

**OSE** IMMUNO  
THERAPEUTICS



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

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February 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 I&I asset Lusvertikimab (UC)**

## Large market opportunities

### Focus on multi-billion \$ markets

- **I&I:** IBD (Ulcerative Colitis), Cardiovascular-Renal-Metabolic diseases (MASH), Kidney Transplantation,
- **I/O:** NSCLC, HNSCC, Leukemia

## 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 12-18 months

- **Tedopi®:** Confirmatory pivotal phase 3 NSCLC 2L and combination Phase 2 update
- **Lusvertikimab (OSE-127):** Full dataset efficacy results Ulcerative Colitis Phase 2 (Open-label extension)
- **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

# An experienced executive leadership team



Nicolas Poirier, PhD  
CEO

- 20+ years of experience in biotech/immunotherapy
- Previously CSO, 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 ...)



Silvia Comis, MD  
CHIEF CLINICAL RESEARCH OFFICER

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



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



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)






Aurore Morello, PhD  
HEAD OF RESEARCH




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



# Clinical Pipeline

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

| I&I | Product candidate                     | Target   | Indication                | Research       | IND-enabling | Phase Ia/Ib | Phase II | Phase III               | Upcoming Milestones                |
|-----|---------------------------------------|--|---------------------------|----------------|--------------|-------------|----------|-------------------------|------------------------------------|
|     | OSE-127<br><i>Lusvertikimab</i>       | Anti-IL-7R   | <b>Ulcerative Colitis</b> | [Progress bar] |              |             |          | <b>Positive Results</b> | Extension data<br>Strategic update |
|     | BI 770371                             | Anti-SIRPα    | MASH                      | [Progress bar] |              |             |          |                         | Phase 2a update                    |
|     | FR104/VEL-101                         | Anti-CD28     | Kidney Transplantation    | [Progress bar] |              |             |          |                         | Phase 2 start                      |
|     | ABBV-230                              | Anti-ChemR23  | Chronic Inflammation      | [Progress bar] |              |             |          |                         | Phase 1 start                      |
|     | OSE-220<br><i>Pro-Resolutive mAbs</i> | Undisclosed GPCR Agonist   | Chronic Inflammation      | [Progress bar] |              |             |          |                         | Preclinical update                 |

| IO                | Product candidate   | Target   | Indication                              | Research       | IND-enabling | Phase Ia/Ib | Phase II | Phase III                          | Upcoming Milestones     |
|-------------------|---|--|---|----------------|--------------|-------------|----------|------------------------------------|-------------------------|
|                   | Tedopi  | Neoepitopes immunotherapy  | <b>NSCLC Mono post-ICI 2L</b>           | [Progress bar] |              |             |          | <b>Pivotal Phase 3<br/>EU + US</b> | Phase 3 update          |
|                   |   |  | PDAC Combo ( <i>exploratory eIIS</i> )  | [Progress bar] |              |             |          |                                    | Phase 2 readout H1-2025 |
|                   |   |  | OC Mono or Combo ( <i>eIIS</i> )        | [Progress bar] |              |             |          |                                    | Phase 2 readout H1-2026 |
|                   |   |  | NSCLC Combo 2L post-ICI ( <i>eIIS</i> ) | [Progress bar] |              |             |          |                                    | Phase 2 readout H2-2026 |
|                   | OSE-279   | Anti-PD1   | Solid tumors                            | [Progress bar] |              |             |          |                                    | Phase 1b combo data     |
|                   | BI 770371   | Anti-SIRPα  | Solid tumors (HNSCC)                    | [Progress bar] |              |             |          |                                    | Phase 1b results        |
| IL-7R CAR-T       | IL-7R CAR-T  | IL-7R+ tumors  | [Progress bar]                          |                |              |             |          | IND                                |                         |
| Anti-PD1/cytokine | Undisclosed  | Solid tumors   | [Progress bar]                          |                |              |             |          | Preclinical update                 |                         |




# Research platforms

Extra(not) Ordinary Research PowerHouse




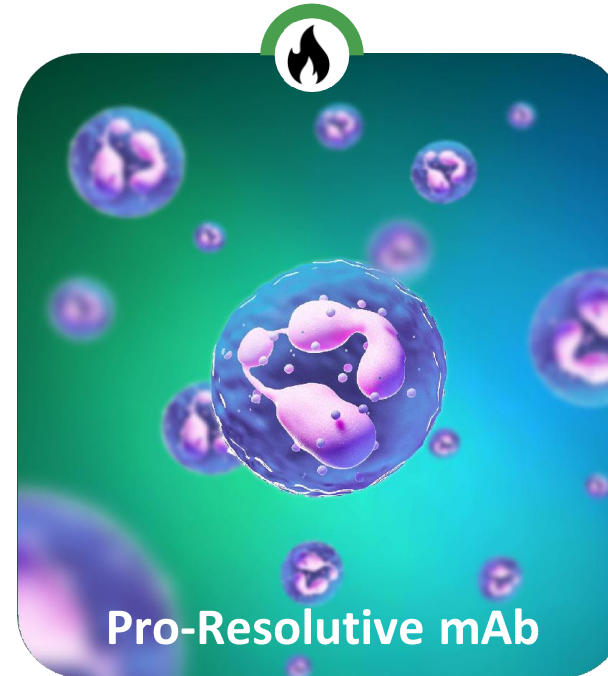
**Myeloid Checkpoint**

- ▶ 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    ■ Potential  
■ Immuno-Inflammation    ■ 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

**abbvie**

Up to **\$713m**

**\$48m** upfront

+ Tiered royalties on Global net Sales

**FR104/VEL-101**  
Kidney transplant

**Veloxis**  
PHARMACEUTICALS  
an Asahi Kasei company

Up to **€315m**

**€13.9m** received

+ Tiered royalties on Global Sales

# Key potential catalysts\*

## Readouts

- **Lusvertikimab**
  - ✓ Full data set Phase 2 induction UC [results](#)
  - ✓ UC phase 2 safety [results](#)  
Extension period Phase 2 UC [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



## 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

- **Undisclosed internal Programs**  
IND/Phase 1
- **New Research 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

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**

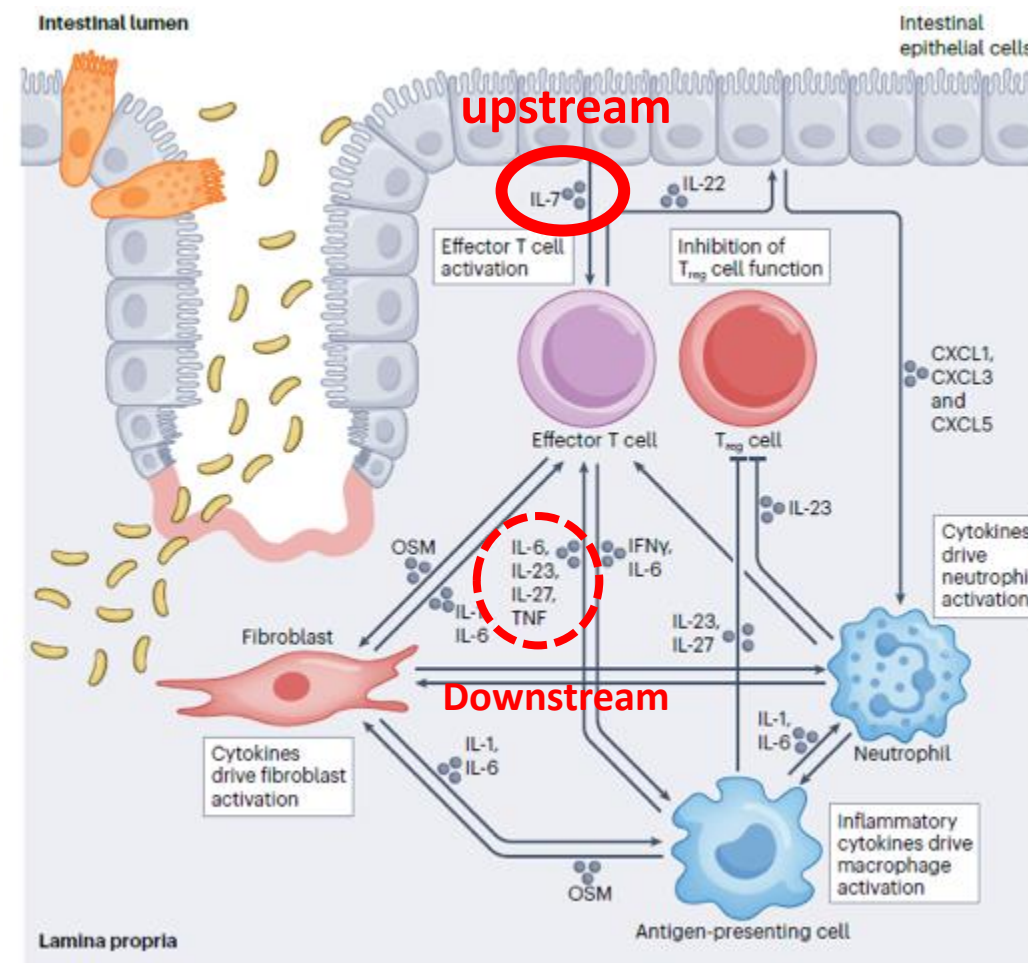
# IL-7 fuels chronic inflammation in Tissues

## Upstream mechanism of resistance in hyper-inflammation

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-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.”



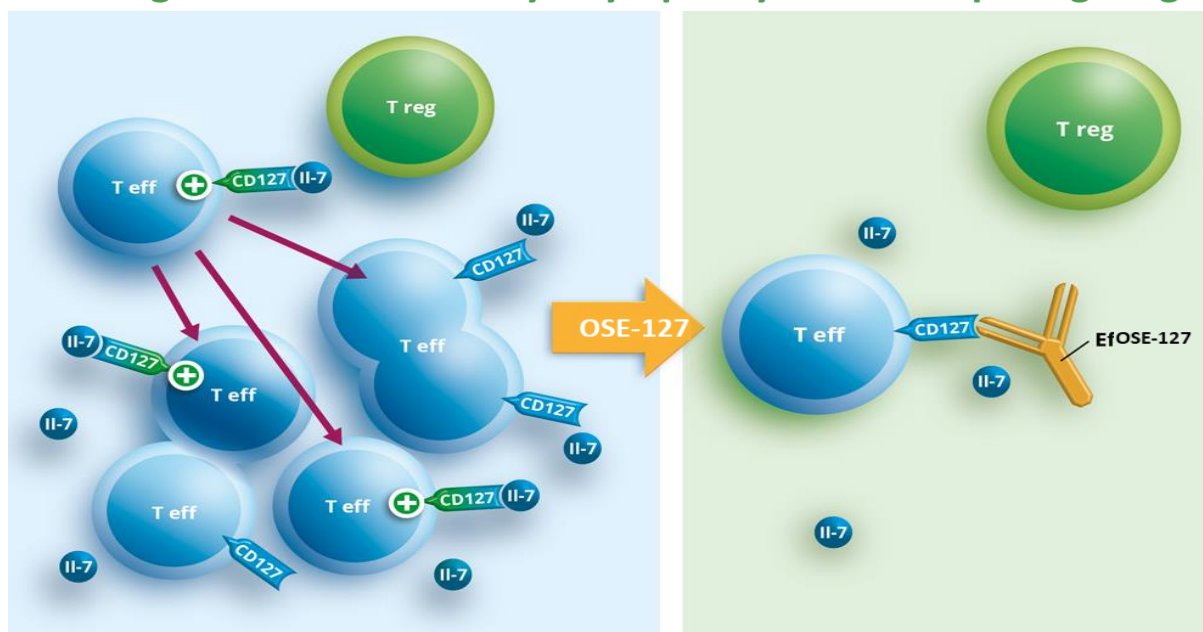
Neurath M. Nature Review Immunology 2024



