptomatic remission was maintained in >90% of the responders at W10 (100% with high dose)  
Among non-responders at W10, 69% experienced symptomatic remission at W34 following 24 weeks of treatment with 850 mg Lusvertikimab
- Lusvertikimab was safe and well tolerated; no increase in rate or severity of infection observed

# Market opportunity for UC supports multiple players

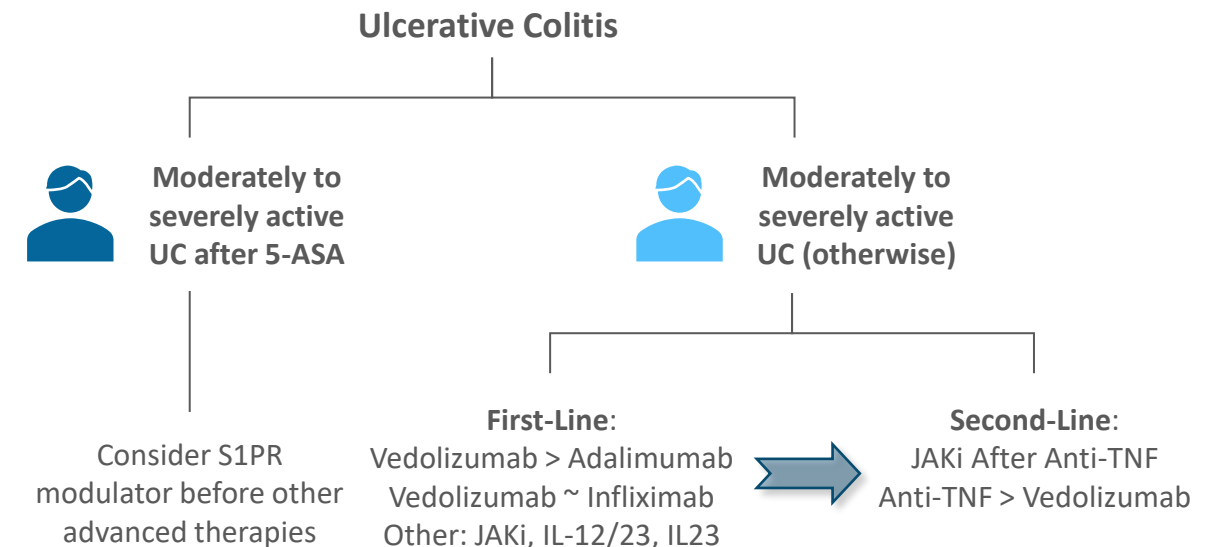
## Background, epidemiology & market opportunity

- Chronic disabling bowel disease characterised by **inflammation of the colon & rectum**, with continuous and non-transmural involvement
- It generally begins in young adulthood and lasts throughout life, with significant impacts on quality of life
- Treatment goals focus on controlling disease & improving patient outcomes
- Affects **~1.5M in NA & 5M globally**, with **annual incidence 15:100,000<sup>1</sup>**
- Market size of **\$7.3B** and growing at a **4% CAGR**



## Unmet need & positioning in the UC market

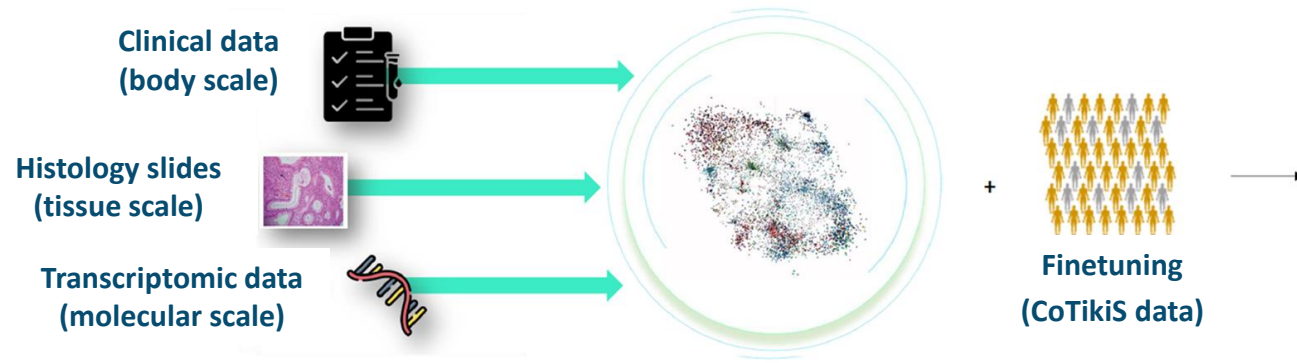
- Despite new agents targeting inflammatory pathways (e.g. anti-TL1-As), only **~20-30%** of UC patients **achieve remission on 1<sup>st</sup> treatment** and < 50% of these maintain remission<sup>1</sup>
- A range of approaches are required for this **heterogeneous disease**, which **Lusvertikimab**, a first-in-class anti-IL-7R, **shows potential to address**
- Predictive biomarker data from CoTikiS **supports a precision medicine approach** for a targeted segment of the population
- Lusvertikimab is differentiated on safety**; no signals of increased risk of infections, PML, CV issues or macular edema as observed in approved therapies



