

Immuno-Oncology And Autoimmune Diseases

We Are Armed to Fight

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This presentation includes only summary information and should be read with the OSE Immunotherapeutics Universal Registration Document filed with the AMF on 15 April 2021 including the 2020 Financial results, and the Amendment to the Universal Registration Document filed with the AMF on 2 June 2021 under number D. 21-0310-A01, all available on the OSE Immunotherapeutics' website.

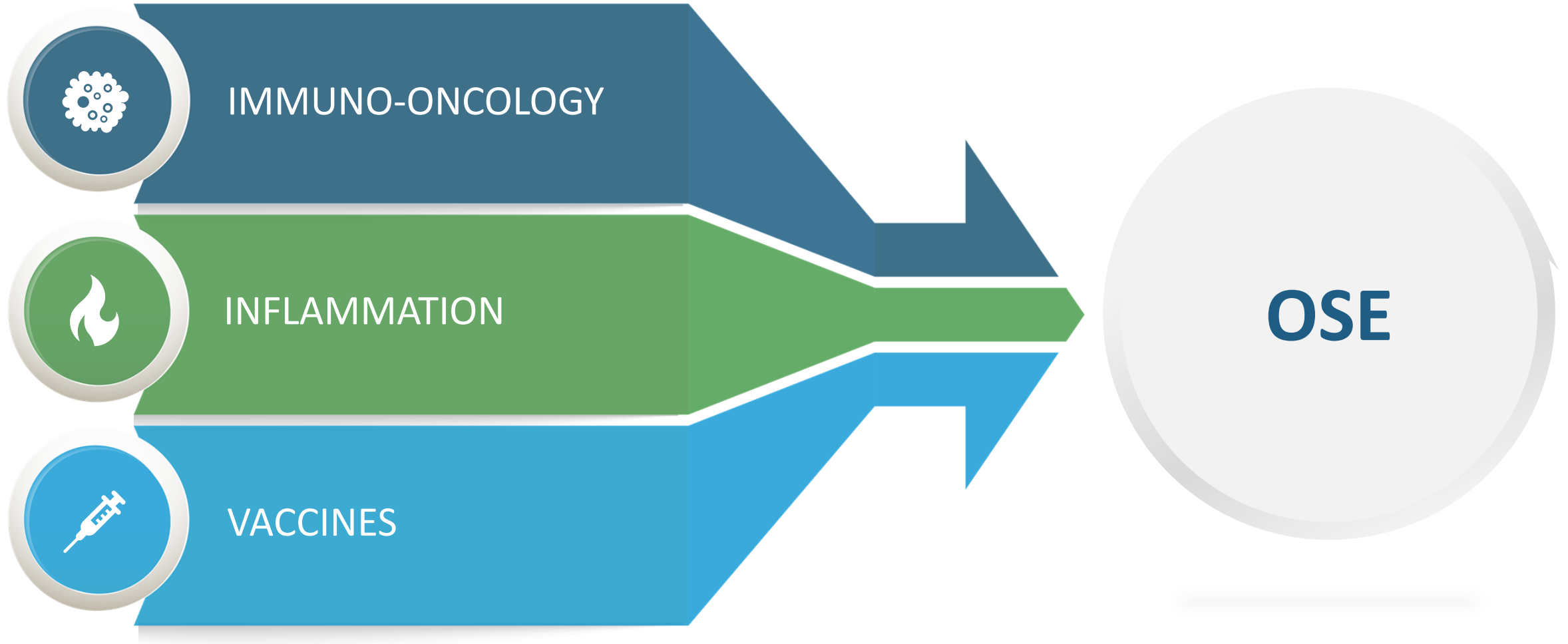
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OSE Immunotherapeutics: Leaders in Immunology



OSE Immunotherapeutics

Delivering from Target to Clinic

KEY FACTS

2012 - 2015
Creation to IPO EuroNext
(OSE)

5 clinical assets in 2021
~70 FTEs

€42m raised
through equity

€80m generated
through partnerships

1

Phase 3 asset: Tedopi® in NSCLC
post-checkpoint inhibitor

- Final positive Atalante results presented at ESMO 2021
- Survival benefit in NSCLC secondary resistant patients

5

Clinical stage assets in 2021

- 2 **Fully** owned
- 3 **Partnered** with Boehringer Ingelheim, Servier and Veloxis

3

Fully owned assets
approaching the clinic

- Funded to **maximize** value to stakeholders

Complementary Platforms and Balanced Pipeline



ASSET	TARGET	INDICATION	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT INFLECTION POINT
Tedopi®	Neopeptides	NSCLC post ICI failure (Ph 3) Phase 2 being initiated: Advanced pancreatic cancer , Ovarian cancer (combo with Keytruda®), NSCLC (combo with Opdivo®)					Final results of Atalante trial presented at ESMO 2021 Phase 2 read-outs starting in 2024
CoVepiT	Epitopes	Second Generation COVID-19 vaccine					
BI 765063 (OSE-172)	SIRPα-CD47 antagonist	Solid Tumors					Phase 1 expansion cohorts : 2023
CLEC-1	Myeloid checkpoint	Various cancers					Phase 1 start: H2 2023
OSE-279 & BiCKI® Bi-Functional Platform	Anti-PD-1 + Innovative targets	Various cancers					Phase 1 OSE-279 start: H1 2022
OSE-127	IL-7R antagonist	Ulcerative Colitis (OSE) ; Sjögren's syndrome (Servier)					Phase 2 read-outs: H2 2022
FR104	CD28 antagonist	Auto-immune diseases (OSE) & Transplant (Veloxis)					Phase 2 CTA (OSE) & US IND (Veloxis) : H1 2022
OSE-230	Anti-ChemR23 agonist	Resolution of inflammation					Phase 1 start: H1 2023



OSE : First-In-Class Targets to Become a Leader in Immuno-Oncology & Immunology

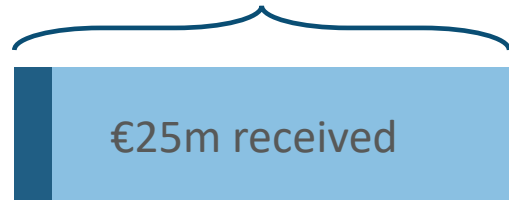


Strong Financial Foundation With Our Notable Strategic Partners

Over €1.6 billion in potential milestones & royalties; €80m already received¹



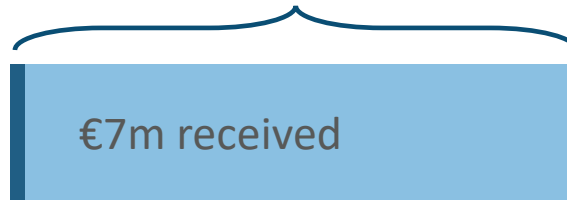
Up to €272m in milestones



+ Low teens royalties
on Global Sales



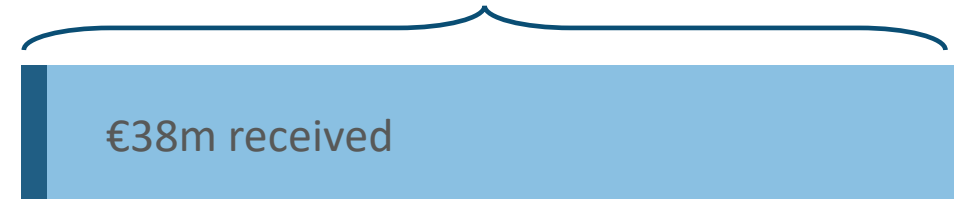
Up to €315m in milestones



+ Tiered royalties on
Global Sales



Up to €1.1bn in milestones



+ High-single digit to low teens royalties on
Global Sales

■ Received ■ Potential

¹ - Including €10m received from JnJ on FR104

An Executive Team with Complementary Expertise and Proven Track Record

Competencies	Immunology	Leading organizational growth	Clinical development	Partnerships	Fund raising	
 Alexis Peyroles Chief Executive Officer		✓	✓	✓	✓	 Guerbet  
 Dominique Costantini Head of Development	✓	✓	✓	✓	✓	  Previously HMR • 10 products registered including 3 at FDA • 10 patents (patent families)
 Nicolas Poirier Chief Scientific Officer	✓	✓		✓		Effimune • 45 publications • 30 patents (patent families)

BI 765063 (OSE-172) SIRP α -CD47 in Solid Tumors in collaboration with



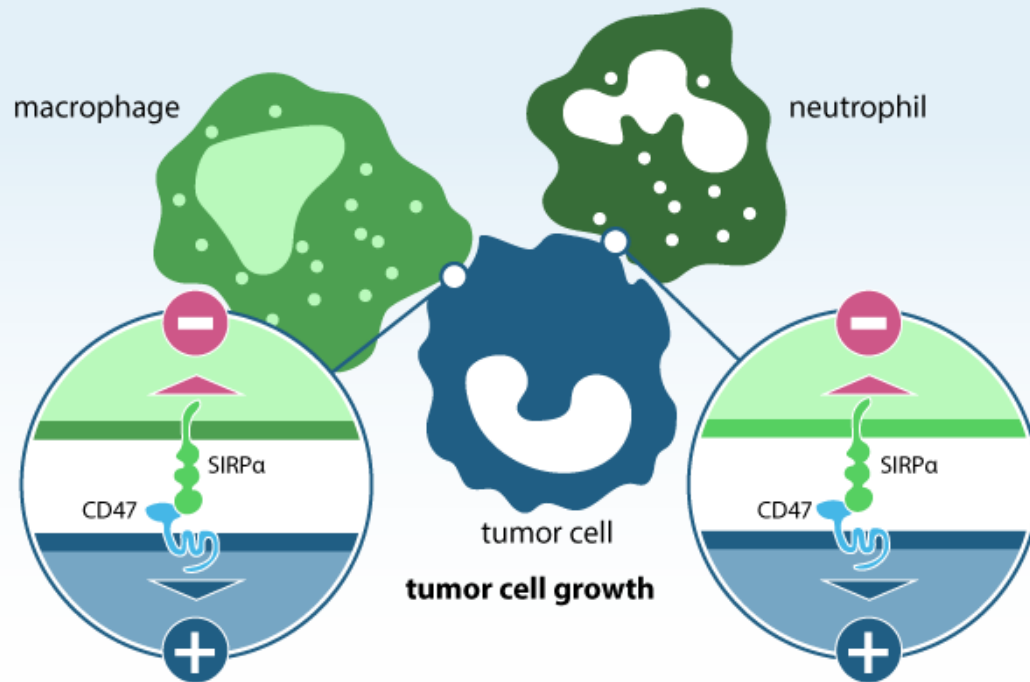
Boehringer
Ingelheim



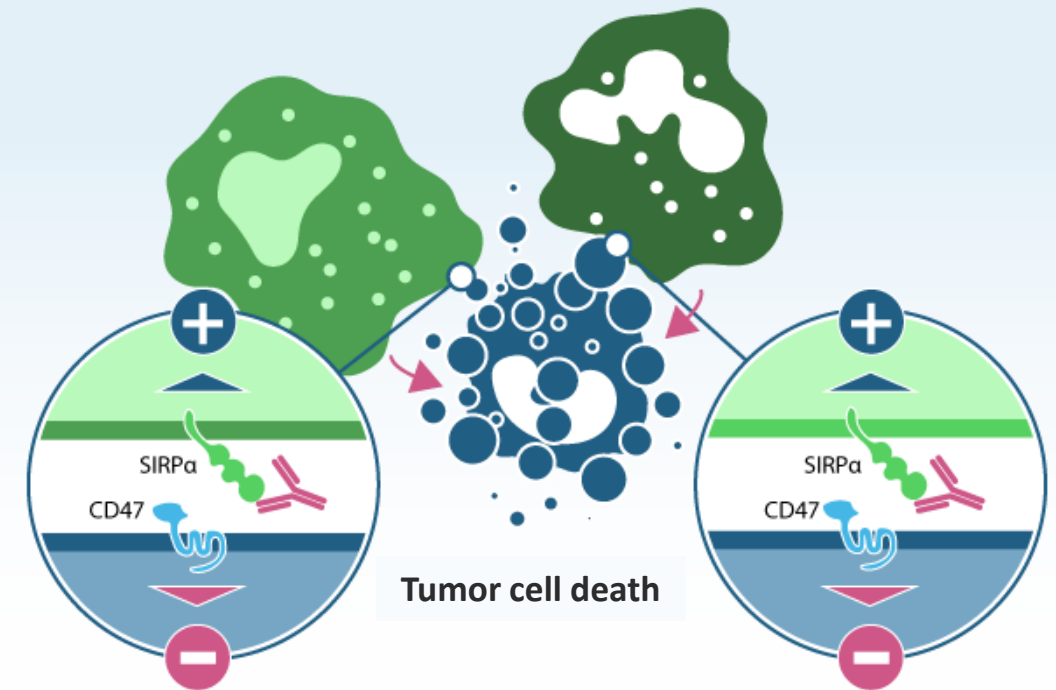
BI 765063 (OSE-172) Controlling the “Don’t-Eat-Me” Signal Without CD47 Antagonists Potential Drawbacks