# 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

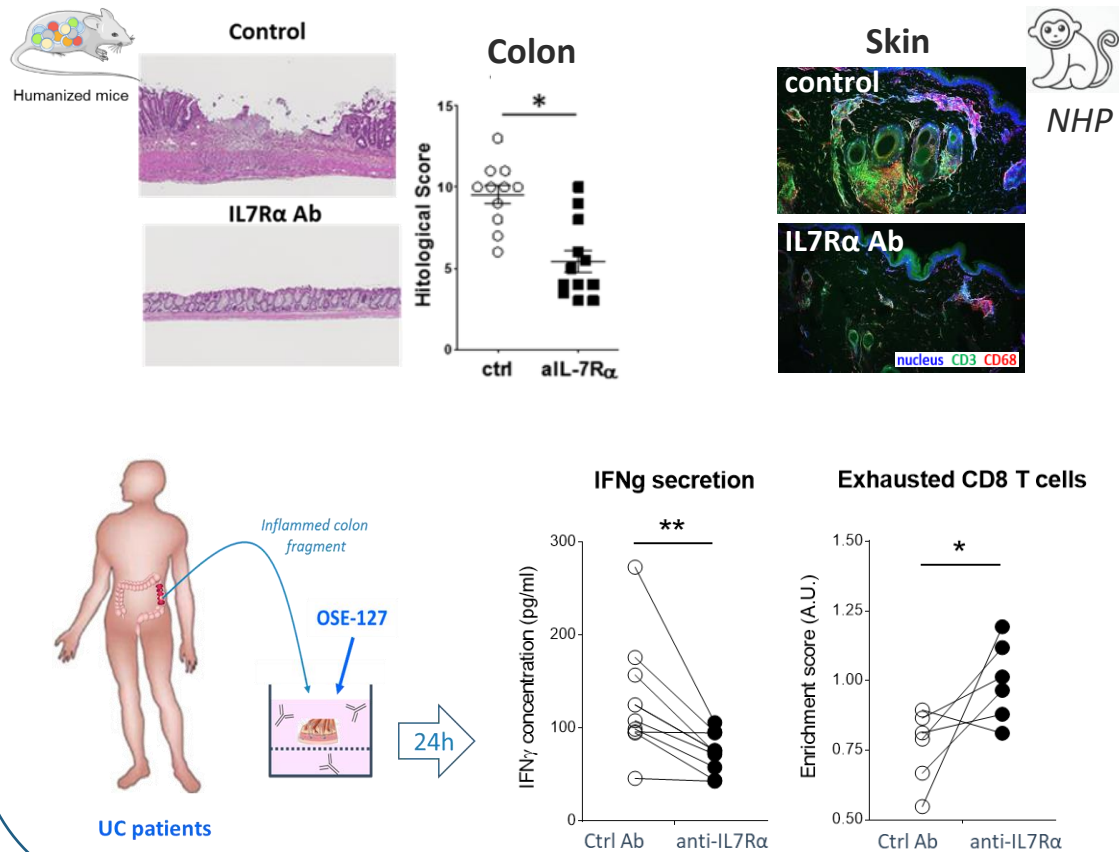
- IL-7 produced by inflamed tissues sustain **T-cell survival and chronicity**, drives **Th1 and Th17** T cell differentiation
- IL-7R pathway overexpression in anti-TNF IBD non-responders<sup>1</sup>
- Lusvertikimab, first non-internalizing (fully antagonist) acting as pure antagonist anti-IL-7R mAb<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 2024



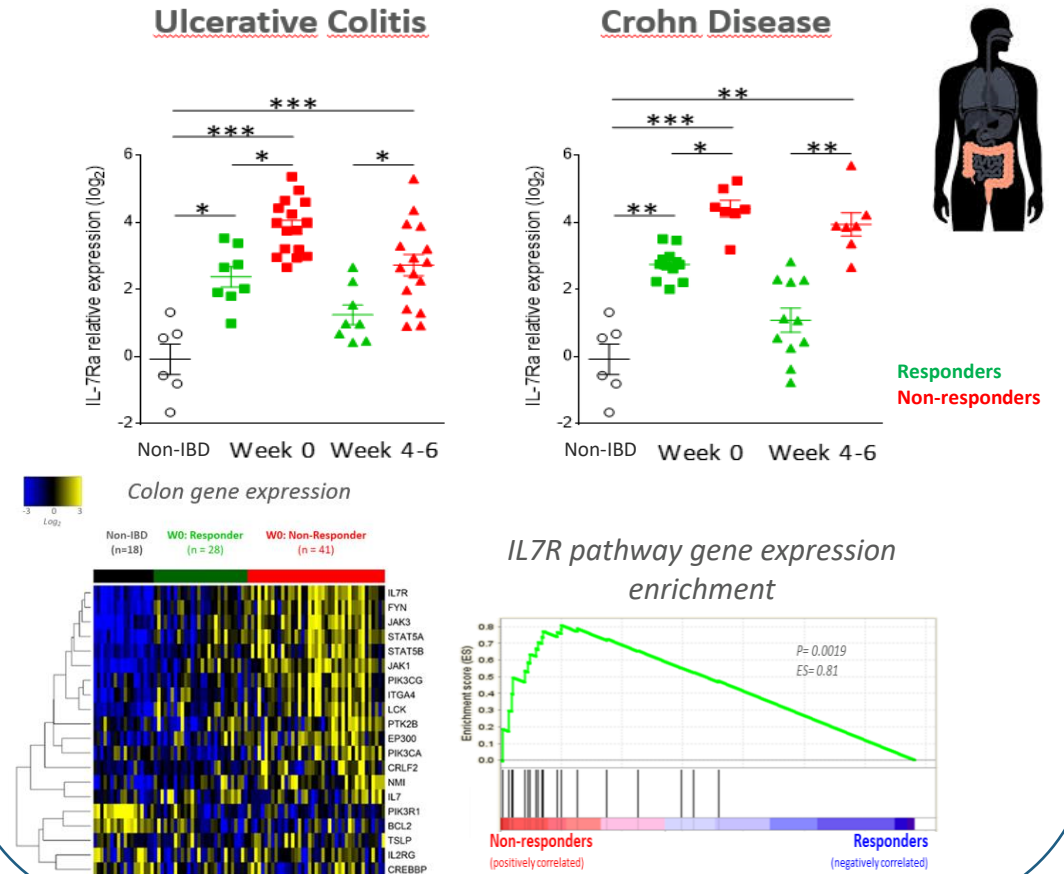
# Preclinical & Translational research of IL-7 in IBD

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

## High preclinical efficacy in different models



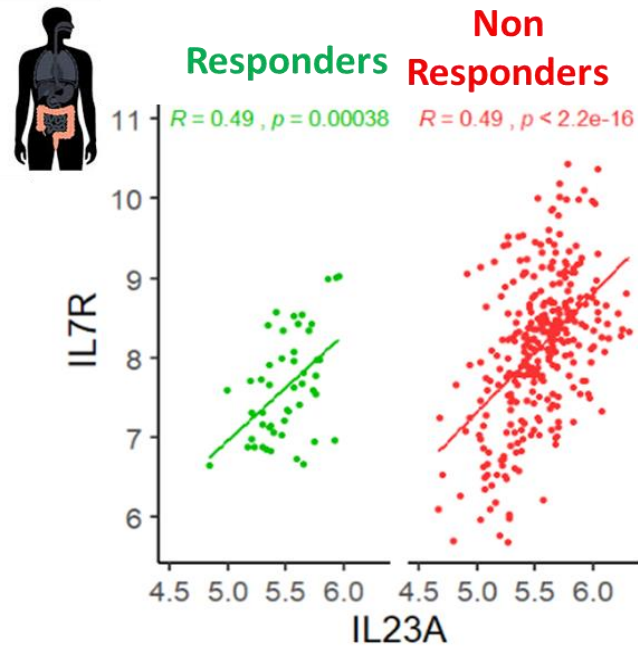
## Mucosal IL7R pathway over-expression in IBD High correlation with SOC unresponsiveness



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

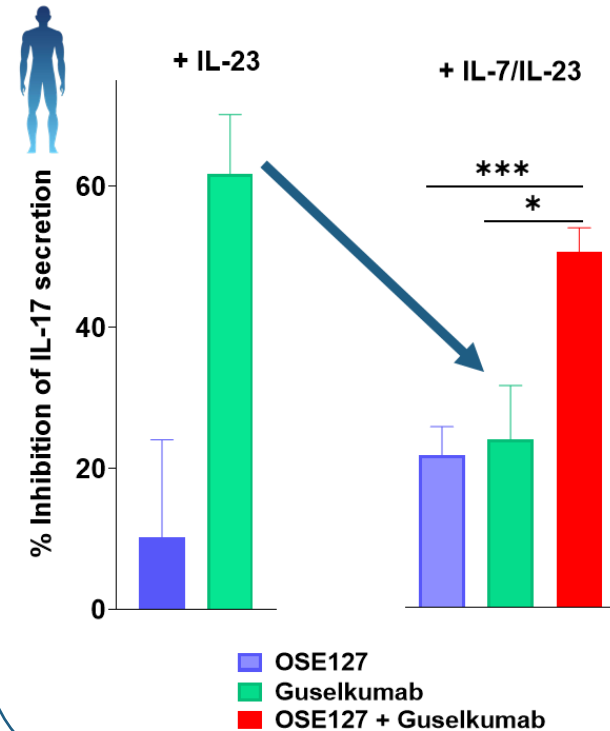


## IL-7R and IL-23 cytokine mucosal over-expression in Ustekinumab UC patients



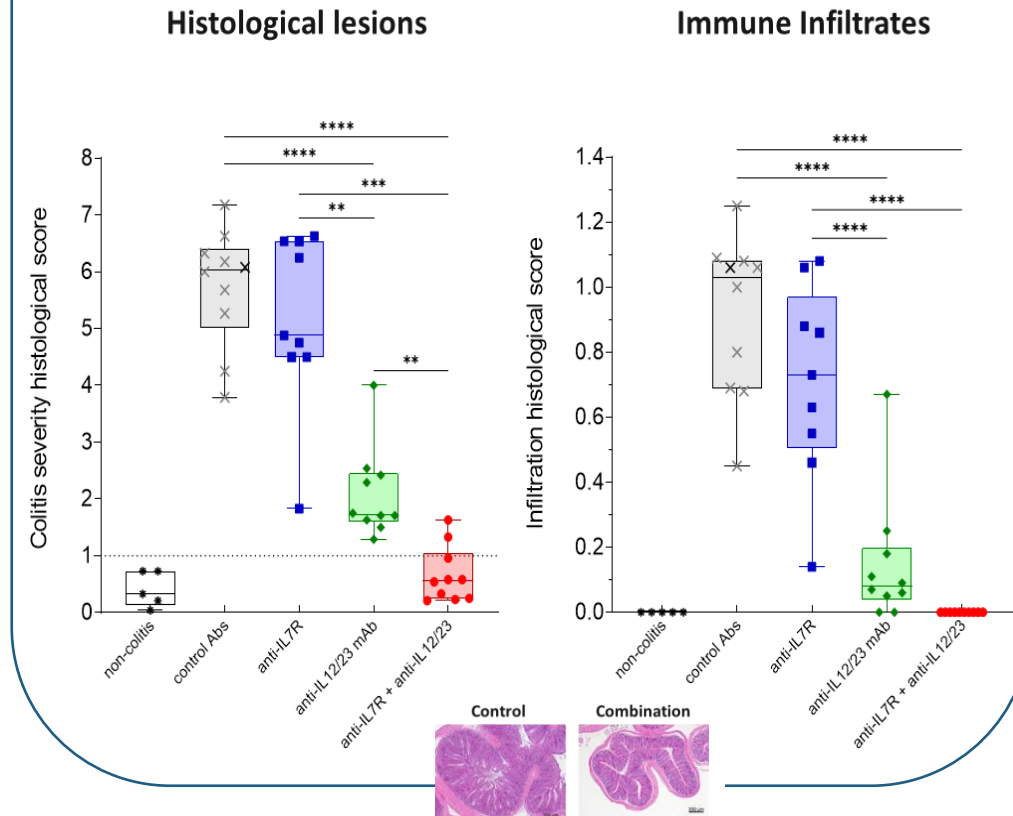
UC colon transcriptomic analysis (GSE206285)