# Potential for highly sensitive and specific prediction\* of clinical remission

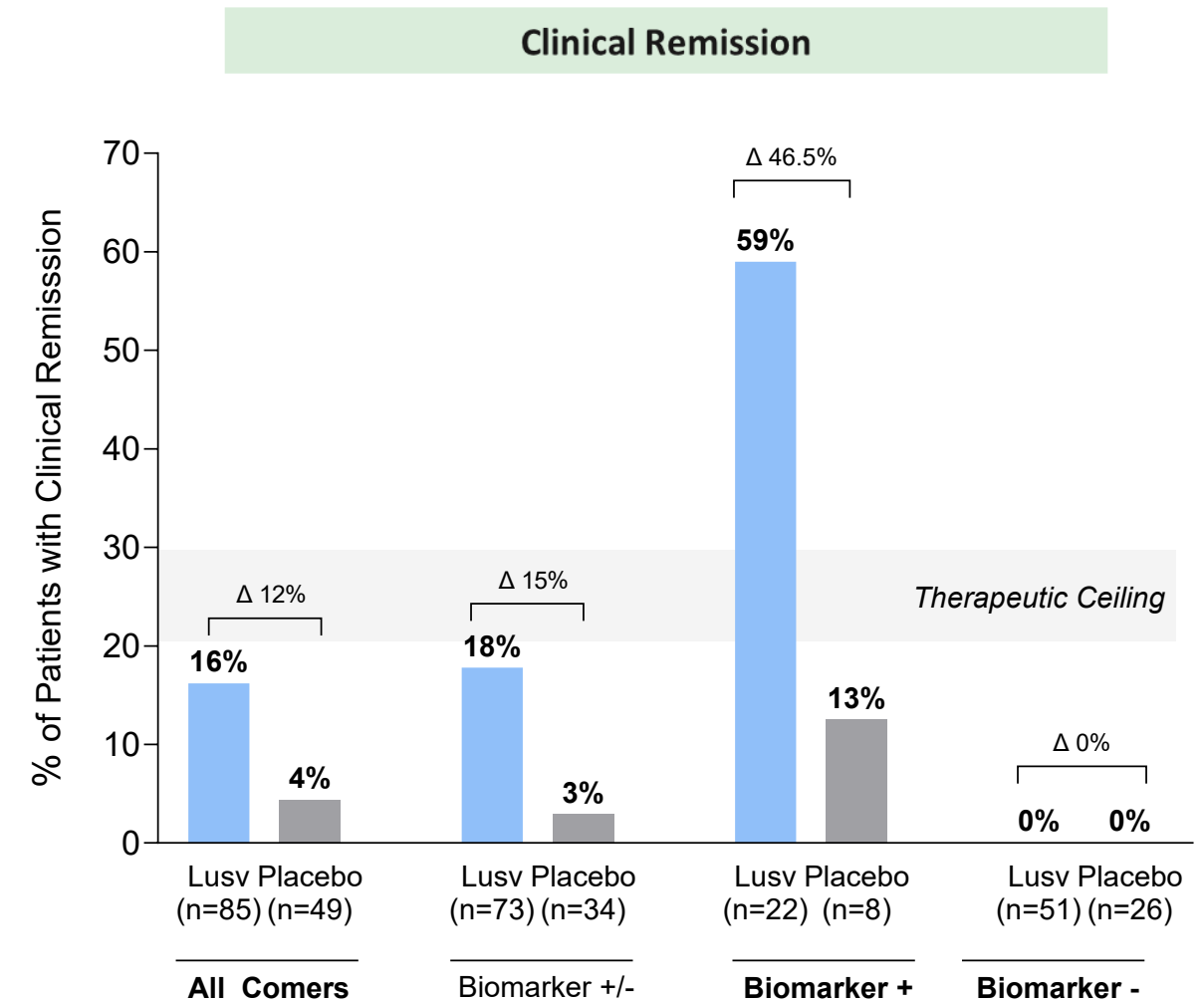
Biomarker-positive population represents ~30% of CoTikiS cohort

## AI-powered precision medicine



Foundation model built with dedicated inflammatory disease

- Pre-trained with data from millions of patients: clinical, transcriptomic & histology = **knowledge network**