CD47- SIRP α interaction blocks immune cell activation leading to tumor cell growth



BI 765063 : stops the “Don’t Eat Me” mechanism by which tumors evade immune detection and allows T lymphocytes to enter the tumor core



BI 765063 Strong Rational for Improved Safety and Synergy with Anti-PD-1

Phase 1 : Monotherapy and combination with anti-PD-1 on-going



Pre-clinical evidence differentiates SIRP α blockade and CD47 blockade

	Anti-CD47	Anti-SIRP α BI 765063	Comment
Broad/restricted expression	Broad	Restricted to cells of the myeloid lineage	Limited side effects expected
Interaction with SIRP γ	Unknown	BI 765063 is SIRP α specific	SIRP γ necessary for T cell responses
Dosing frequency	High	Low	Limited side effects expected
Interference with T cell responses	Negative	Positive	Higher efficacy in solid tumors in synergy with Anti-PD-1 expected
Safety signals	Acute anemia, Thrombocytopenia	No hematotoxicity	Higher therapeutic window expected

Gauttier et al ; JCI 2020 Selective SIRP α blockade reverses tumor T cell exclusion and overcomes cancer immunotherapy resistance

BI 765063 - Phase 1 Monotherapy data shows preliminary efficacy and good safety profile



Monotherapy (n=50)



Study design

- A two-step, open-label, multicenter Phase 1 study in V1/V1 homozygous and V1/V2 heterozygous patients (n=50) with advanced solid tumors who progressed or were not eligible for standard therapy
- Step 1: dose escalation monotherapy and in combination with anti-PD-1
Step 2: dose confirmation/expansion
- Nine dose levels were evaluated in the absence of DLTs: 0.02, 0.2, 1, 3, 6, 12, 18, 24, and 36 mg/kg, given IV every 3 weeks
- Primary endpoints: DLT (dose limiting toxicity) and MTD (maximum tolerated dose); secondary endpoints: Safety, PK, RO in peripheral CD14⁺ monocytes and efficacy



The first-in-class SIRP α inhibitor BI 765063 showed promising initial results in monotherapy

- Preliminary **anti-tumor activity**, with **1 patient with HCC experiencing a durable PR (>9 months, ongoing)**
- Well tolerated with **no reported DLTs, no hemotoxic AEs, frequently associated with CD47-targeting therapies, were observed as BI 765063 targets SIRP α on myeloid cells, preserving red blood cells and platelets.**
- MTD was not reached
- **Dose-proportional systemic exposure** and **full RO saturation** in Cycle 1 from the 6 mg/kg dose
- Dose-escalation in combination with (anti-PD-1 antibody) is ongoing

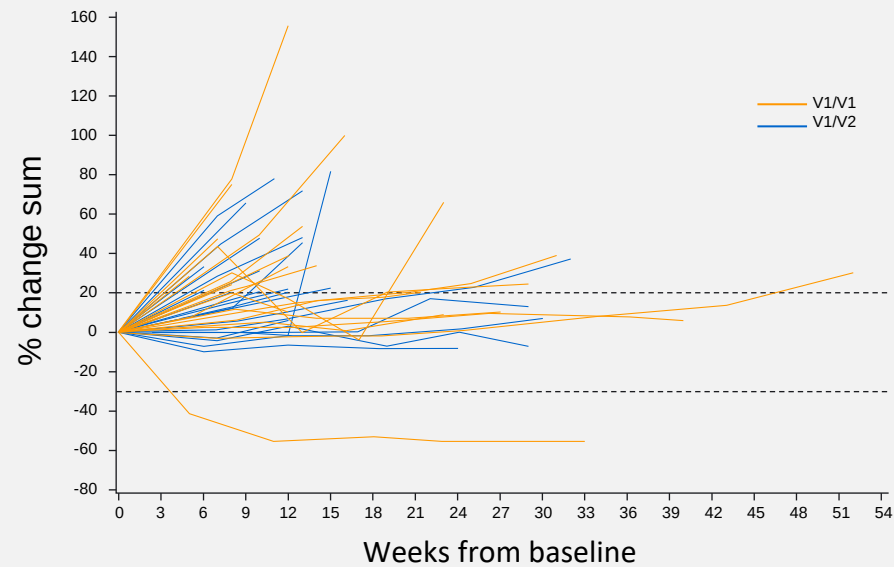
Adapted from
ASCO 2021
Champiat et al

Clinical Efficacy Demonstrated in Monotherapy

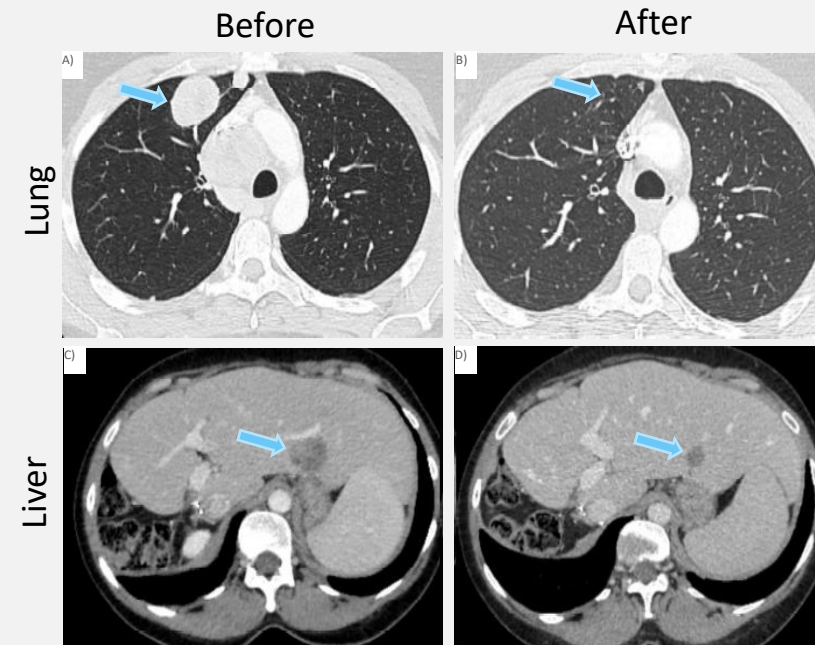


Monotherapy (n=50)

Spider plot of percentage change in sum of target lesions from baseline



CT scans of a patient with Hepatocellular carcinoma with a durable PR



Maintained tumor shrinkage of 55% after 9 months

Adapted from
ASCO 2021
Charniat et al

BI 765063 Continues to Demonstrate Exceptional Tolerability Profile In Combo



Dual Combination (n=18)

- Two dose levels of BI765063 at 18 and 24 mg/kg by intravenous (iv) Q3W were tested in combination with ezabenlimab 240 mg iv Q3W
- The RP2D of BI 765063 was determined as 24 mg/kg Q3W with full RO saturation

Treatment related adverse events in ≥ 3 (16%) of patients

Adverse events n = 18 (%)	All grades	Gr 1-2	Gr 3-4
Total with TRAEs*	12 (67)	10 (56)	1 (6)
IRR	5 (28)	5 (28)	
Fatigue	5 (28)	5 (28)	
Arthralgia	4 (22)	4 (22)	
Rash maculo-popular	4 (22)	3 (17)	1 (6)
Pruritis	3 (17)	3 (17)	

Key points

- **No** Dose Limiting Toxicity
- **No** Thrombocytopenia
- **Only 1** Anemia of low-severity (grade 2)
- The incidence of IRR was decreased after systematic premedication and BI765063 prolonged iv infusion used in COMBO

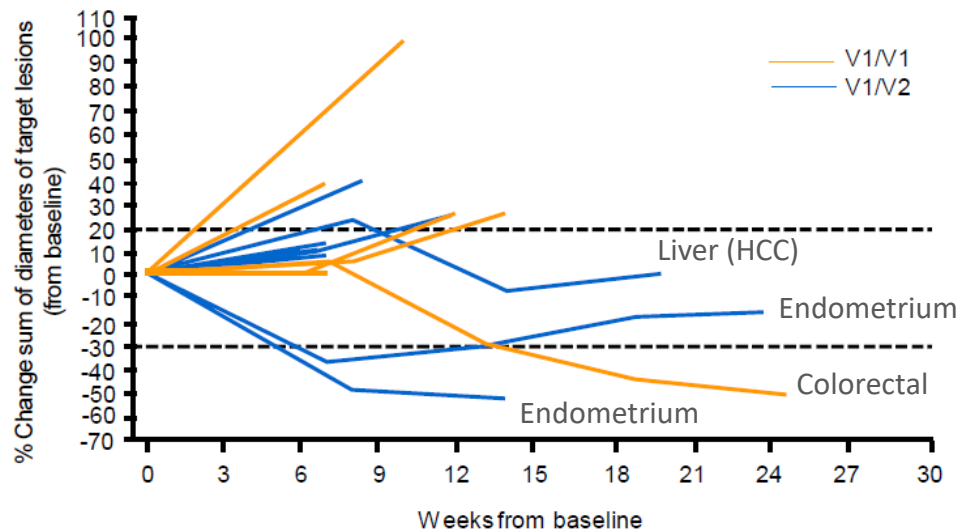
No Grade 4 or Grade 5 related TEAEs were observed in COMBO

BI 765063 Preliminary Activity in Combo

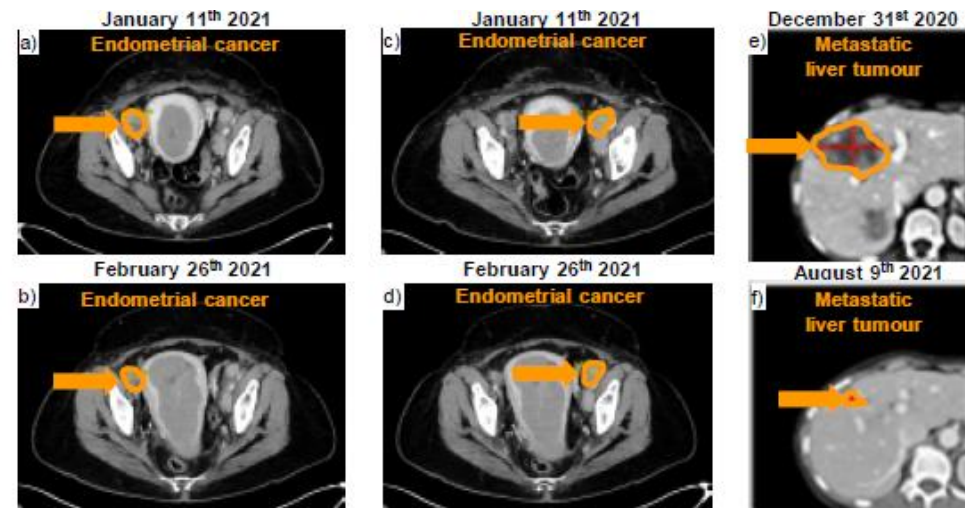


Dual Combination (n=18)

Spider plot of percentage change in sum of target lesions from baseline (cut off 04Aug21)