## IL-7 drives IL-23 antagonist resistance



In-vitro model: naive human primary Th17 cells differentiation

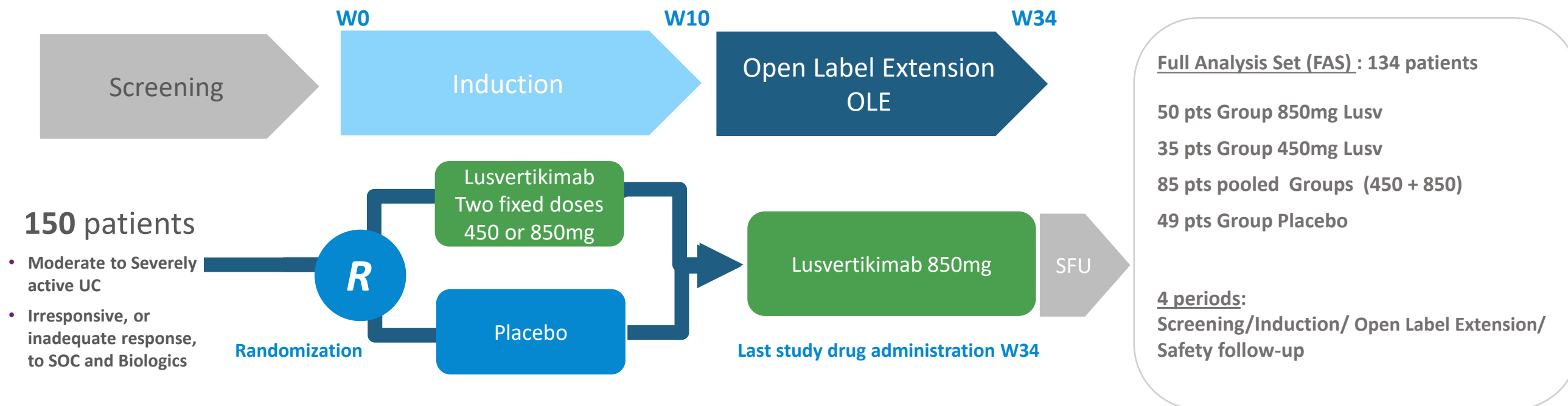
## IL-7R + IL-12/23 blockade synergizes to induce complete mucosal healing in chronic colitis



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

# CoTikiS Phase 2 randomized study of Lusvertikimab

## Moderate-to-severe Ulcerative Colitis



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)

# Demographics and disease characteristics

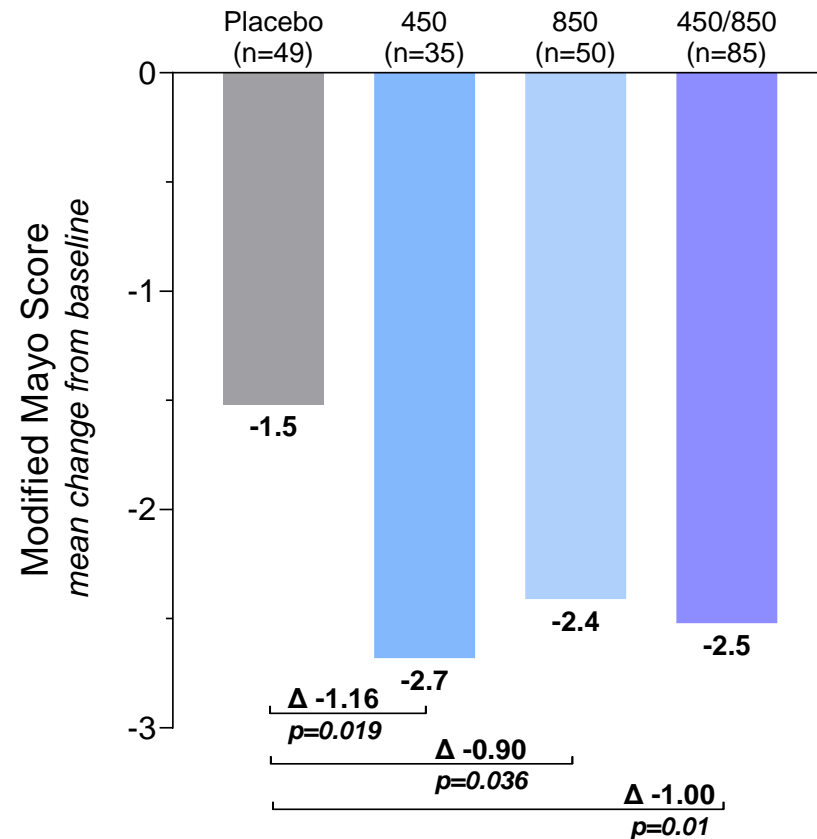
|   | L850 mg (n=50)    | L450 mg (n=35)    | Placebo (n=49)    | Total (n=134)     |
|---|-------------------|-------------------|-------------------|-------------------|
| Age: mean (SD)                            | 42.5 (15.1)       | 38.8 (10.5)       | 42.7 (15.9)       | 41.6 (14.4)       |
| Sex: Male                                 | 27 (54.0%)        | 22 (62.9%)        | 28 (57.1%)        | 77 (57.5%)        |
| Weight (kg) Mean (SD)                     | 71.5 (18.0)       | 72.8 (16.2)       | 75.3 (15.2)       | 73.2 (16.5)       |
| Never Smoker                              | 43 (86.0%)        | 25 (71.4%)        | 39 (79.6%)        | 107 (79.9%)       |
| Never Alcohol Consumption                 | 40 (80.0%)        | 25 (71.4%)        | 34 (69.4%)        | 99 (73.9%)        |
| Region: EU Country                        | 22 (44.0%)        | 8 (22.9%)         | 22 (44.9%)        | 52 (38.8%)        |
| UC Duration (Years) Mean (SD)             | 9.3 (8.6)         | 7.2 (6.5)         | 8.2 (7.5)         | 8.4 (7.7)         |
| <b>Previous Exposure to Biologics</b>     | <b>19 (38.0%)</b> | <b>5 (14.3%)</b>  | <b>19 (38.8%)</b> | <b>43 (32.1%)</b> |
| <i>Previous biologics: 2+</i>             | <b>13 (68.8%)</b> | <b>2 (40%)</b>    | <b>11 (57.9%)</b> | <b>26 (60.4%)</b> |
| <i>Previous biologics: 3+</i>             | 6 (31.5%)         | 0 (0%)            | 5 (26.3%)         | 11 (25.6%)        |
| Concomitant Use of Steroids               | 25 (50.0%)        | 18 (51.4%)        | 23 (46.9%)        | 66 (49.3%)        |
| Modified Mayo Score (MMS) Mean (SD)       | 6.5 (1.0)         | 6.0 (1.4)         | 6.6 (1.2)         | 6.4 (1.2)         |
| <b>Category of MMS</b>                    |                   |                   |                   |                   |
| 5-6                                       | 25 (50.0%)        | 17 (48.6%)        | 21 (42.9%)        | 63 (47.0%)        |
| <b>7-9</b>                                | <b>25 (50.0%)</b> | <b>13 (37.1%)</b> | <b>26 (53.1%)</b> | <b>64 (47.8%)</b> |
| Endoscopic Subscore Mean (SD)             | 2.6 (0.5)         | 2.4 (0.5)         | 2.5 (0.5)         | 2.5 (0.5)         |
| <b>Category of Endoscopic Subscore: 3</b> | <b>32 (64.0%)</b> | <b>15 (42.9%)</b> | <b>26 (53.1%)</b> | <b>73 (54.5%)</b> |
| C-Reactive Protein (mg/L) Mean (SD)       | 11.2 (18.1)       | 9.4 (16.7)        | 8.6 (13.6)        | 9.8 (16.1)        |
| Serum Albumin (g/L) Mean (SD)             | 40.8 (5.4)        | 42.6 (4.5)        | 42.3 (4.4)        | 41.8 (4.9)        |
| FCP (µg/g) Mean (SD)                      | 1191.8 (1603.3)   | 1088.0 (1600.5)   | 1459.5 (1865.0)   | 1261.6 (1696.7)   |



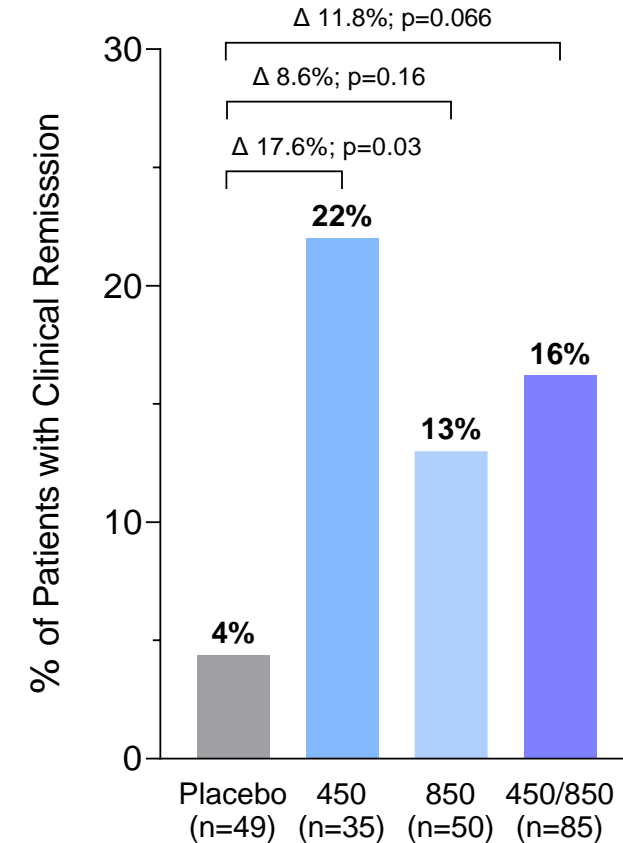
# Clinical induction results at week-10

Clinically and statistically relevant clinical remission in the Lusvertikimab groups