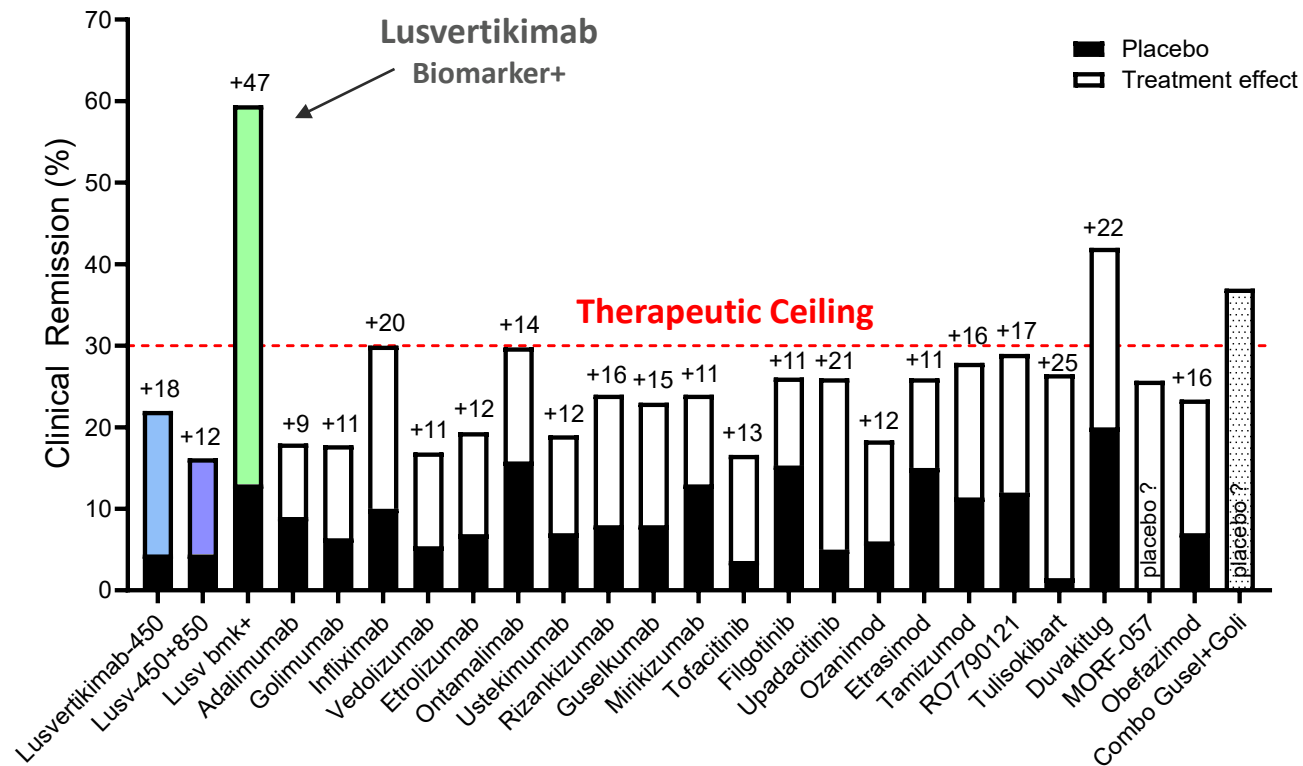


\*Composite IL7R axis biomarker identified with fine-tuning on CoTikiS phase 2

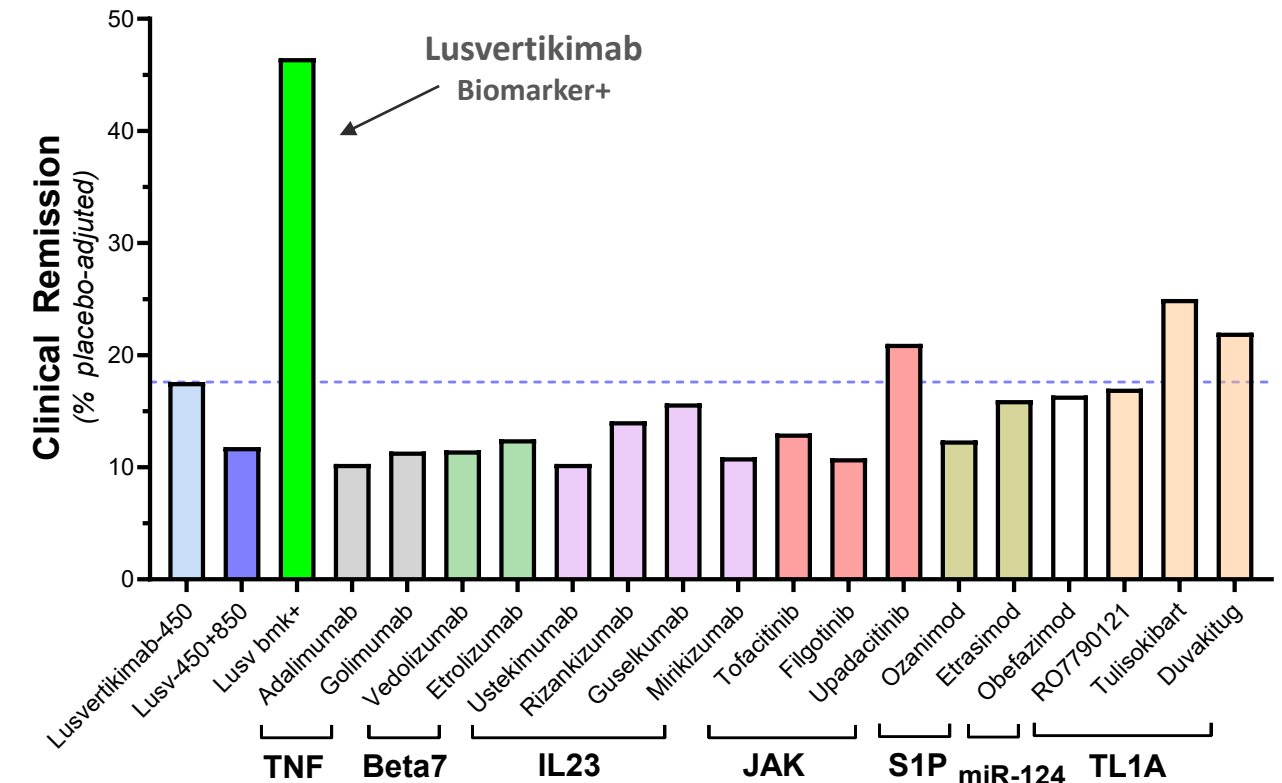
# Lusvertikimab in the context of the therapeutic ceiling & competitive landscape\*

In the CoTikiS biomarker-positive population (~30% of UC population)

Clinical Remission



Clinical Remission (Placebo-adjusted)



\*Based on placebo-adjusted Induction Phase 2b/3 results, not head-to-head comparison

A medical illustration of human lungs. The left lung (viewer's right) is shown with a glowing, yellow and orange tumor in the upper lobe. The right lung (viewer's left) is shown with a network of dark, branching vessels. The background is a deep blue with a subtle grid pattern.

# TEDOPI®

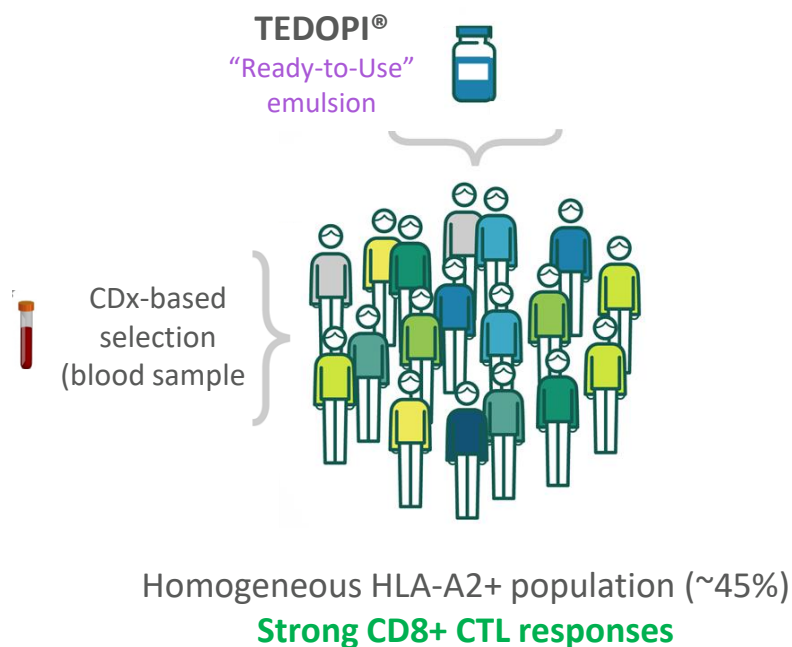
**Most Advanced Therapeutic Cancer Vaccine**