CT scans of two patients (endometrial and HCC) with a durable PR



- In 16 patients evaluable for efficacy (RECIST/iRECIST), 3 (19%) shown a confirmed Partial Response: 2 patients with endometrial cancer and 1 patient with colorectal cancer
- Another patient with hepatocellular carcinoma (HCC) had stable disease (tumor shrinkage: -7%) with normalised levels of alpha fetoprotein (AFP)

BI 765063 Potential Best-in-Class Asset in Blockbuster Market



Boehringer Ingelheim Deal Structure

Signed in 2018 at Pre-Clinical stage

Up to €1.1bn

in milestones

€38m
received

■ Received ■ Additional potential

+ High-single digit to low
teens royalties on Global
Sales

Market events raise expectations and
valuations for the CD47 pathway



\$2.3bn

Acquisition by Pfizer



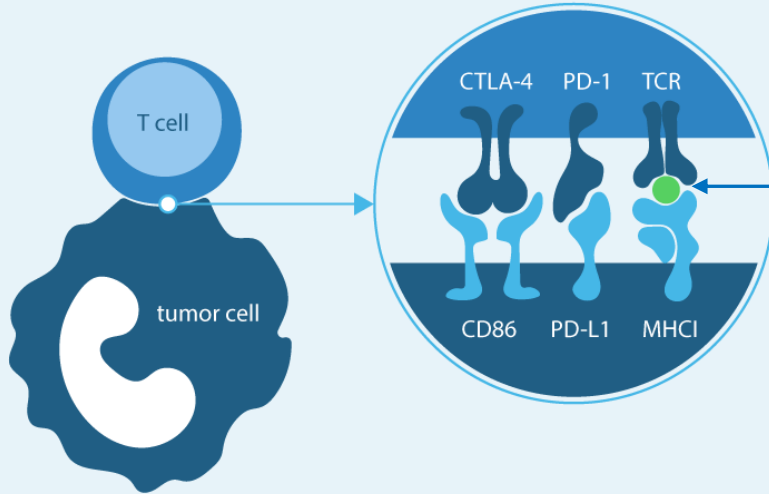
\$4.9bn

Acquisition by Gilead



Market opportunity in advanced NSCLC
post-Immune Checkpoint Inhibitors





NEOEPITOPES / HLA / TCR binding*:

- **Mandatory** to activate cytotoxic T-cell response
- Neoepitopes: Small peptides deriving from **tumor specific** antigens expressed in various cancers
- 1st T-lymphocyte **activation** signal



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

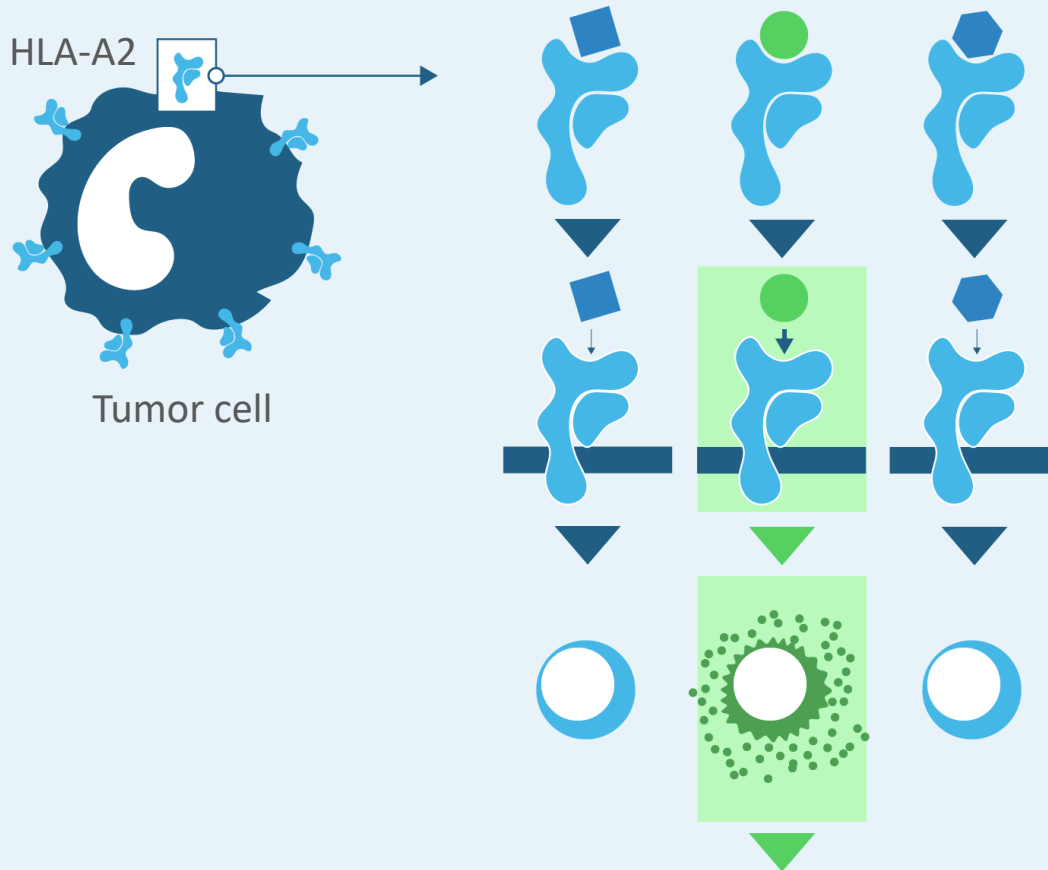
Restores **immuno-surveillance**
of cancer cells in HLA-A2
positive responder patients

Induces early T cell
memory responses

Strong patent family plus
orphan status in the US

Identifying Epitopes to Trigger Optimal Immunogenicity

Based on 10 Years of R&D

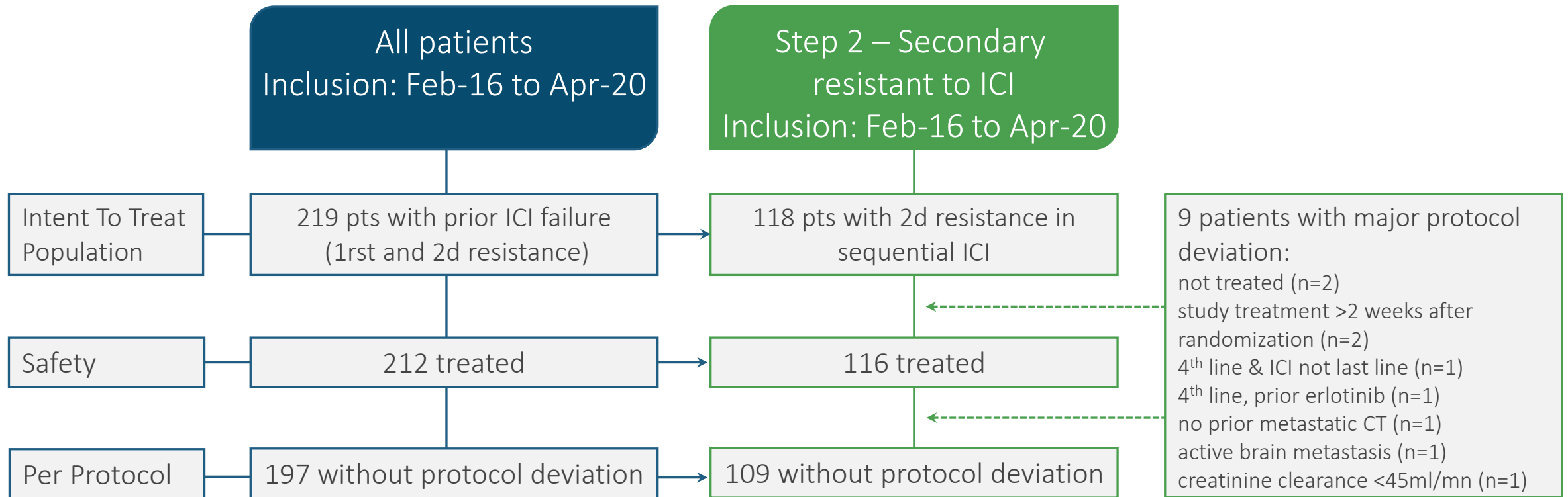


1 *Epitope prediction*
In silico motif analysis

2 *Affinity determination*
In vitro capture assays

3 *Immunogenicity*
In vivo T cell activation

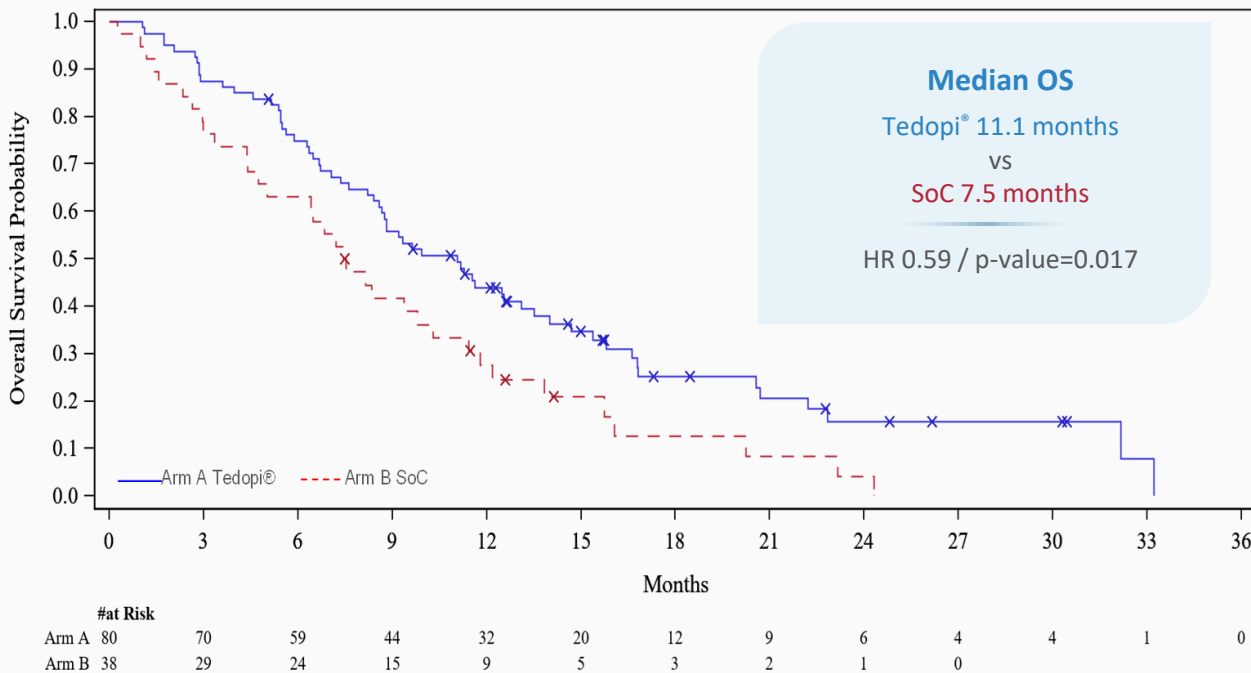
Secondary Resistance to ICI Identified as Population of Interest



Tedopi[®] Demonstrated Overall Survival Benefit in NSCLC post-ICI in Phase 3 in Patients Secondary Resistant to ICI