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



## Clinical Remission at W10

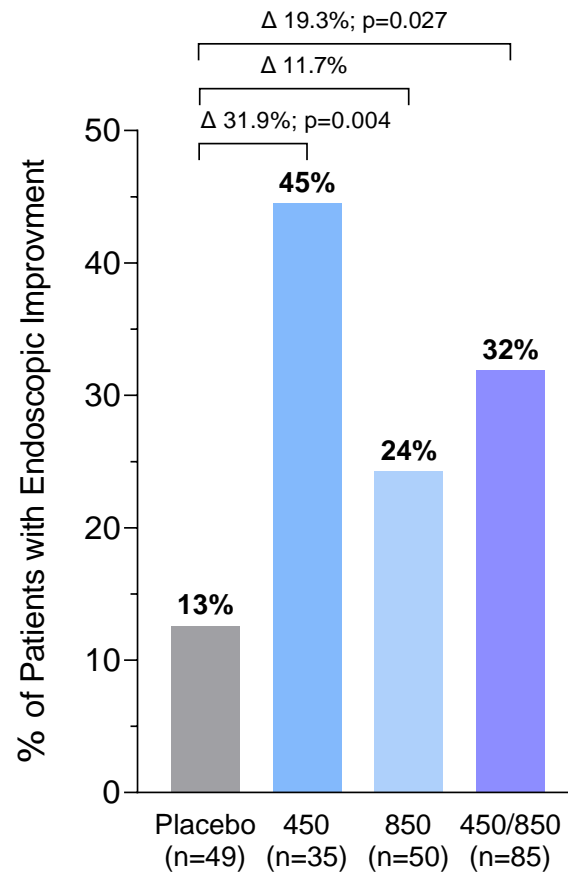


clinical remission: MMS  $\leq 2$  with no subscore  $> 1$  and a RB 0, SF  $\leq 1$ , MES 0 or 1

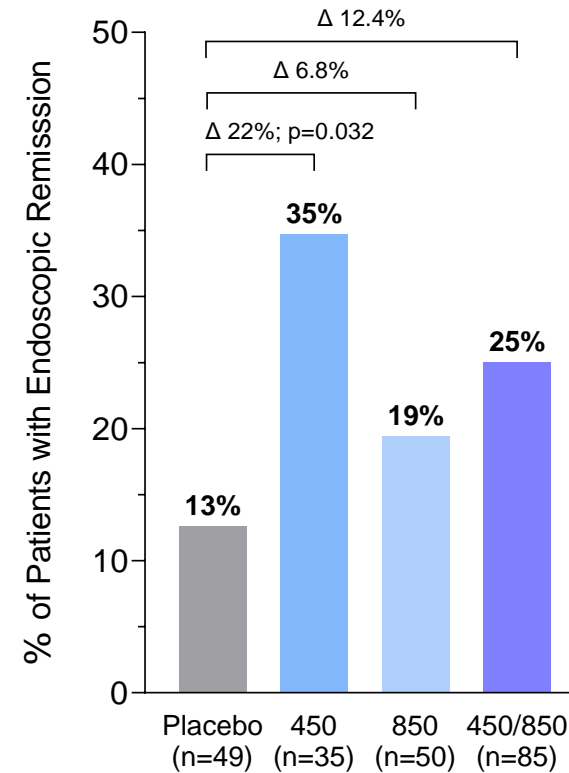
# Clinical induction results at week-10

Clinically meaningful and significant endoscopic improvement and remission

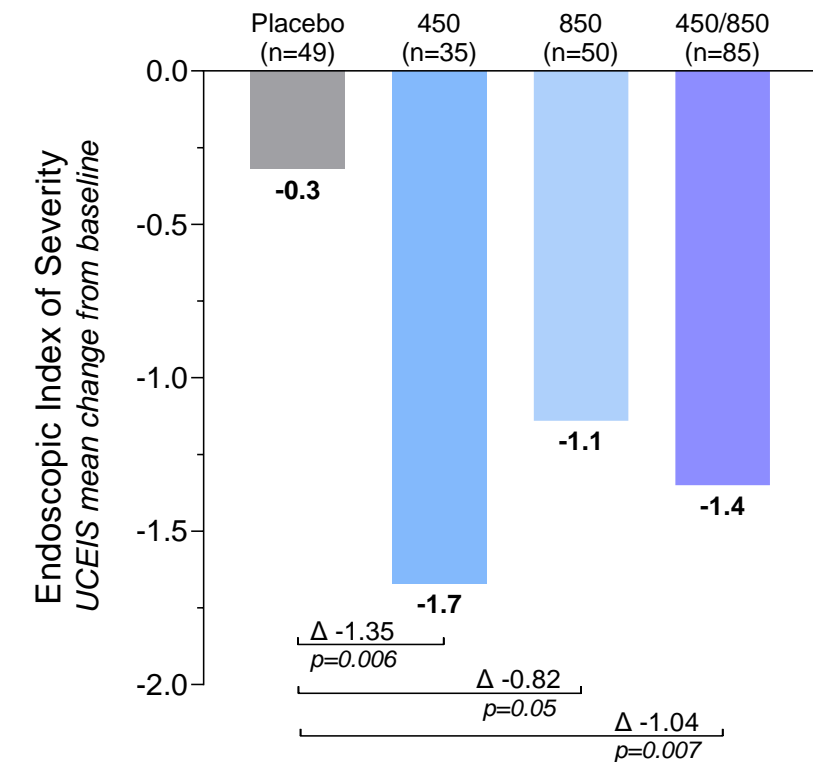
## Endoscopic Improvement\* at W10



## Endoscopic Remission\*\* at W10



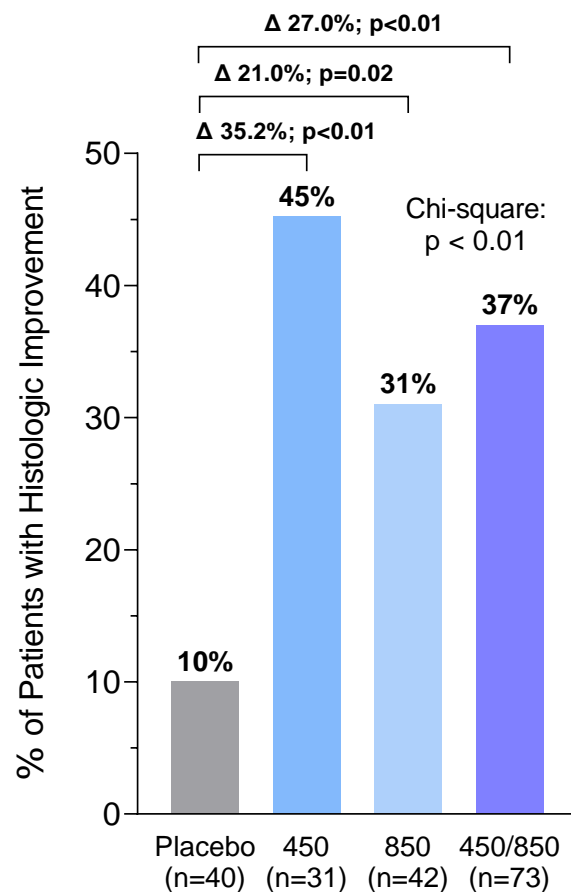
## UC Endoscopic Index of Severity UCEIS\*\*\* change from baseline at W10



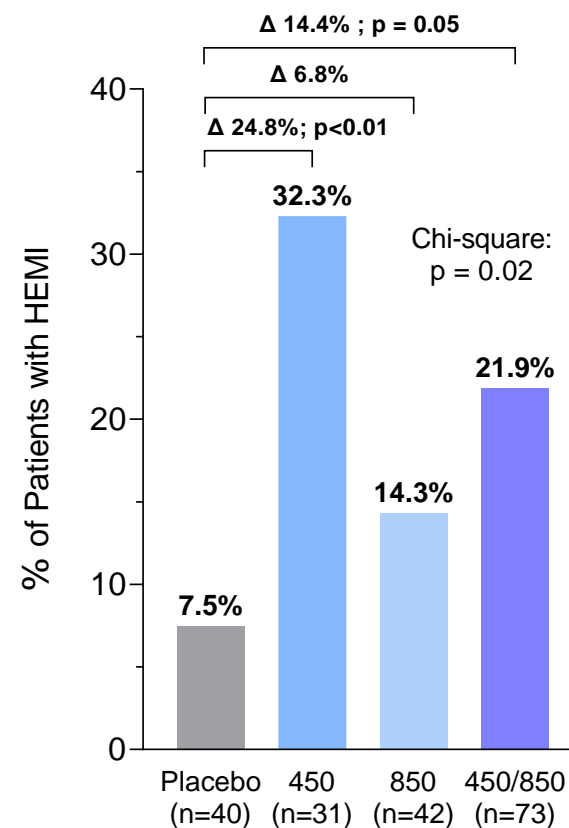
# Clinical induction results at week-10

Clinically meaningful and significant histologic and histo-endoscopic mucosal improvement

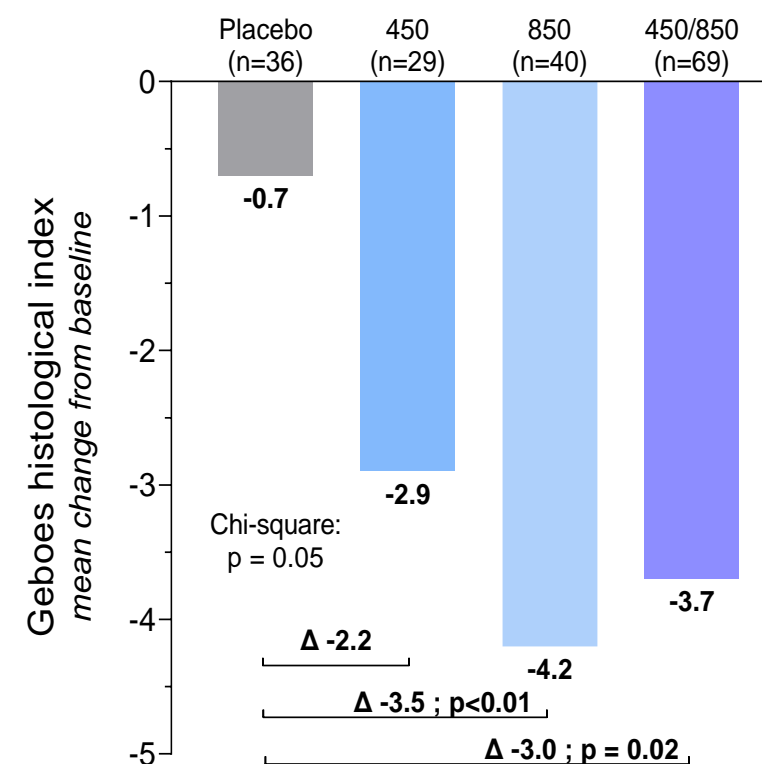
## Histological Improvement at W10\*



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



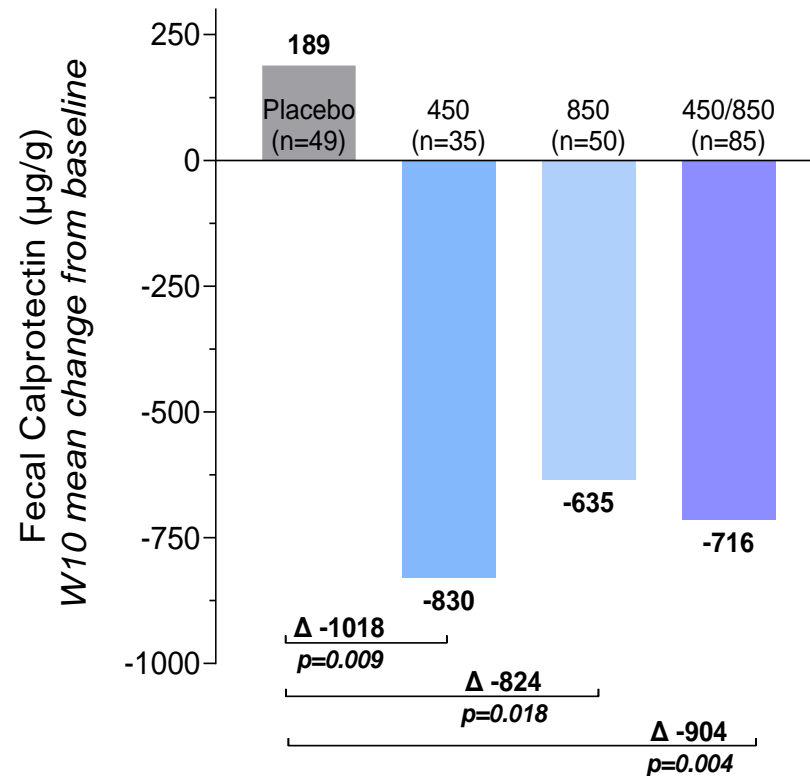
## Histological Geboes index change from baseline at W10