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



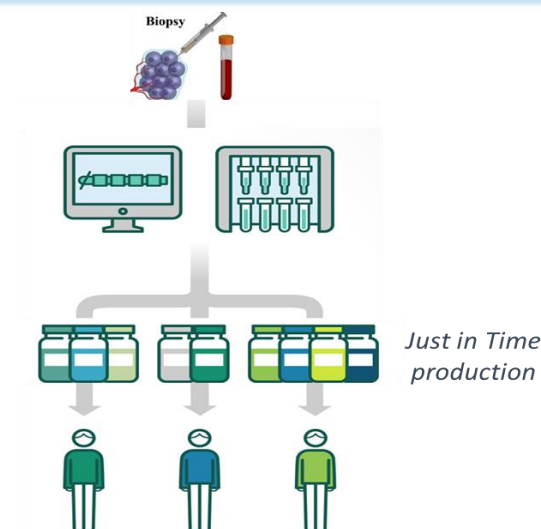
# Personalized vs *Off-the-Shelf* cancer vaccines

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



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

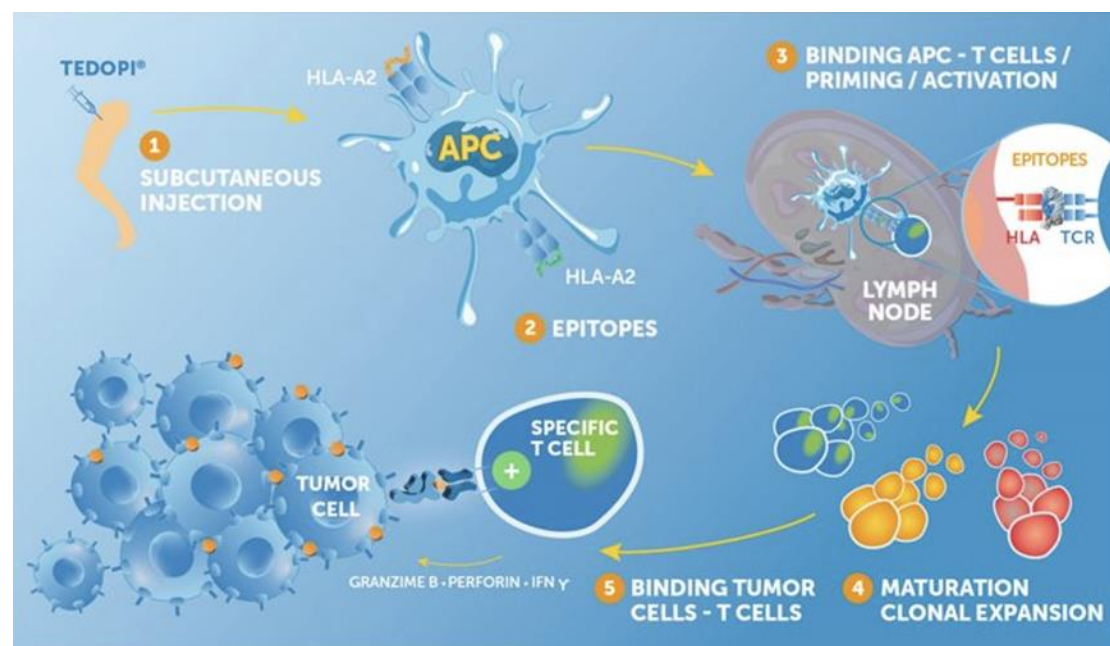
Neoantigen cancer vaccine  
= **Personalized Medicine**  
-> *Custom*



**Cons:** Tumor biopsy, **Cost**, Time  
Epitope prediction robustness  
**Variable responses/immunogenicity**

**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 **neoepitopes**: 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 neoepitopes**  
+ 1 epitope giving universal  
T helper response)

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

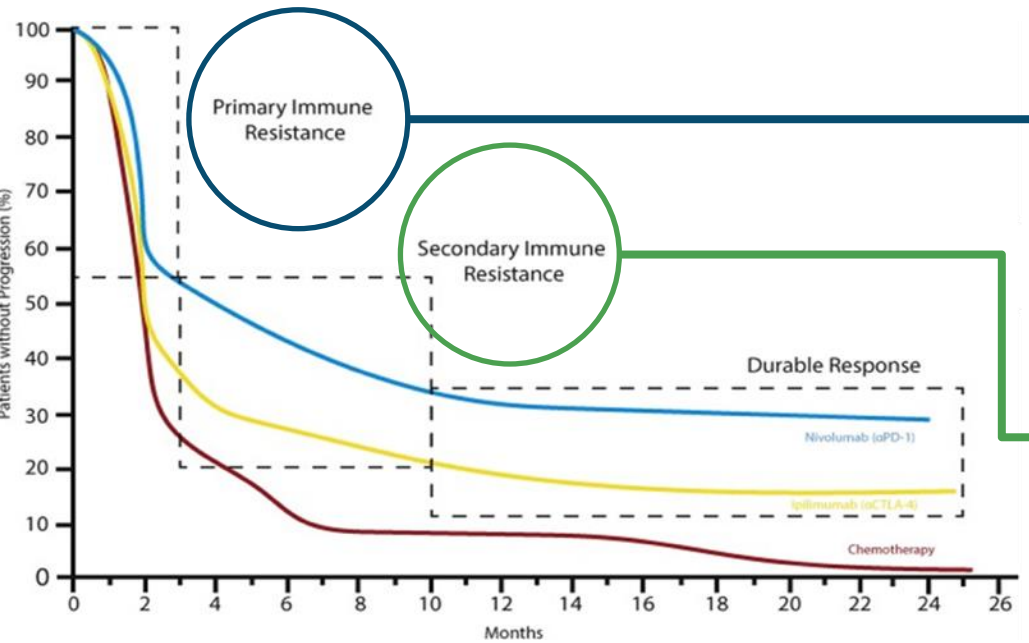
**Ready to Use**  
**subcutaneous** formulation  
with Q3W injection