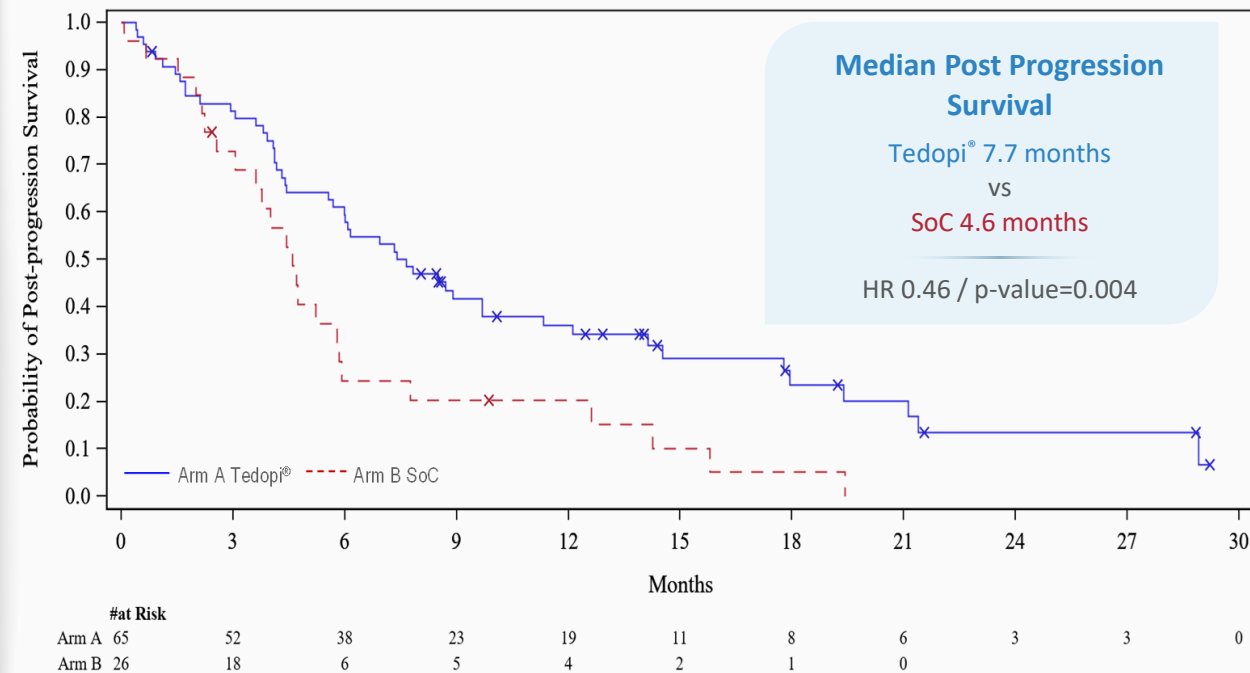
Overall Survival Benefit Clinically Meaningful

In patients secondary resistant to ICI



Post Progression Survival

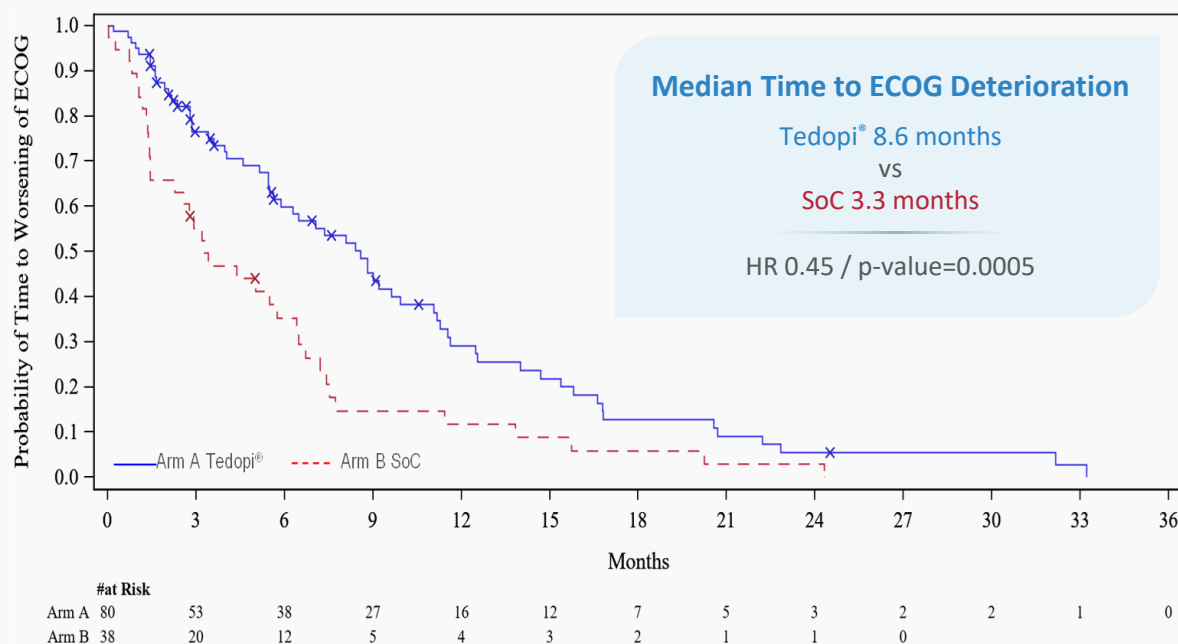
Benefit of Tedopi[®] Continued Beyond Progression



B.Besse et al., ESMO 2021

Tedopi® Proved Safe and Provided Enduring Quality of Life Positive Benefit/Risk vs Standard of Care in Patients Secondary Resistant to ICI

Significant Increase in Time to ECOG deterioration



Significantly Safer than Standard of Care

	Tedopi® (n=79)		Standard of Care (SoC) (n=37)	
	All grades n (%)	Severe* G3-4 n (%)	All grades n (%)	Severe* G3-4 n (%)
All Drug-Related Aes	60 (76)	9 (11)*	29 (78)	13 (35)*
Injection site reaction**	31 (39)	1 (1)	-	-
Pyrexia	15 (19)	2 (3)	3 (8)	-
Arthralgia	9 (11)	-	1 (3)	-
Asthenia	13 (17)	-	15 (41)	6 (16)
Alopecia	-	-	8 (22)	1 (3)
Diarrhea	3 (4)	-	8 (22)	1 (3)
Neutropenia	-	-	6 (16)	6 (16)
Fatigue	6 (8)	-	5 (14)	-
Anemia	1 (1)	-	5 (14)	-
Nausea	5 (6)	-	5 (14)	-
Vomiting	5 (6)	1 (1)	5 (14)	1 (3)
Decrease appetite	4 (5)	-	4 (11)	-

B.Besse et al., ESMO 2021

ECOG Performance status evaluates the performance from individual and includes 5 Grade (Grade 1 is fully active to 5 is dead)

Positioning Tedopi® as a New Standard of Care in NSCLC after Checkpoint Failure

**Final positive results of Atalante-1 study
in NSCLC secondary resistant patients after Immune Checkpoint failure
Presented at ESMO 2021**

Based on Atalante-1 study final results
FDA/EMA discussions on optimal regulatory paths for potential approval
in NSCLC after Immune Checkpoint failure

Next steps and business development options in NSCLC to be evaluated
Additional clinical trials launched in NSCLC (combination with ICI) and other indications
(Ovarian, Pancreatic)

Tedopi® - Expanding Targeted Markets In 3 Additional Settings

Combining Tedopi® with leading IO treatments



2nd line post ICI



Combi-TED - NSCLC
In Combination with nivolumab



Tedopi® plus docetaxel or Tedopi® plus nivolumab as 2nd line therapy in metastatic NSCLC progressing after failure to 1st line chemo-ICI¹

Readout expected in 2024

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 cancer²

Readout expected in 2025



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 Folfirinox³

Readout expected in 2024

CoVepiT, 2nd generation COVID-19 vaccine

Multi-Target T cell responses against COVID-19
(provides long immune memory, anticipates viral mutation)

CoVepiT to Add T Cell Memory to B Cell Response for COVID-19

Viral clearance requires T cell stimulation



B Cell – Humoral Response

PROS

- **Validated** concept
- Large **global** manufacturing capacity

CONS

- **Unknown** power and durability of immune response
- Manufacturing/cold chain challenges (esp. mRNA vaccines)
- **Uncertain** protection in immunocompromised responders
- Virus may evade by evolution/mutation
- Predominant focus on **spike proteins**

T Cell – Cellular Response

PROS

- Fast and **potent** immune response
- Stimulates direct **T cell attack** against COVID-19
- **Universal** – supplements all vaccine types
- **Addresses and anticipates** viral evolution/mutation
- Synergistic activity, ideal for people with low immune system or low immune response to traditional/mRNA vaccines

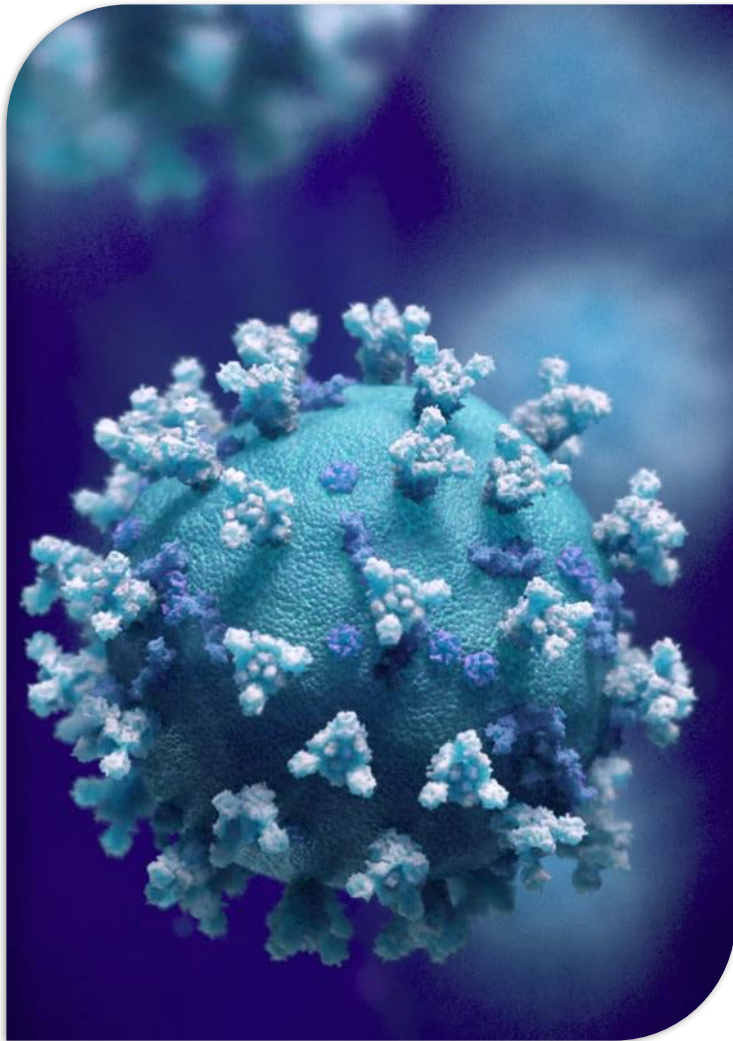
CONS

- **Validated** approach at pre-clinical level, but **no vaccine approved yet**

CoVepiT : Second Generation Multi-Epitope CD8+ T Cell Vaccine Against COVID-19 Variants

Booster Strategy Against Multi-Variants

Confirmed *In vivo* and Human *Ex vivo* Results



Broad and diversified targeting of most conserved epitopes (12 epitopes CD8+ T cells against 11 conserved viral proteins and one CD4+ T cell epitope)

CoVepiT T cell epitopes ***induce in vivo*** tissue-resident memory T cell sentinels (Trm) ***in lung***

Immune Responses validated in human ex vivo data

- Potent CD8+ T cells responses (IF gamma responses Elispot)
- Potential to target MERS and SARS (and future coronavirus threats)

CoVepiT ideally ***positioned for a Booster strategy in already vaccinated population with first generation Spike vaccines***

In Phase 1 clinical trial
Voluntary and temporary suspension of enrollment ongoing

OSE-127 in Ulcerative Colitis and Sjögren's Syndrome in collaboration with



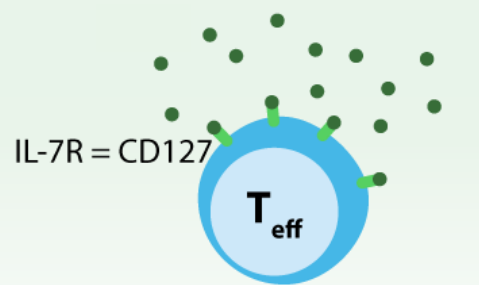
OSE-127 - Differentiated MoA as Full IL-7 Receptor Antagonist