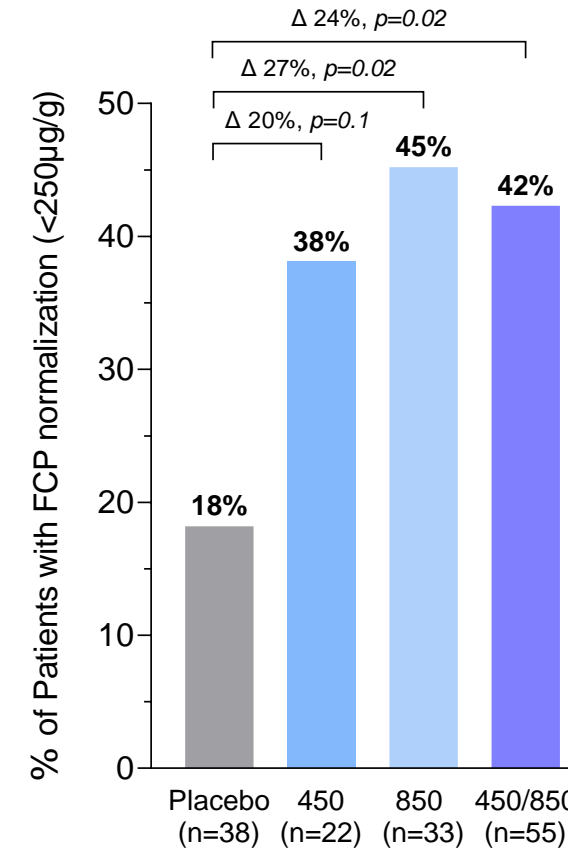
# Clinical induction results at week-10

Significant Fecal Calprotectin decrease and normalization

Fecal Calprotectin (FCP) changes from baseline at W10



FCP normalization at W10 in patients with high baseline FCP (>250µg/g)

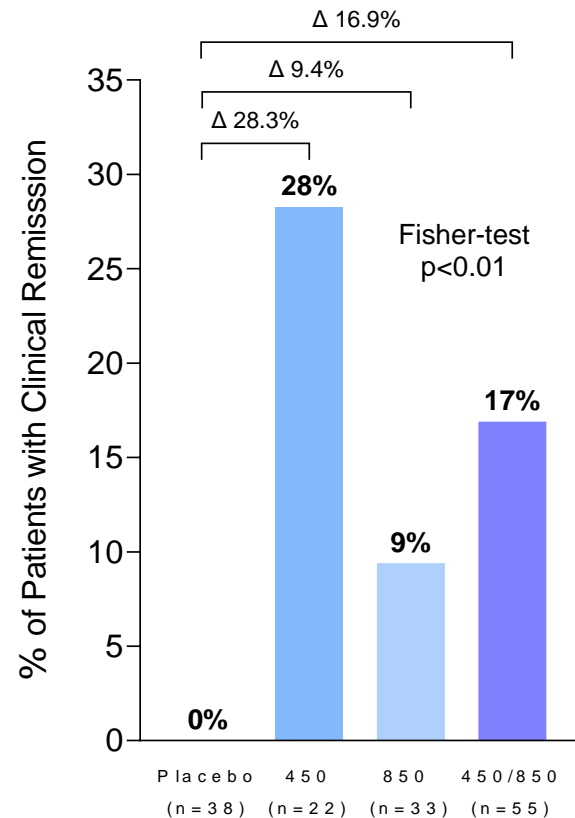




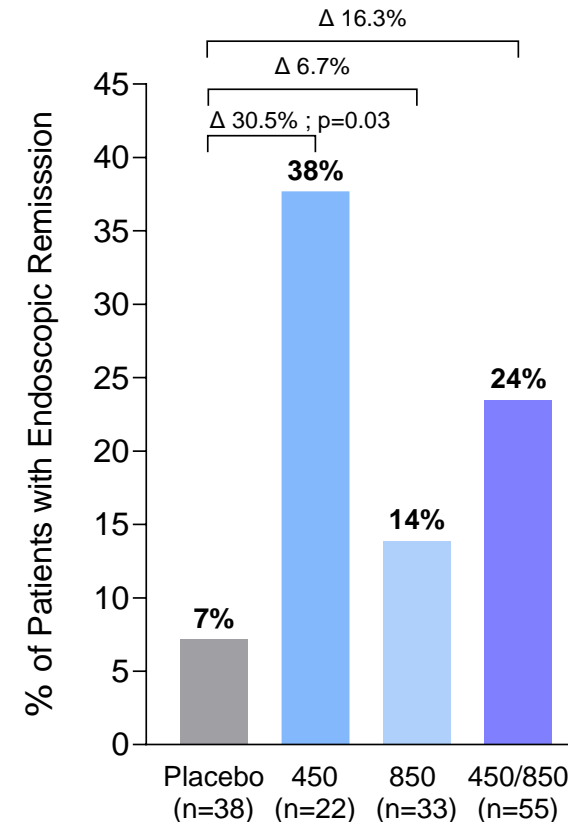
# Clinical induction results at week-10

Clinically meaningful and significant clinical and endoscopic remission in patients with high baseline FCP (>250µg/g)

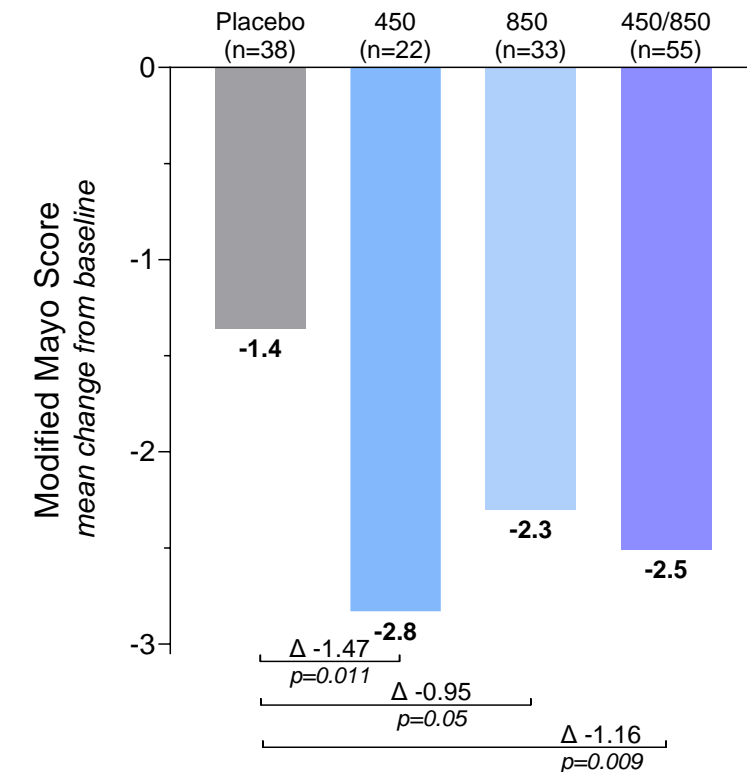
**Clinical Remission at W10  
in patients with high baseline FCP**



**Endoscopic Remission at W10  
in patients with high baseline FCP**



**MMS Improvement at W10  
in patients with high baseline FCP**



# Safety during induction period

|  | L450 mg<br>(N=36)<br>N(%) [E] | L850 mg<br>(N=51)<br>N(%) [E] | Placebo<br>(N=49)<br>N(%) [E] | Total<br>(N=136)<br>N(%) [E] |
|--|-------------------------------|-------------------------------|-------------------------------|------------------------------|
| At least one TEAE                                    | 17 (47.2) [33]                | 20 (39.2) [42]                | 16 (32.7) [29]                | 53 (39.0) [104]              |
| At least one TEAE related to study treatment         | 3 (8.3) [4]                   | 4 (7.8) [14]                  | 1 (2.0) [1]                   | 8 (5.9) [19]                 |
| At least one serious TEAE                            | 2 (5.6) [3]                   | 2 (3.9) [3]                   | 3 (6.1) [3]                   | 7 (5.1) [9]                  |
| At least one serious TEAE related to study treatment | 1 (2.8) [1]                   | 0 (0.0) [0]                   | 0 (0.0) [0]                   | 1 (0.7) [1]                  |
| At least one severe TEAE                             | 1 (2.8) [2]                   | 0 (0.0) [0]                   | 2 (4.1) [2]                   | 3 (2.2) [4]                  |
| At least one severe TEAE related to study treatment  | 1 (2.8) [1]                   | 0 (0.0) [0]                   | 0 (0.0) [0]                   | 1 (0.7) [1]                  |
| At least one related TEAE leading to death           | 0 (0.0) [0]                   | 0 (0.0) [0]                   | 0 (0.0) [0]                   | 0 (0.0) [0]                  |
| At least one TEAE leading to drug withdrawal         | 2 (5.6) [3]                   | 0 (0.0) [0]                   | 3 (6.1) [3]                   | 5 (3.7) [6]                  |
| At least one TEAE leading to drug interruption       | 1 (2.8) [1]                   | 0 (0.0) [0]                   | 2 (4.1) [2]                   | 3 (2.2) [3]                  |
| At least one TEAE leading to study discontinuation   | 2 (5.6) [3]                   | 0 (0.0) [0]                   | 3 (6.1) [3]                   | 5 (3.7) [6]                  |
| At least one AESI                                    | 7 (19.4) [7]                  | 9 (17.6) [10]                 | 6 (12.2) [7]                  | 22 (16.2) [24]               |
| At least one infection                               | 5 (13.9) [5]                  | 7 (13.7) [8]                  | 6 (12.2) [7]                  | 18 (13.2) [20]               |
| At least one lymphopenia < 500 10 <sup>6</sup> /L    | 2 (5.6) [2]                   | 2 (3.9) [2]                   | 0 (0.0) [0]                   | 4 (2.9) [4]                  |