**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 rational 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

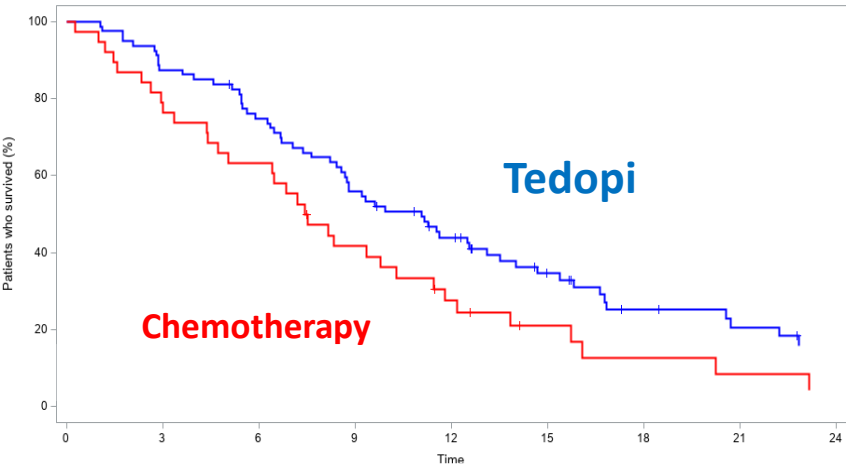
**Tedopi®** has the **potential to rejuvenate & refresh specific TILs** in immuno-sensitive tumors.  
 Neoepitope-specific T cells have tumor killing potential and limited side effects.

# 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

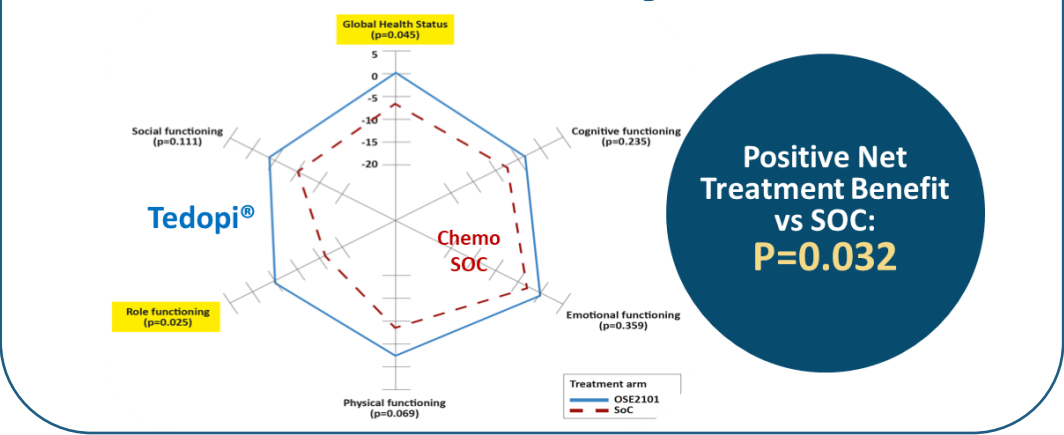


OS rate at 12 months  
**44%**  
in Tedopi® vs.  
**27.5%**  
in SoC

Delta OS: **3.6** months  
**Tedopi® 11.1 months**  
**VS**  
**SoC 7.5 months**  
HR 0.59 /  
p-value=0.017