License Option to Servier after Phase 2

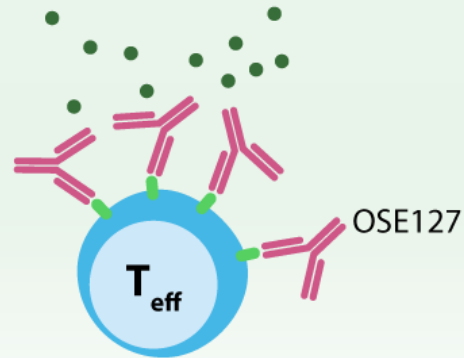


Activated Proliferating T cell

IL-7 : specific T-cell growth factor



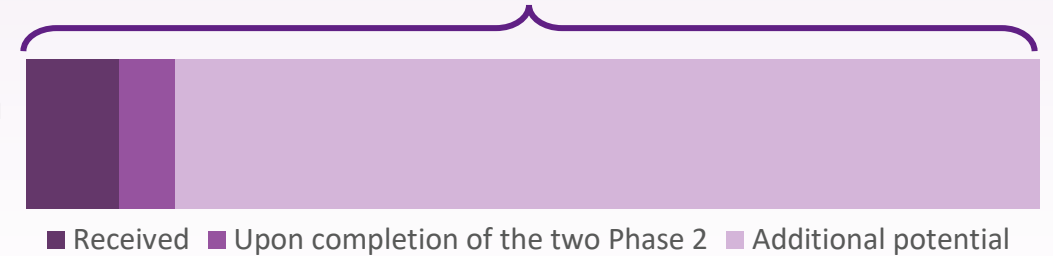
Inactivated T cell



A collaborative deal underpinning differentiated science

Up to €272m
in milestones

€25m
received



+ High-single digit to low teens
royalties on global sales

OSE-127 – Ulcerative Colitis

License Option to SERVIER after Phase 2

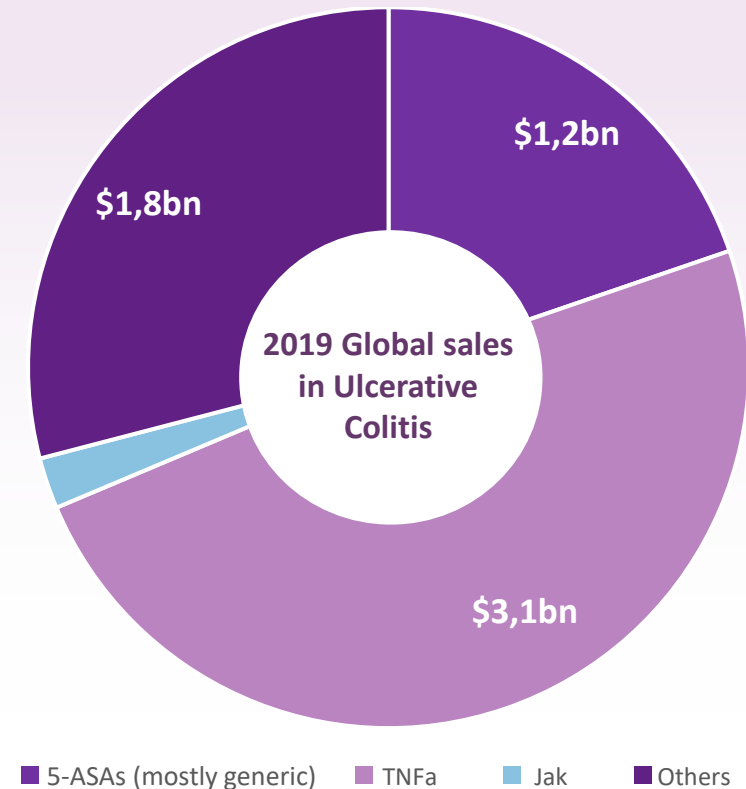


Ulcerative Colitis developed by OSE

- 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%² leaving most patients without satisfactory treatment
- **15% of patients**³ fail to respond to all therapies and get surgery as last option

**Phase 2 trial started
in December 2020**

Current standard of care largely calls on two main therapeutics classes with a total market of \$6.3 billions¹



OSE-127 – Sjögren's Syndrome

License Option to SERVIER after Phase 2



Sjögren's syndrome developed by SERVIER

- **3rd most common** autoimmune disease affecting the body's moisture-producing glands, lungs, kidney and nervous system. Often found in patients suffering from Rheumatoid Arthritis and Systemic Lupus Erythematosus
- Affects **~600,000 patients** in US, EU and Japan, including over 50% in US
- OSE-127 will target **~40%** of moderate-to-severe patients with ESSDAI scores over 5

- **Well identified** patient population; over 75% of Sjögren's syndrome patients are treated
- **Current treatment** depends on:
 - Genericized cevimeline hydrochloride (Exovac)
 - Lubricants / topicals
 - Off-label use of B cell modulators (Rituxan, Benlysta)
- Sole approved drug, cevimeline, **proven to** increase salivary flow; dosed 3 times day (TID)

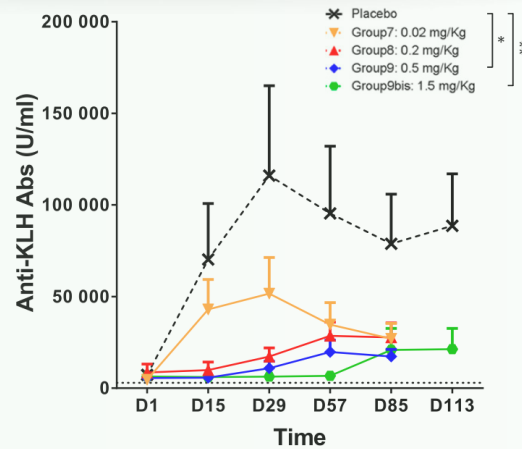
**Phase 2: First patient enrolled August 2021
€5 M milestone payment triggered**



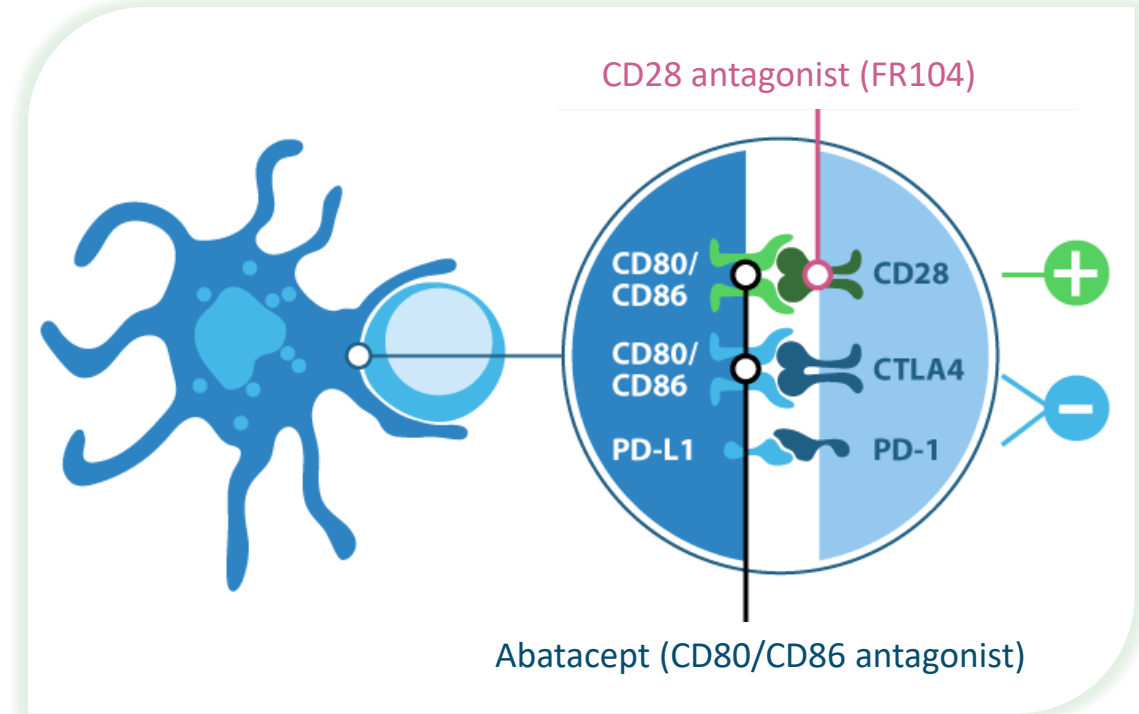
FR-104 in Auto-Immune diseases and Transplantation



Phase 1 results: Selective CD28 antagonist FR104 persistently reduces antibody responses



- **Good safety** - demonstrated
 - Absence of clinical or biological events
 - No change in total lymphocyte counts
 - No cytokine elevation
- Controls model IgG (anti-KLH) response for up to 57 days
- Controls T follicular helper and IgG responses
- Tfh cells correlated with autoimmune diseases activity



FR104 – Ambitious Development Plan in 2021 through our Partnership in Transplantation with Veloxis and our focus in Auto-Immune diseases



Global license agreement with Veloxis in transplantation

- Global partnership agreement with Veloxis, a leading transplantation company
 - To develop, manufacture and commercialize FR104 in the organ transplantation market
 - OSE eligible to receive up to €315 million in potential milestones, including a €7 million upfront, and tiered royalties on sales.
- Phase 1 / 2 in kidney transplantation, sponsored and conducted by the Nantes University Hospital is on-going

OSE has FR104 rights in Auto-Immune indications

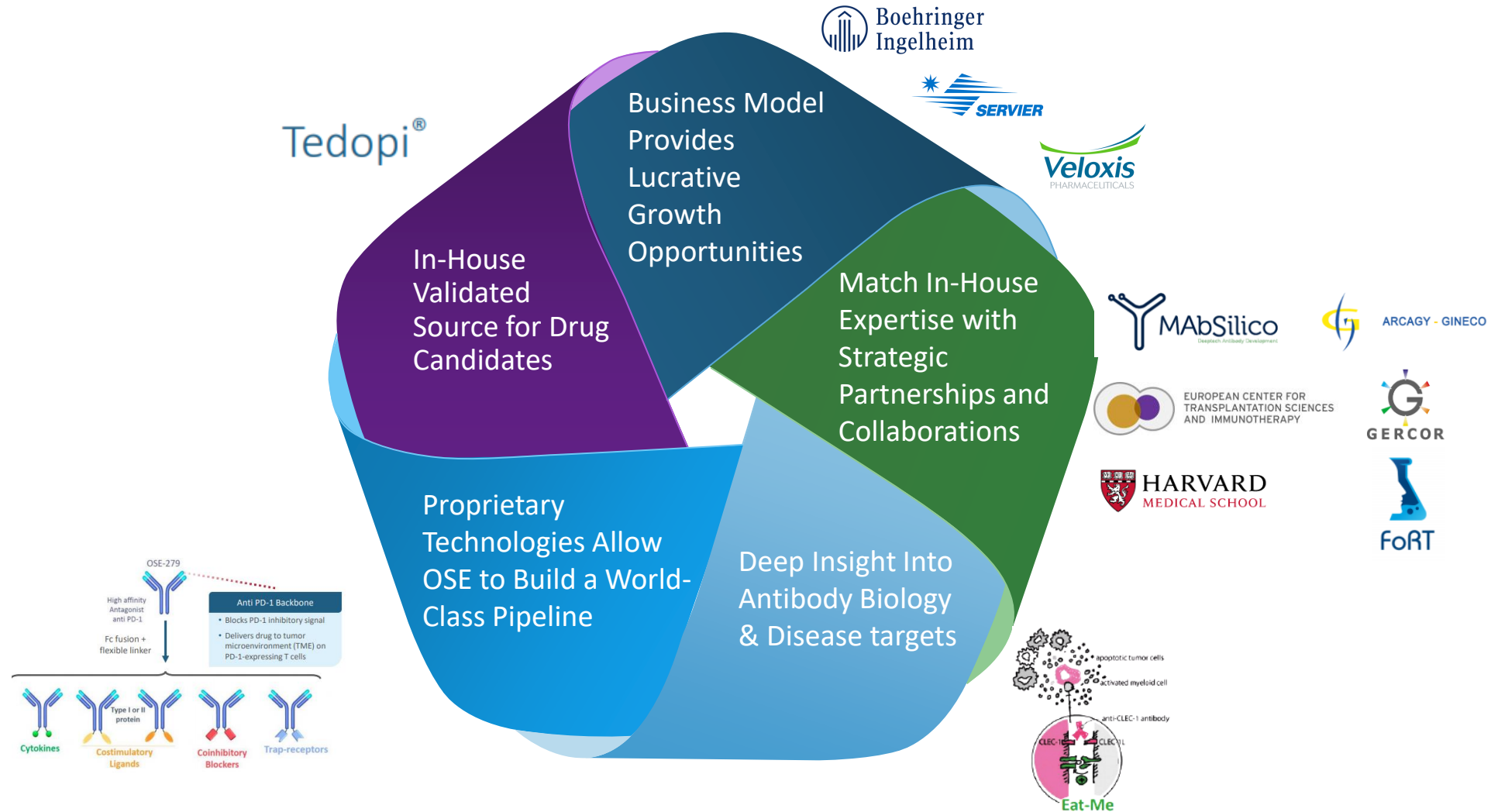
Phase 2 Grave's disease (Autoimmune niche indication) start in H1 2022