Lusvertikimab was well tolerated with an acceptable safety profile

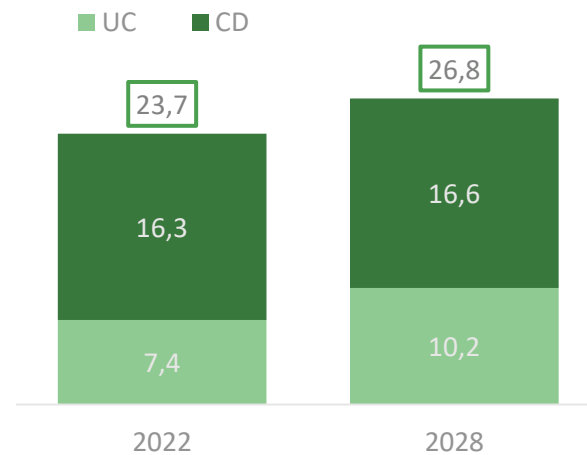
Lymphopenia was transient, not associated with a higher rate or severity of infection, was more frequent in patients treated with corticosteroids or with baseline values <1\*10<sup>9</sup>/L and did not lead to treatment discontinuation

# Significant opportunity in Ulcerative Colitis & Pipeline-in-a-Product potential (Multi-indications asset)

## 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

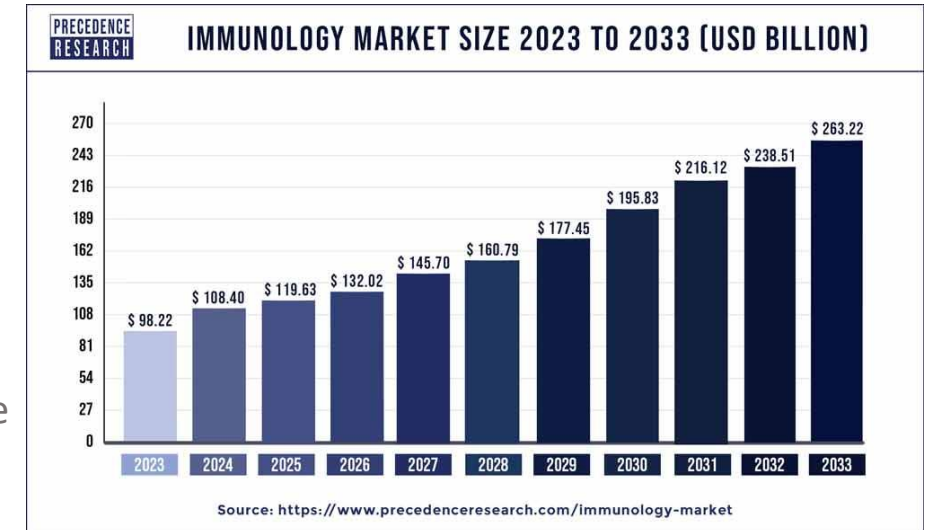
IBD **global market** projections for G7 major markets (USDbn<sup>1</sup>)



## Immuno & Inflammation (I&I) space

### Key Therapeutic Areas

- IBD
- Dermatology
- Rheumatology
- Neuro-Inflammation
- Systemic Autoimmune
- Nephrology



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 the upper lobe. The right lung (viewer's left) is shown with a network of bronchi and smaller nodules. The background is a dark blue gradient.

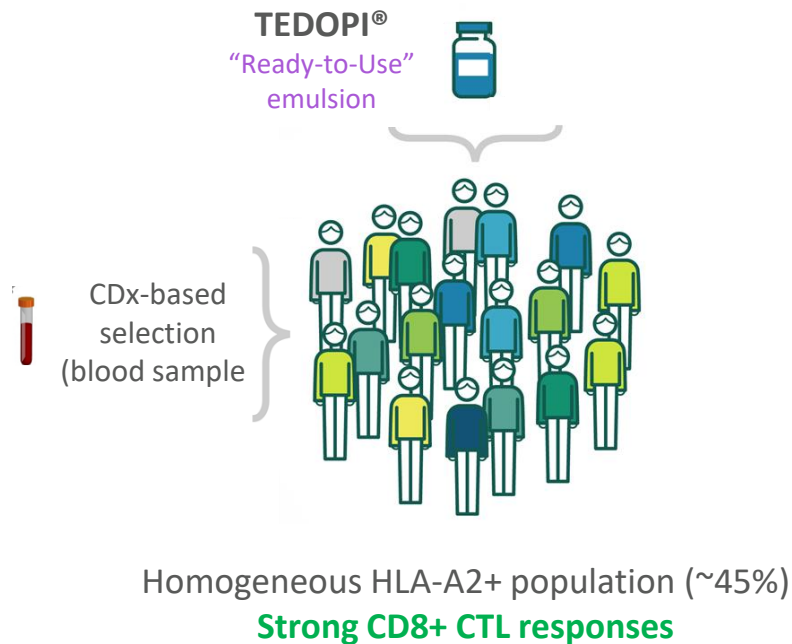
# TEDOPI®

**Most Advanced Therapeutic Cancer Vaccine**

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

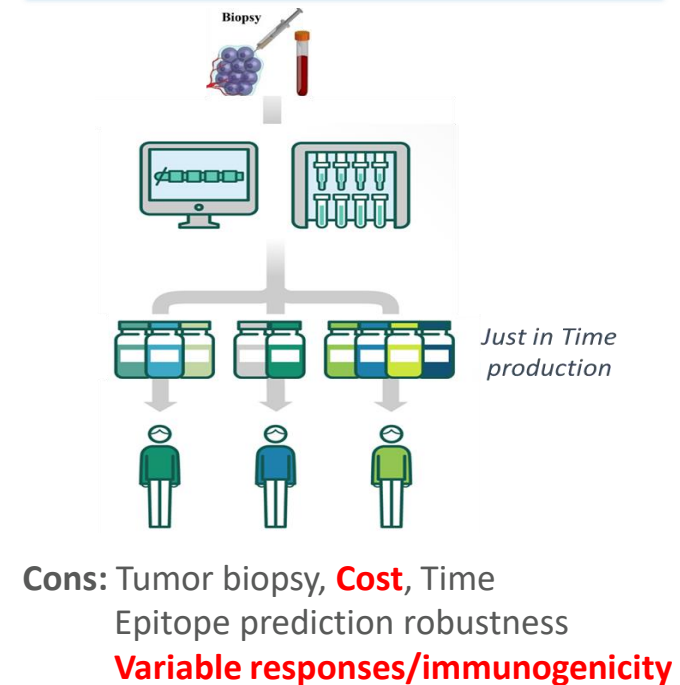
# Personalized vs *Off-the-Shelf* cancer vaccines

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



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

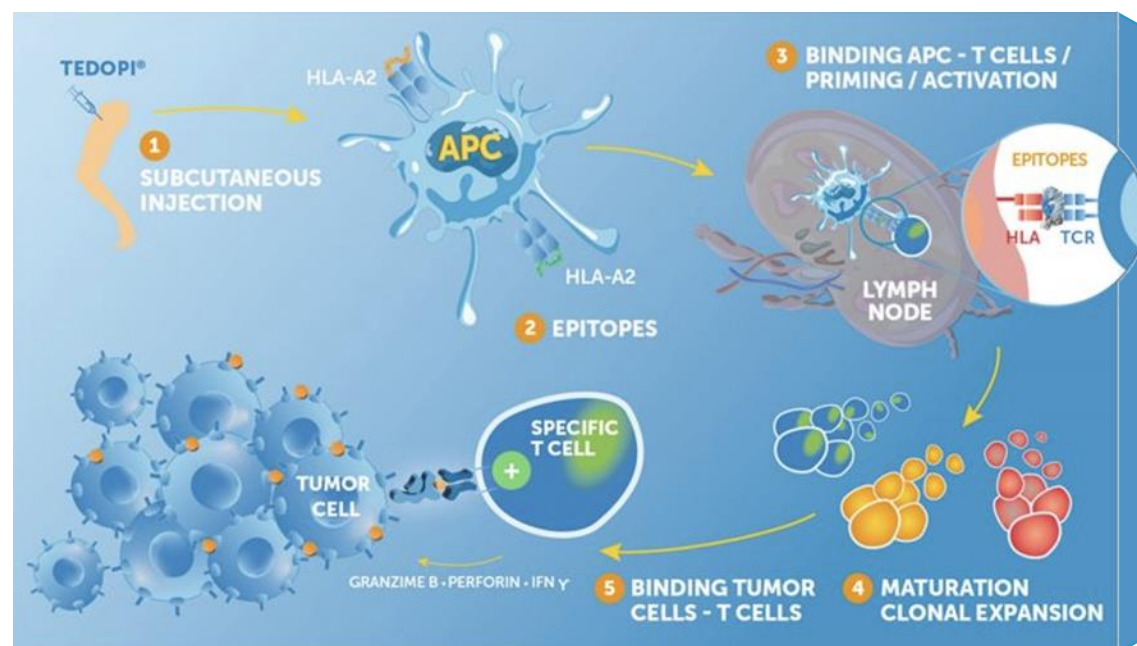
Neoantigen cancer vaccine  
= **Personalized Medicine**  
-> *Custom*



**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

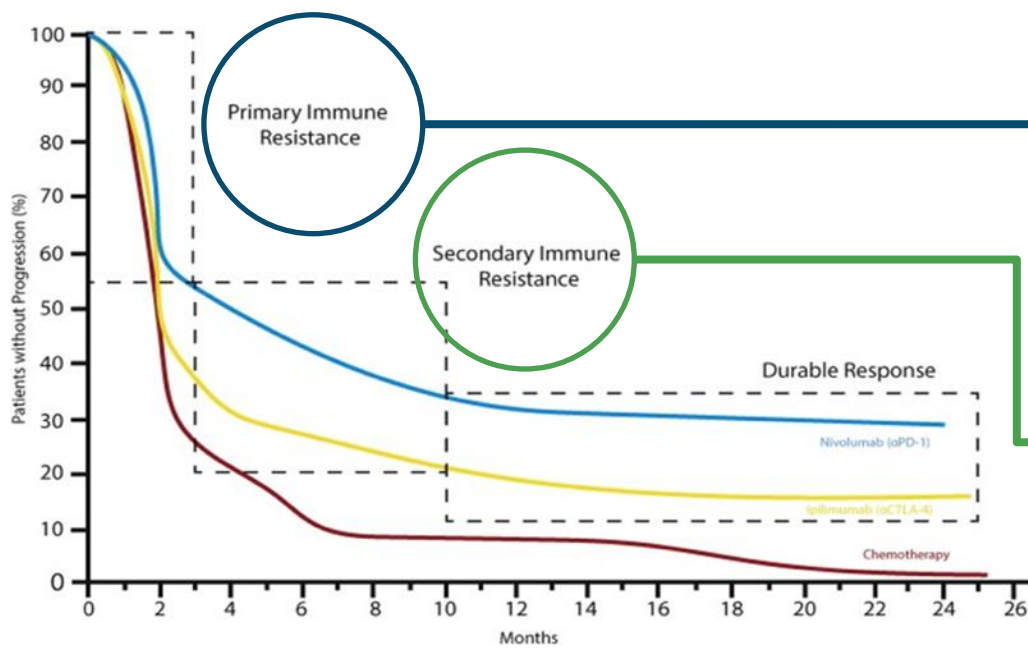
**Ready to Use**  
**subcutaneous** formulation  
with Q3W injection

**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

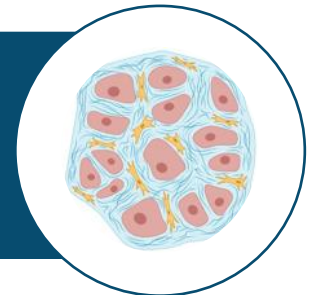
Shifting paradigms with cancer vaccine immunotherapy