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

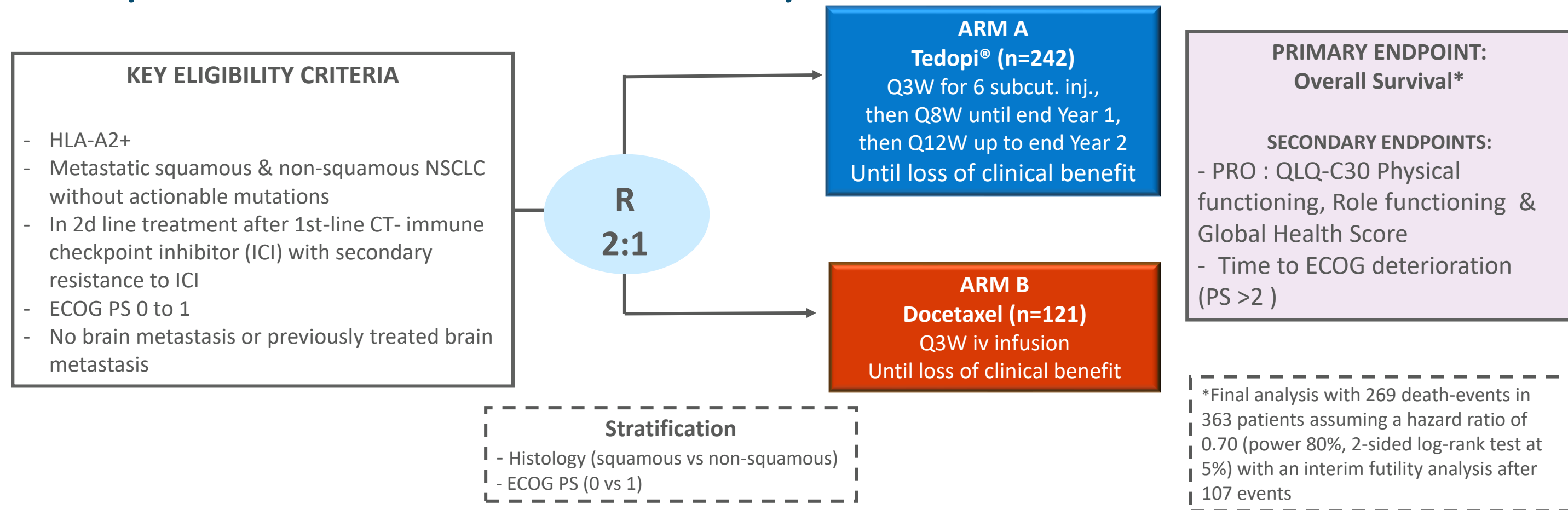
## Better Quality of Life



Positive Net Treatment Benefit vs SOC:  
**P=0.032**

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

# 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.

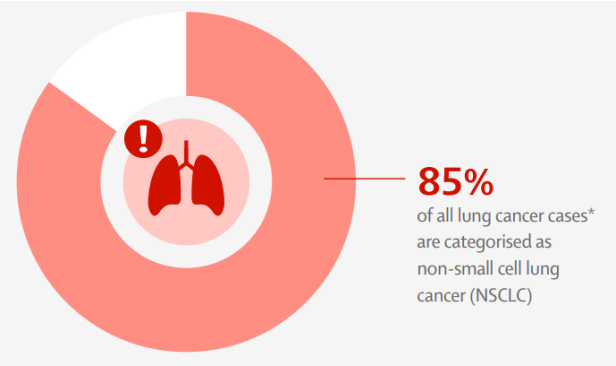
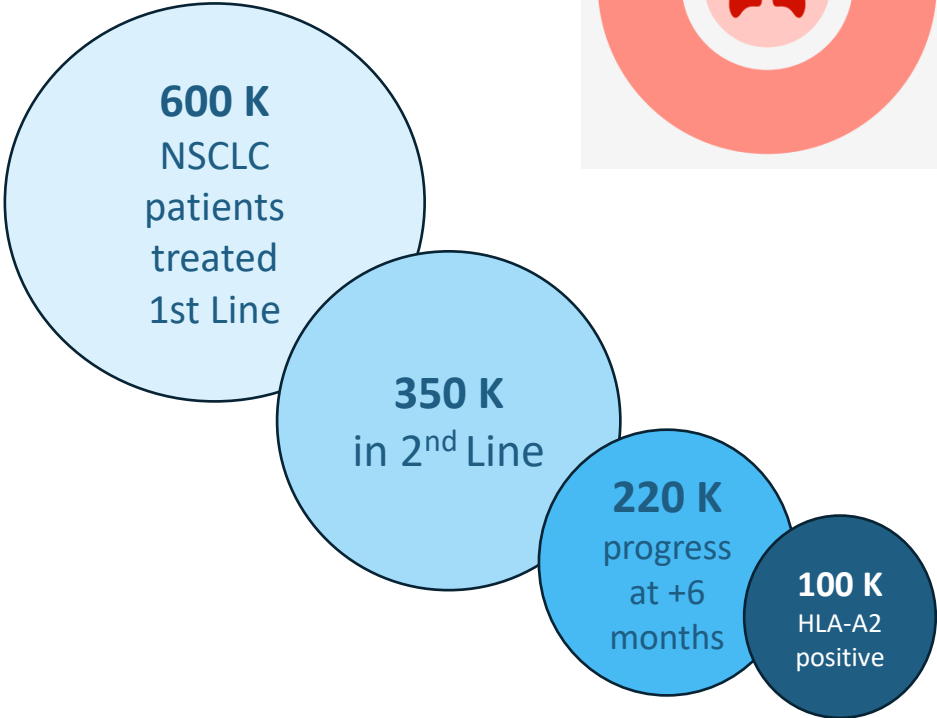
## Treatment paradigm in NSCLC with no driver mutation

- 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



# 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			
					TIM-3	CTLA-4	TROP2	TROP2	CEACAM5	c-MET
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-hzyi 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