- Autoimmune disorder affecting 4 million patients¹ in the US/EU and leading to hyperthyroidism
- Mostly affect 30-50 year-old women
- Often leads to cardiologic complications and osteoporosis
- Phase 2 to be conducted in around 80 patients

Early-stage pipeline and R&D engine

Fully-Integrated Drug Development Engine

Innovation Powerhouse Transforming Standard-Of-Care Treatments



Proprietary Technologies Allow OSE to Build a World-class Pipeline

In-house know-how & platforms covering all stages of early drug discovery

MEMOPI®

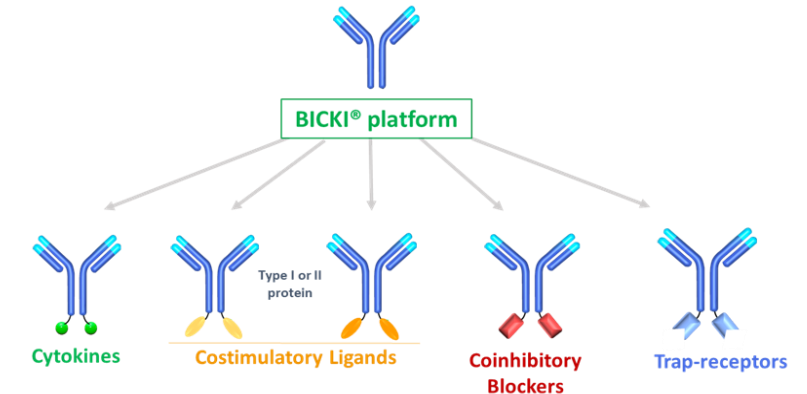
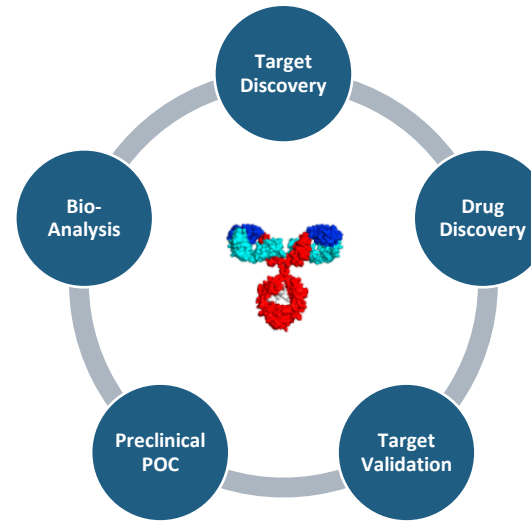
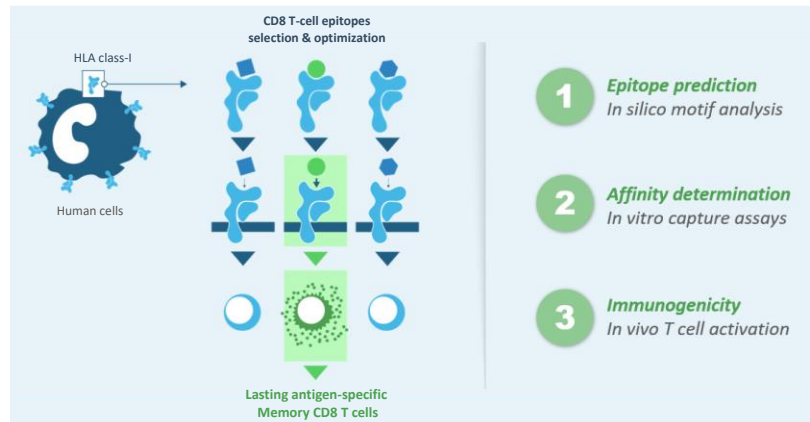
Identifying Epitopes to Trigger
Optimal Immunogenicity

mAb

Engineering powerful
Monoclonal Antibodies

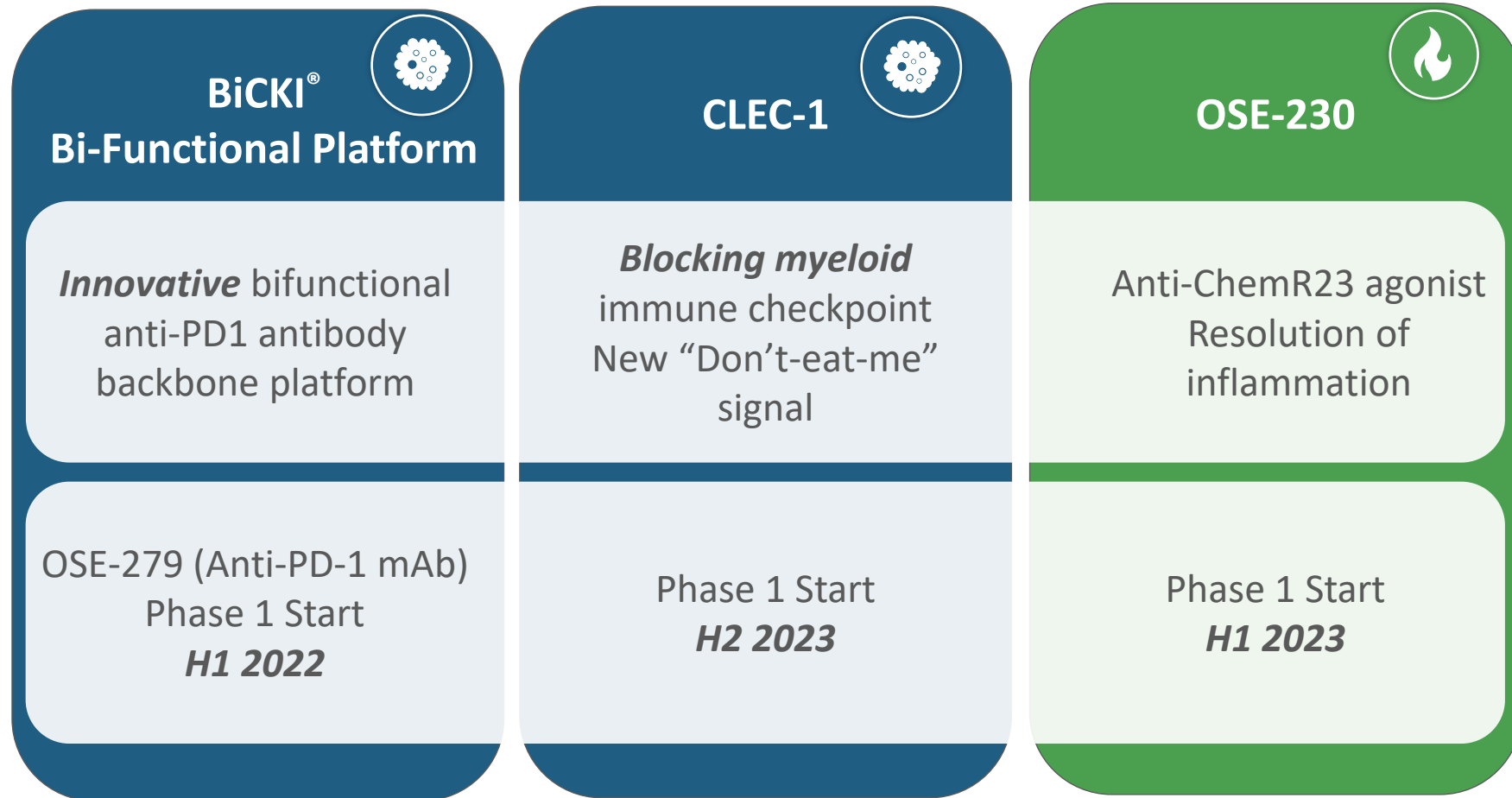
BiCKI®

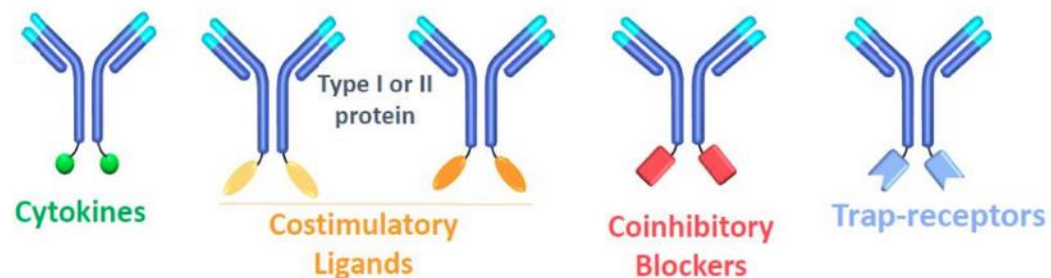
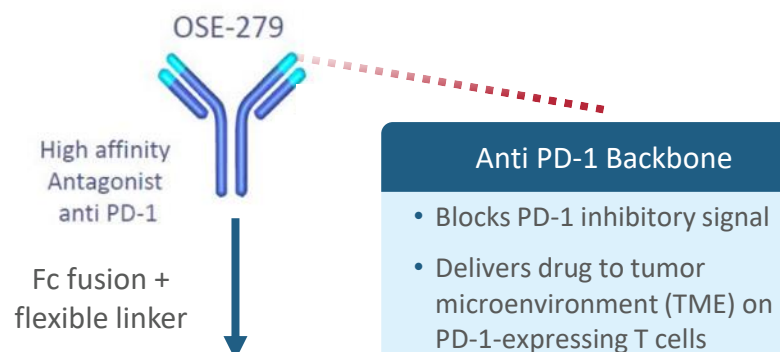
Selective bispecific for anti-
PD-(L)1 resistant tumors



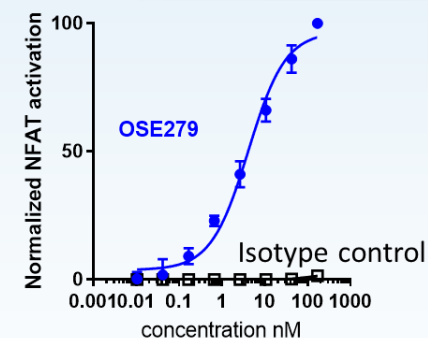
Building The Next Wave Of Cutting-Edge Medicines By Investing In Diversified Modalities

Proprietary Early-Stage Assets : Creating Significant Value Over the Next Three Years and Beyond

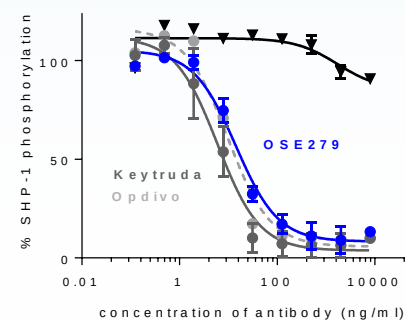




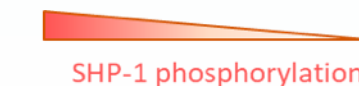
OSE-279: Humanized Anti-PD1 mAb blocking binding of PD-L1 and PD-L2