### Primary (intrinsic) resistance

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

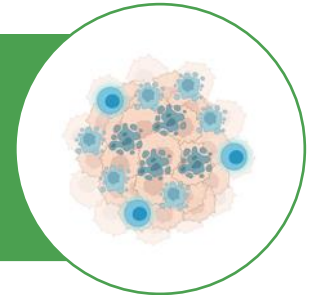
No T-cell refractory tumors



### 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



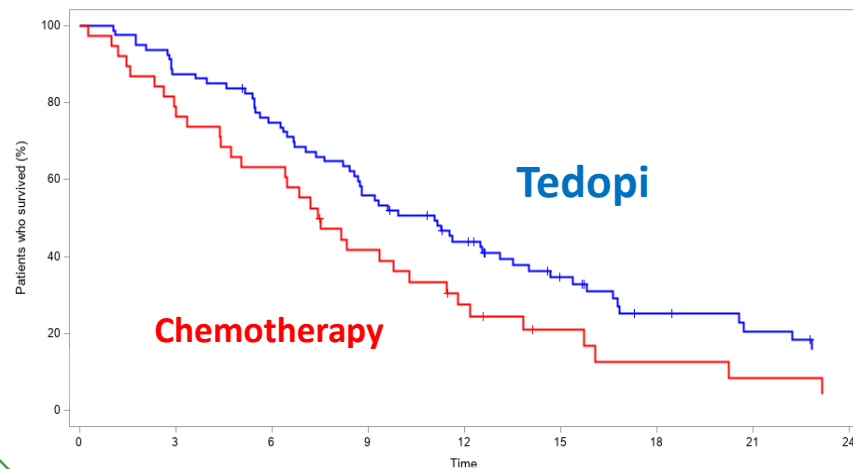
**Tedopi®** has the **potential to rejuvenate & refresh specific TILs** in immuno-sensitive tumors. Neopeptide-specific T cells have tumor killing potential and limited side effects.

# 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

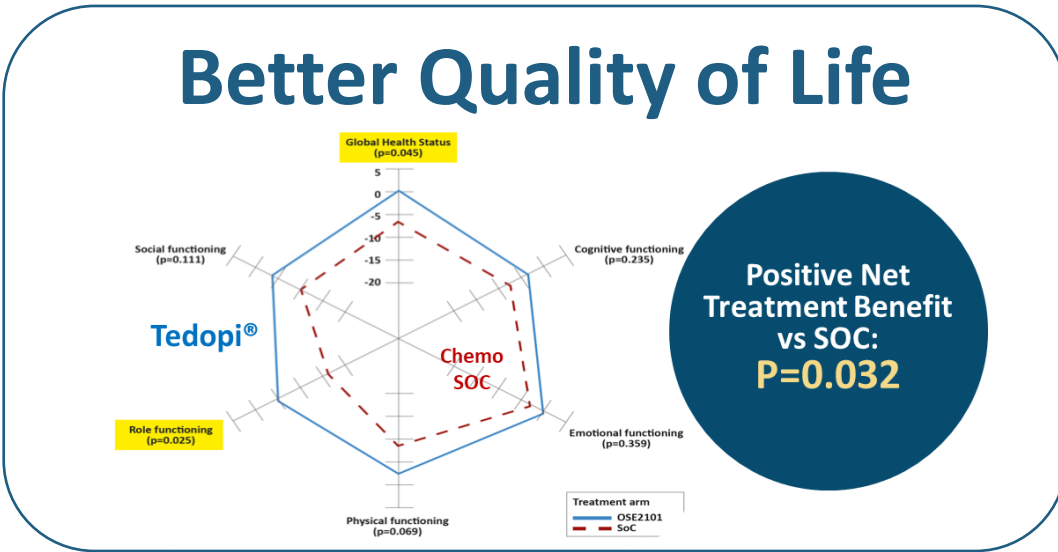
Delta OS: **3.6** months

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

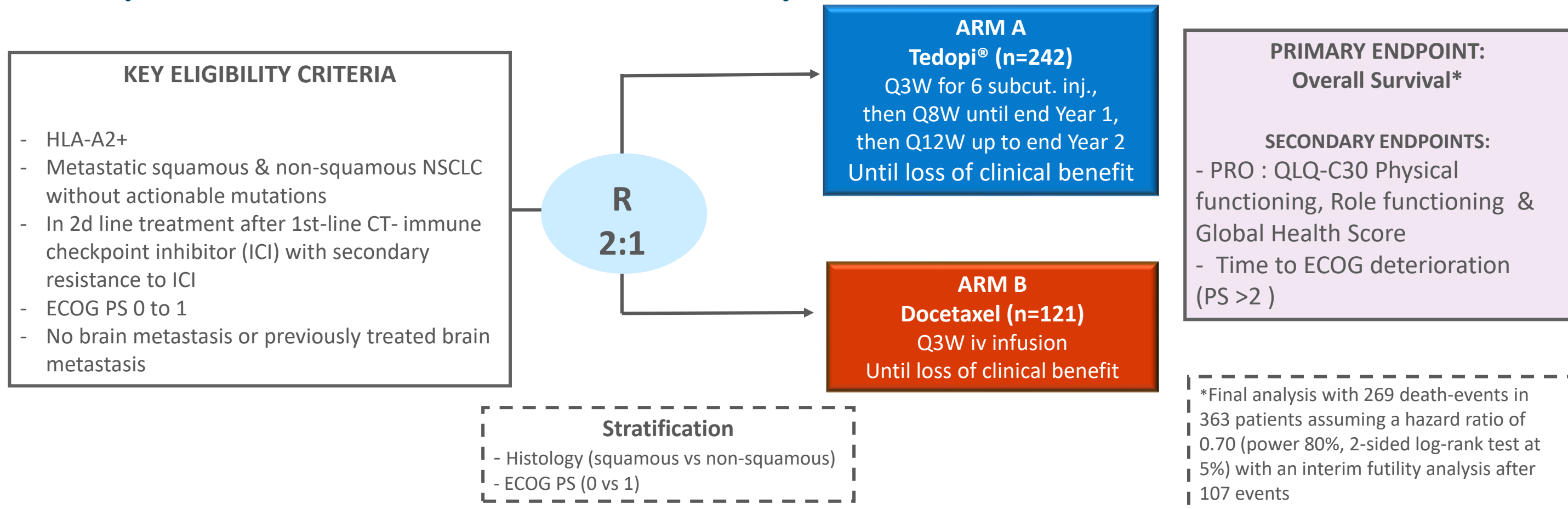
HR 0.59 /  
 p-value=0.017

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

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



# Tedopi® 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.

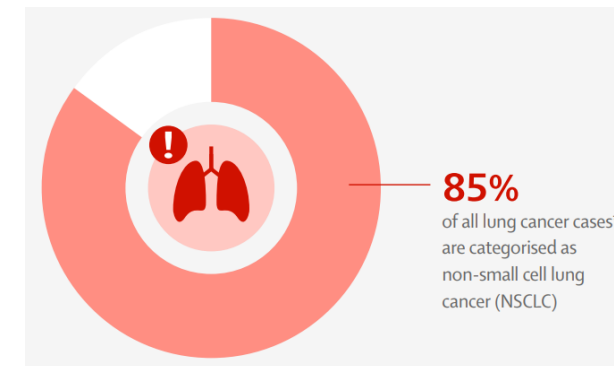
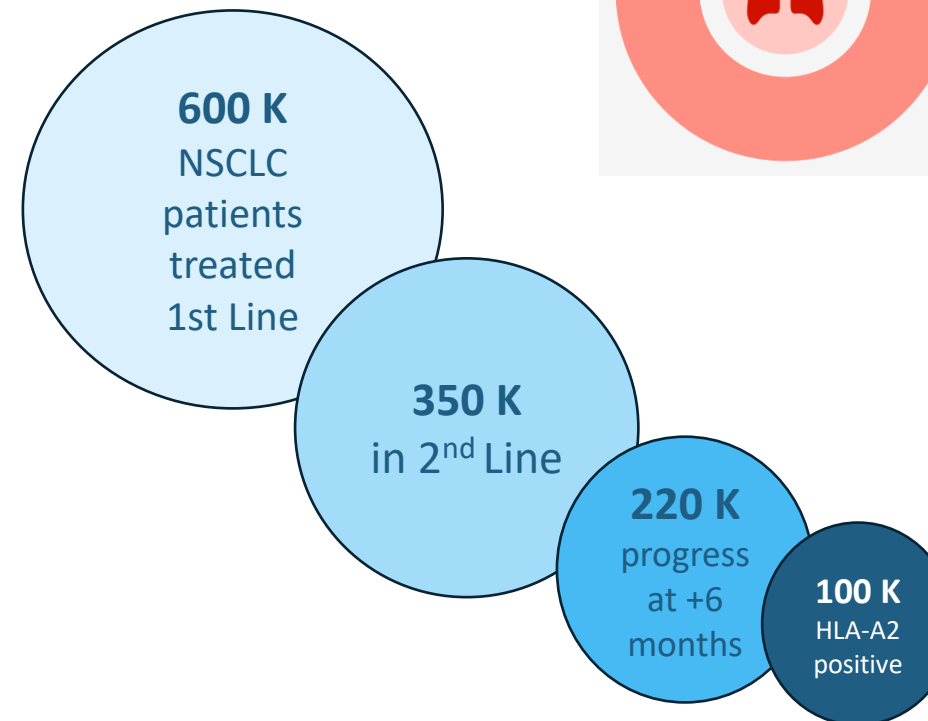
## Treatment paradigm in NSCLC with no driver mutation

- 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  |   |   |   |
| Current Study   | ATALANTE-1  | SAPPHIRE  | CONTACT-01  | LEAP-008  | COSTAR Lung   | PRESERVE-003  | Tropion-LUNG1   | EVOKE-01  | CARMEN-LC03   | NCT04928846   |
| n   | 219<br>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  |