# 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*



Recruitment completed Q3 2025

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)*

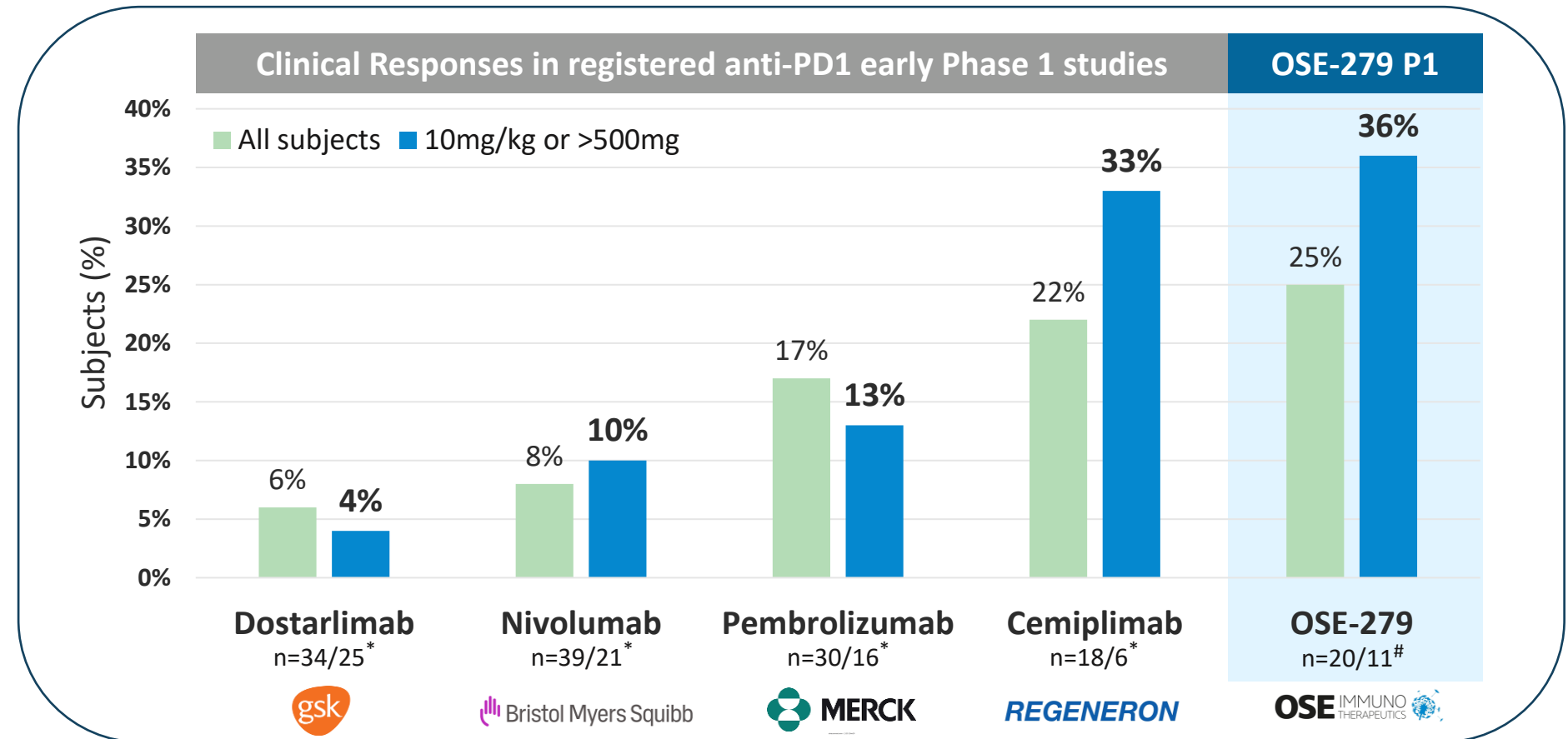


Positive Topline Result with primary endpoint met (ASCO 2025)

# 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.



Partnered clinical programs

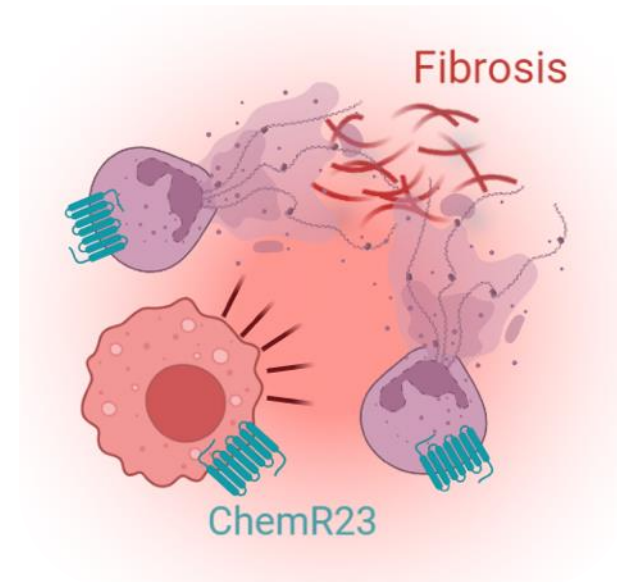


# ABBV-230 - Resolving inflammation is an active immune process

abbvie

## During chronic inflammation

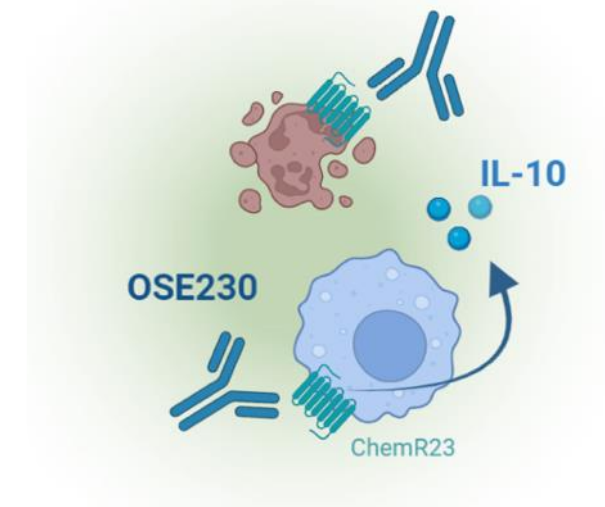
Dying neutrophils **send out inflammatory signals (e.g. NETosis)** that are important in maintaining chronic inflammation & fibrosis



## With ChemR23 agonistic mAbs

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

Restoration of homeostasis



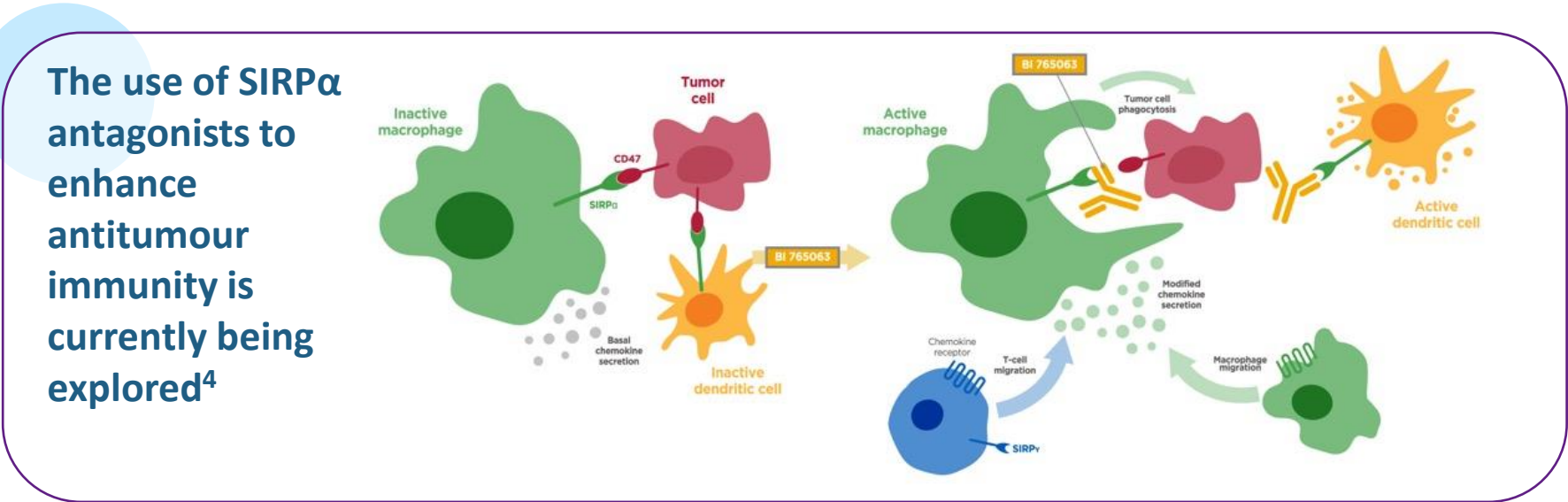
Potential First-in-class pre-IND candidate