Increases TCR signaling



Inhibits PD-1 signaling



OSE-279 Phase 1 to start in H1 2022

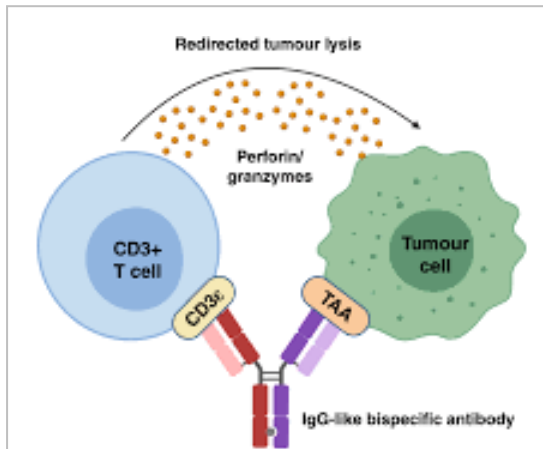
Next-Generation Immuno-Oncology Bispecifics

Aim: To selectively improve the quality of T-cell responses

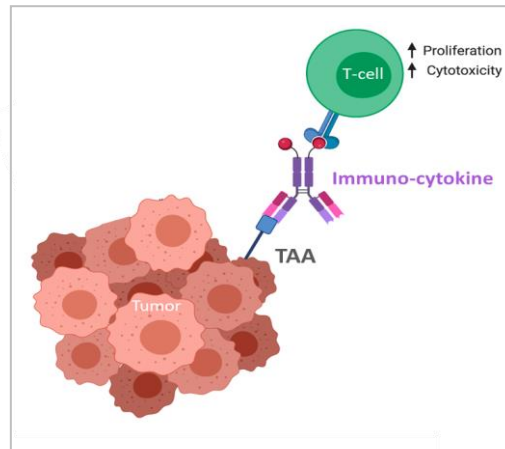
First Bispecific approaches focus on the tumor
but require T-cell already in place & surviving

Selective targeting of Tumor-
specific PD1+ T cells

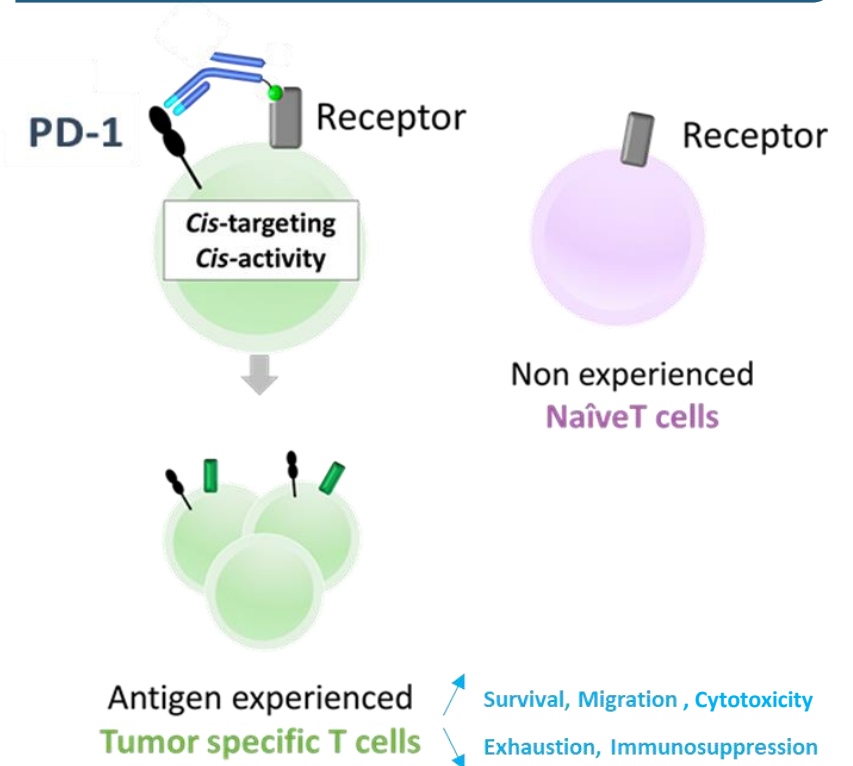
T-cell redirection



Tumor targeting



Next-Generation
bispecific





BiCKI® IL-7 Preclinical Efficacy

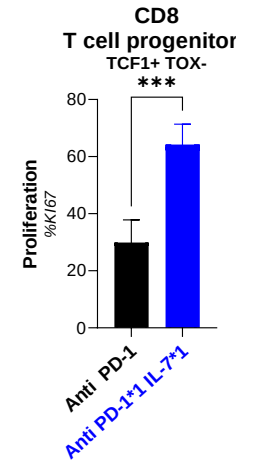
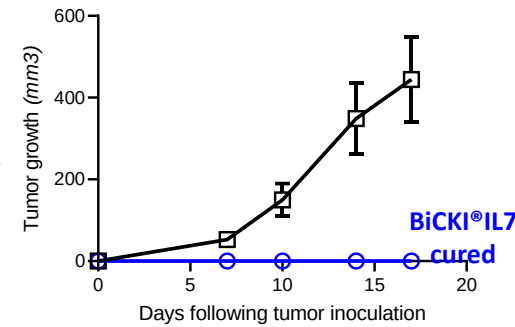
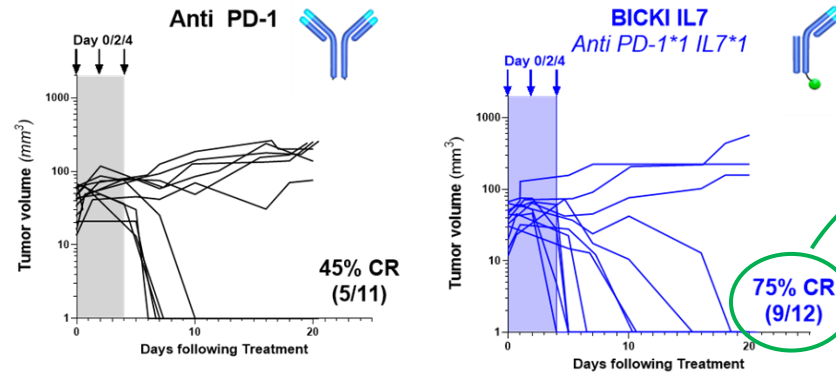
High and lasting anti-tumor immune responses in PD1 refractory models in monotherapy

High preclinical monotherapy efficacy
(syngeneic & humanized mice models)

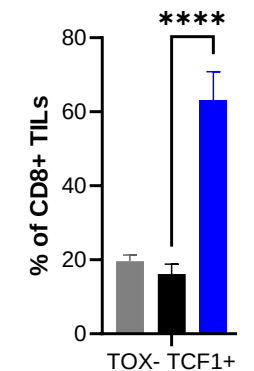
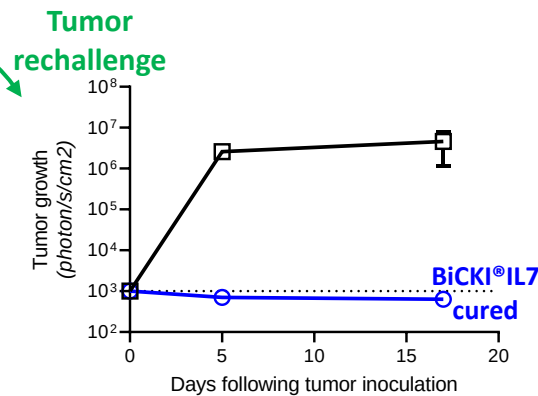
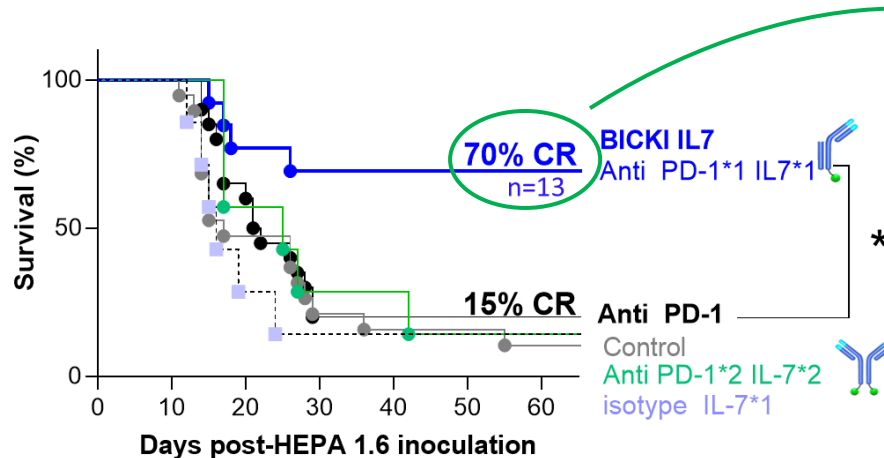
Broad memory responses

**Selective expansion of
stem memory CD8+ TILs**

Partially PD1-sensitive
model



PD1-resistant
model

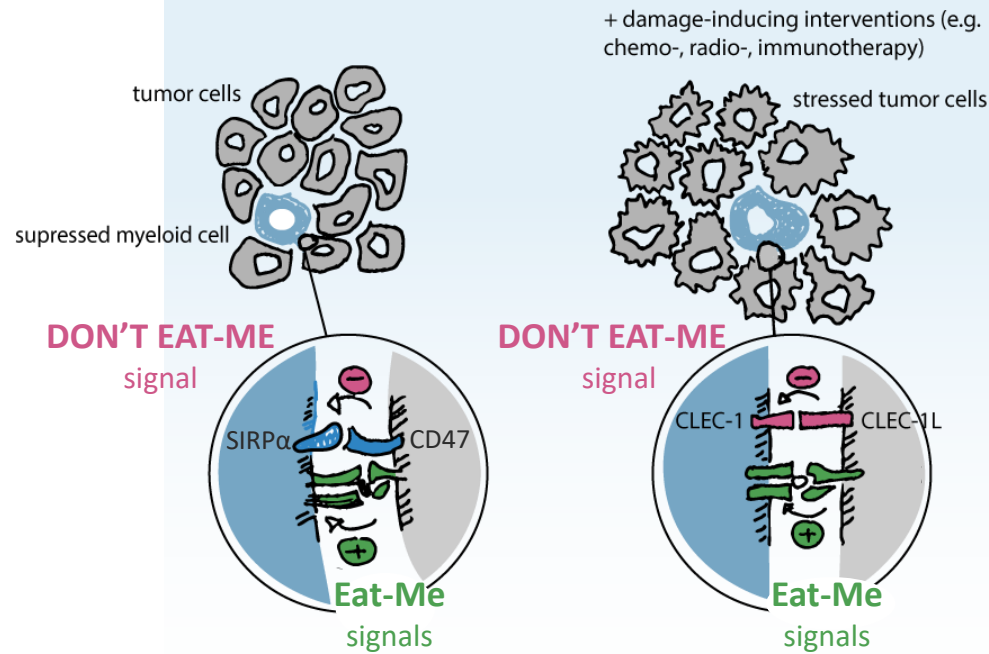




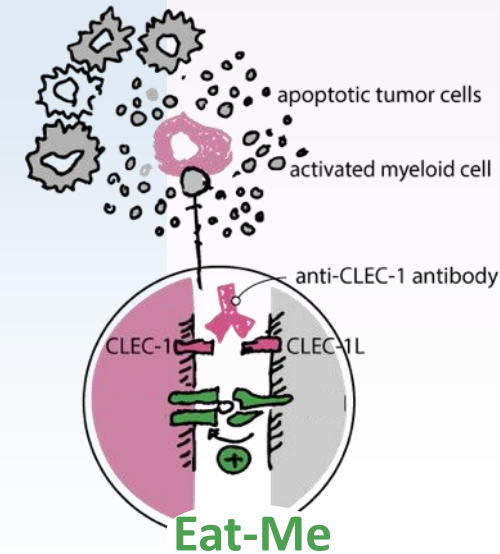
CLEC-1: Another Way to Not Get Eaten

Blocking myeloid immune checkpoint from delivering another “Don’t-eat-me” signal

Tumor homeostasis



CLEC-1 mAbs disrupt tumor homeostasis



Anti-CLEC-1 mAbs **increase killing efficacy** of myeloid cells & T cell responses