# 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*



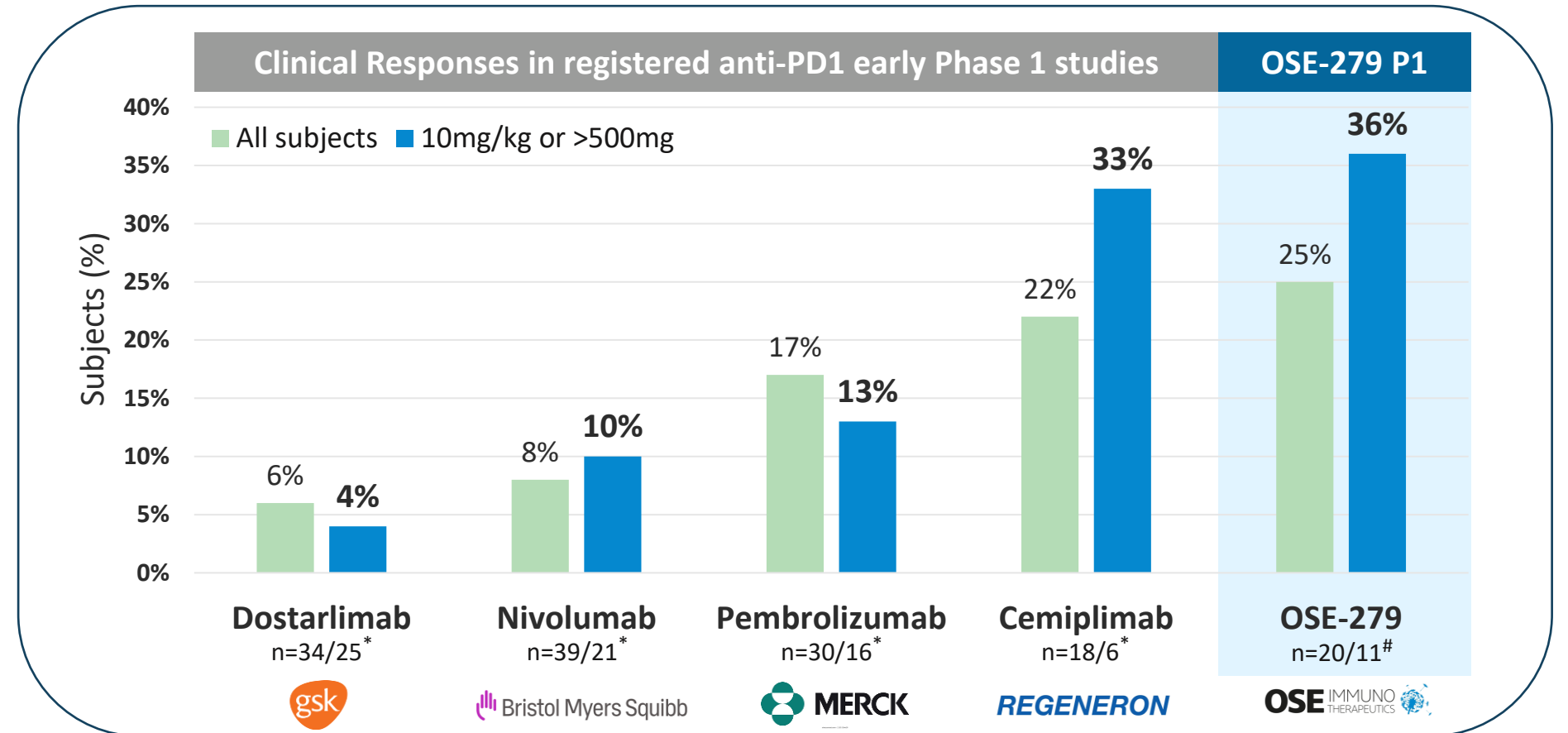
*Recruitment completed Q2 2023*

*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 petri dish with a petri dish lid, a gloved hand, and a petri dish lid, overlaid with a blue and green gradient.

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

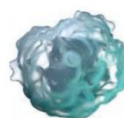
An assortment of molecules shut down inflammation and promote tissue healing by targeting different cells.



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



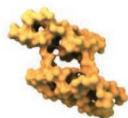
**Protectins**  
Lipids that curtail release of inflammation-promoting molecules and are protective in the nervous system.



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



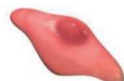
**Resolvins**  
Family of lipids that block neutrophils' exit from the bloodstream and prod macrophages to eat cellular debris.



**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.



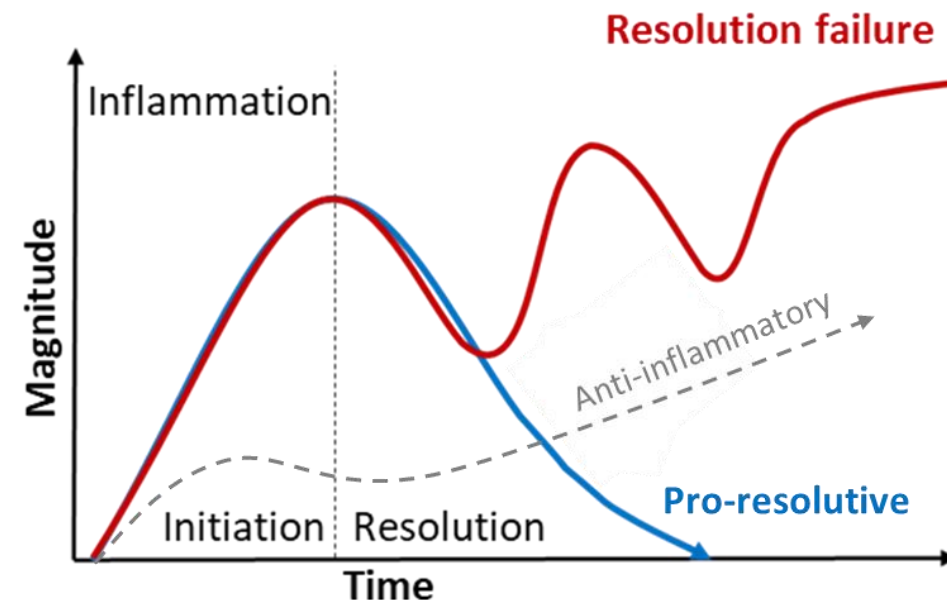
**Hydrogen sulfide**  
Message-carrying gas that reduces pain and stimulates neutrophils to commit suicide.



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

SCIENCE sciencemag.org

2 JANUARY 2015 • VOL 347 ISSUE 6217 19



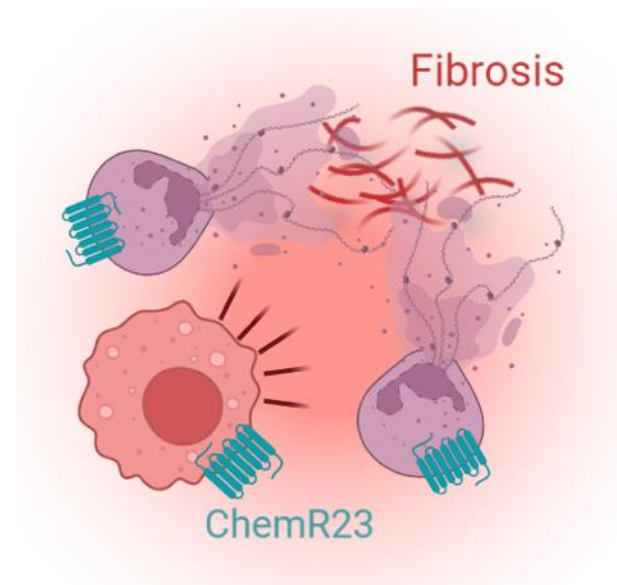


# ABBV-230 - Resolving inflammation is an active immune process



## During chronic inflammation

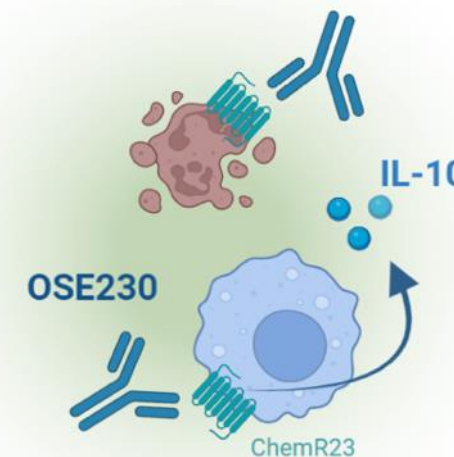
Dying neutrophils **send out inflammatory signals (e.g. NETosis)** that are important in maintaining chronic inflammation & fibrosis



## With ChemR23 agonistic mAbs

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

### Restoration of homeostasis



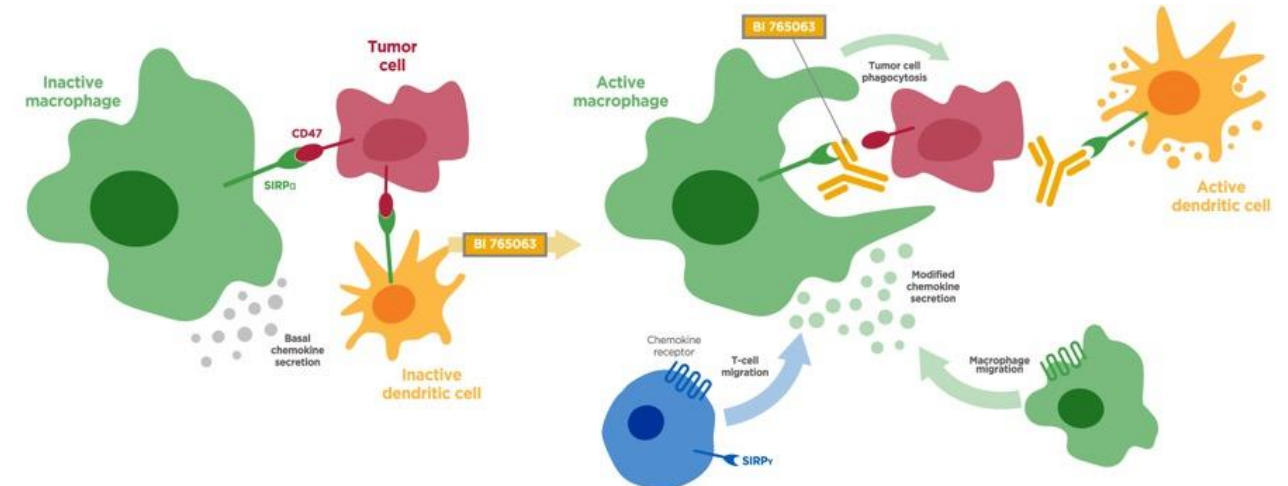
Potential First-in-class pre-IND candidate

Published in **ScienceAdvances**  
MAAS

# 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>

The use of SIRPα antagonists to enhance antitumour immunity is currently being explored<sup>4</sup>



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

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

Higher therapeutic window expected

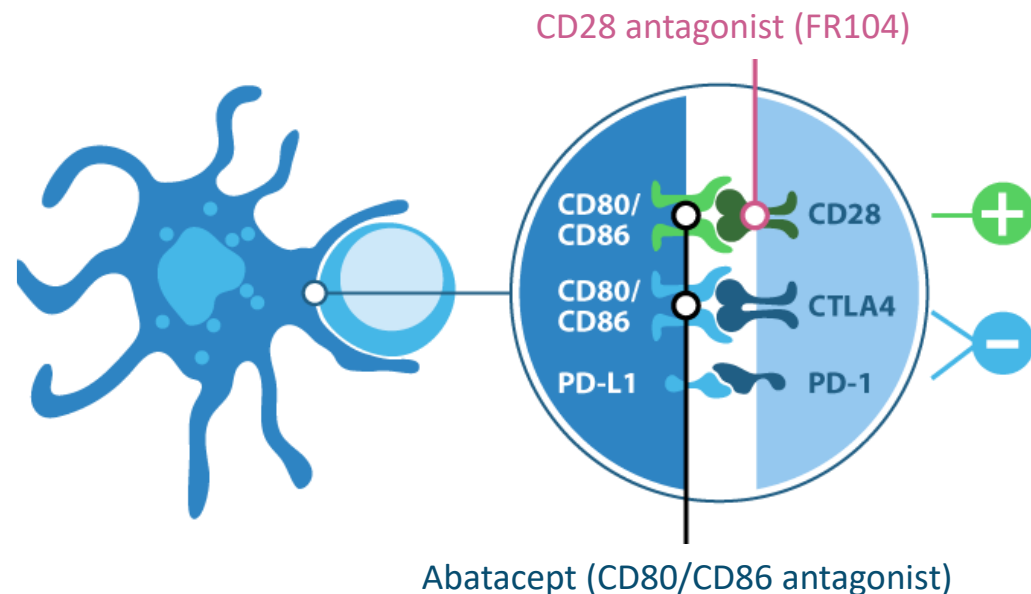
Favors T cell responses in solid tumors

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

# 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

# OSE's Boards





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



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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)



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**Bernard Malissen, PhD**

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**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

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

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