Published in **ScienceAdvances**  
AAAS

# SIRPα 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–SIRPα interaction transduces inhibitory signals on macrophages and other myeloid cells<sup>2</sup>
- Preclinical studies have indicated that **CD47 or SIRPα blockade in combination with ICIs** may have a synergistic antitumour effect<sup>3</sup>

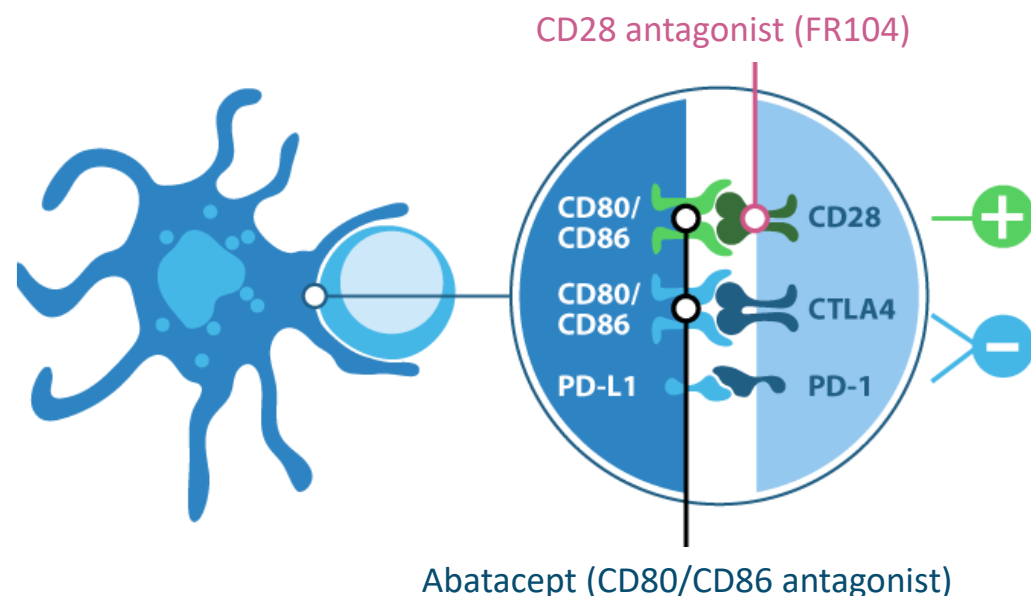


	Anti-CD47	Anti-SIRPα	
Broad/restricted expression	Broad	Restricted to cells of the myeloid lineage	Limited <b>side effects</b> expected and less frequent dosing
Safety signals	Acute anemia, Thrombocytopenia	<b>No hematotoxicity</b>	Higher therapeutic window expected
Interaction CD47/SIRPγ	<b>Inhibit human T cells</b>	OSE-172 is SIRPα specific	Favors T cell responses in solid tumors

CD: cluster of differentiation; ICI: immune checkpoint inhibitor; SIRPα: signal regulatory protein-α.

# Pegrizeprium (FR104) 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*

# Governance





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



**Markus Cappel**  
Chairman



- 30+ years in biotechnology
- Global experience in product devt, commercialization (ChemoCentryx)
- Experience in acquisitions, strategic alliances and fundraisings
- MBA Harvard Business School, PhD in Pharmaceutical Sciences from J.W. Goethe University in Germany



**Pascale Briand**  
Independent Director



- Head of the first French National Cancer Plan (2003-2007)
- Former Director of the French Food Safety Agency (ANSES) and a former Director of the National Research Agency (ANR)
- Locally elected official in Loire-Atlantique (since 2004)
- Medical doctor, PhD in biochemistry specialized in genetics



**Jonathan Cool**  
Independent Director



- +35 years biotech, biopharma, medical devices, materials sciences
- Founder, management, board level at early-stage companies (e.g., Human Genome Sciences, Molecular Devices, Gene Networks, Immunicon)
- CEO of Ultra High Materials
- MBA Harvard Business School, BA Stanford University



**Marc Le Bozec**  
Independent Director



- Currently supports numerous biotech companies as an advisor, board member, and investor
- Previously created and managed two biotech investment funds within Financière Arbevel
- Previously CEO of Collectis
- Graduated from HEC



**Caroline Mary**  
Director representing employee shareholders



- 19 years at OSE Immunotherapeutics (Tcl Pharma / Effimune renamed OSE in 2016)
- Head of the research laboratory
- Director of Antibody Engineering & Discovery
- Conducted several preclinical programs incl. currently partnered products
- Master's degree in Biology



**Shihong Nicolaou**  
Independent Director



- Advisor in Intellectual Property at NPS consulting, TPLG and Larta Institute
- Directed and managed intellectual property portfolio at OIC from the University of California (San Diego)
- Extensive R&D experience in biotech and pharma industry (Agouron, Warner-Lambert, and Pfizer)
- PhD in Pharmaceutical Chemistry from the University of Kansas



**Alexis Peyroles**  
Independent Director



- CEO of BetaGlue Therapeutics S.p.a.
- Co-founder of Inside Therapeutics and co-founder of OWL Lifesciences
- Previously CEO of OSE Immunotherapeutics, COO of Cherry Biotech
- Graduated from EDHEC, Executive MBA from Imperial College London



# International research Scientific Advisory Board (research 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

**OSE** IMMUNO  
THERAPEUTICS



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

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Immuno-Oncology & Immuno-Inflammation

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44200 Nantes, France

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10, Place de Catalogne  
75014 Paris, France

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