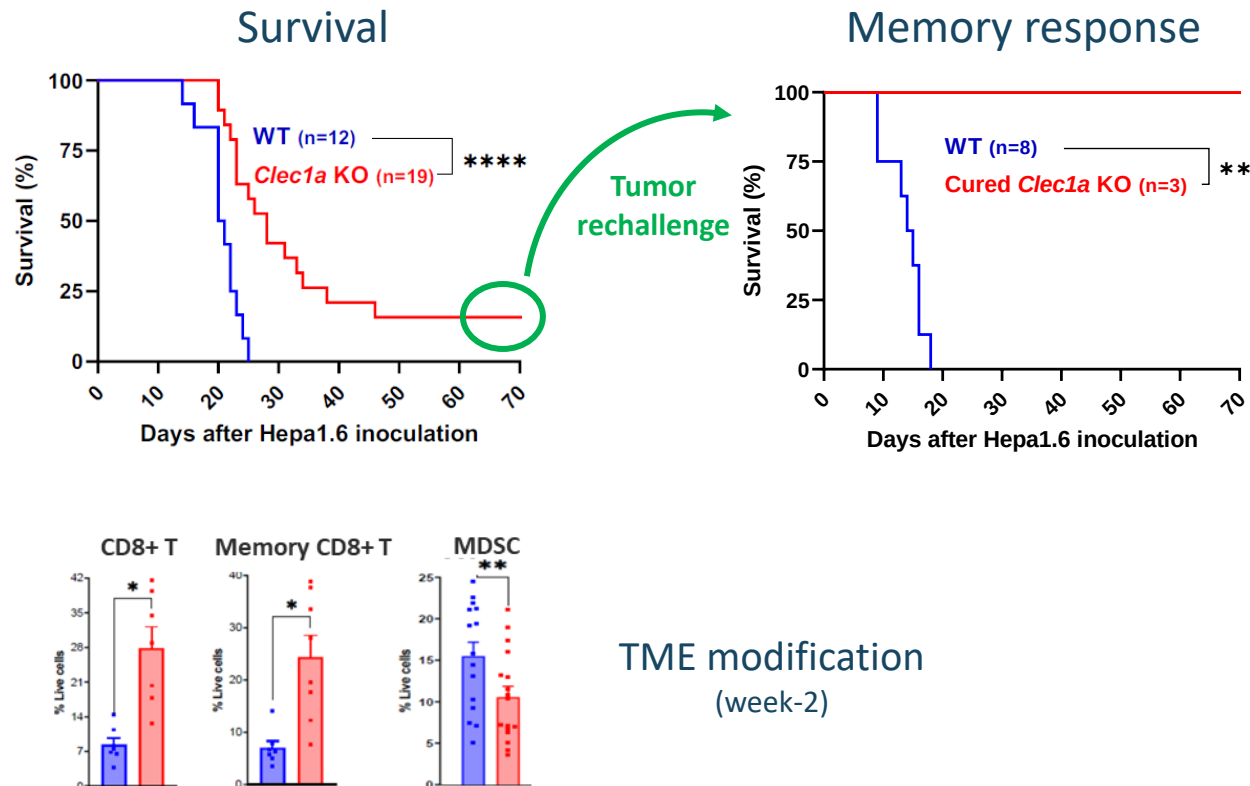
Start of clinical trial scheduled for 2023

Inhibition of CLEC-1 Promotes Anti-Tumor Responses (Monotherapy)

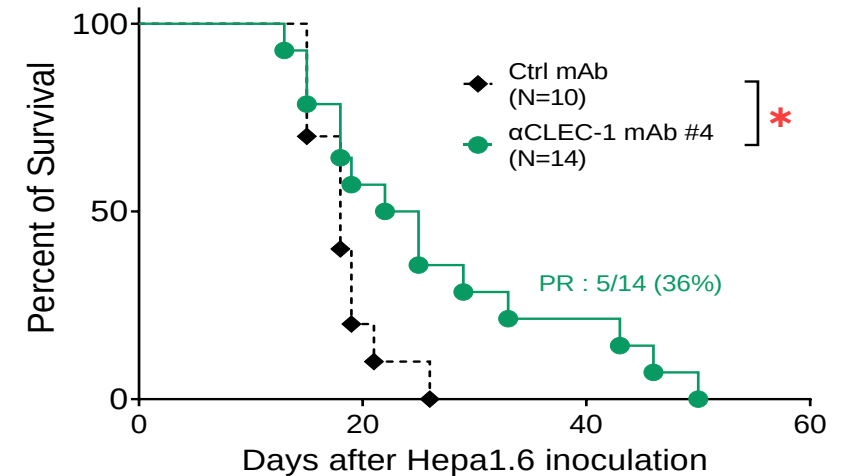


Robust memory anti-tumor response & TME modification generated in orthotopic tumor model

CLEC-1 inhibition monotherapy induces anti-tumor memory response & strong TME modification

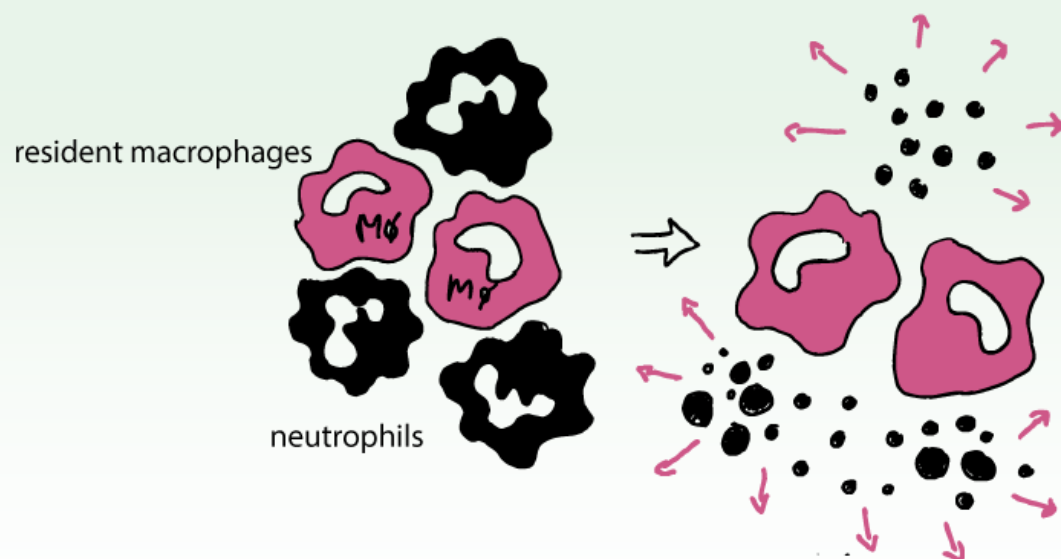


CLEC-1 antagonist mAb in monotherapy





During chronic inflammation



Dying neutrophils **send out inflammatory signals** that are important in maintaining chronic inflammation & recruiting Lymphocytes

With ChemR23 agonistic mAbs

Restoration of homeostasis



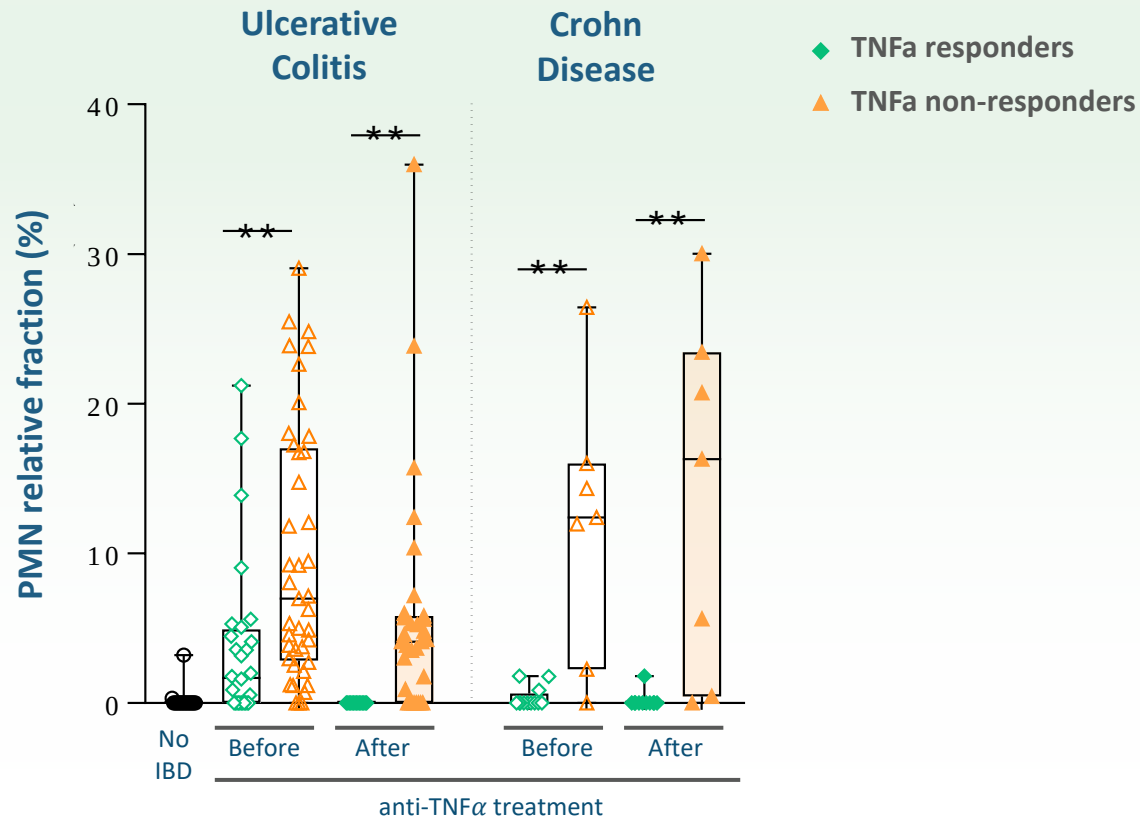
OSE-230-mediated activation of resident macrophages induces efferocytosis of apoptotic neutrophils, **removing further inflammatory signals**

Start of clinical trial scheduled for H1 2023

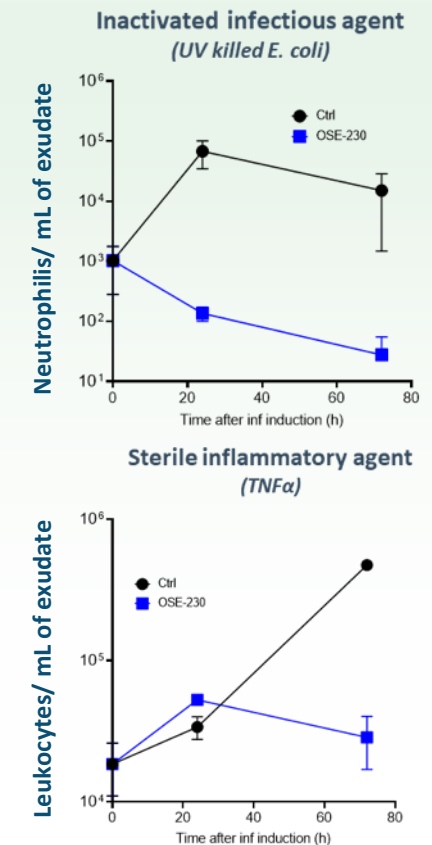
OSE-230 – Pre-Clinical Data Demonstrate Strong Effect on Neutrophils and Leucocytes



Higher ChemR23 expression in anti-TNF α refractory patients



OSE-230 significantly reduces neutrophils and leucocytes in inflammatory models in monkeys



Summary

Transitioning from World-Class Science to Commercial Readiness



Adjusting strategy to prepare for proprietary pipeline acceleration and next phase of growth

World leading research capabilities having delivered 3 platforms with mid-late stage assets

Tedopi® in NSCLC post-ICI showed strong clinical benefit in secondary resistant patients
Final results presented at ESMO 2021 and additional cancer indications launched
Strategy is to position Tedopi® as new standard of care in NSCLC after Immune Checkpoint

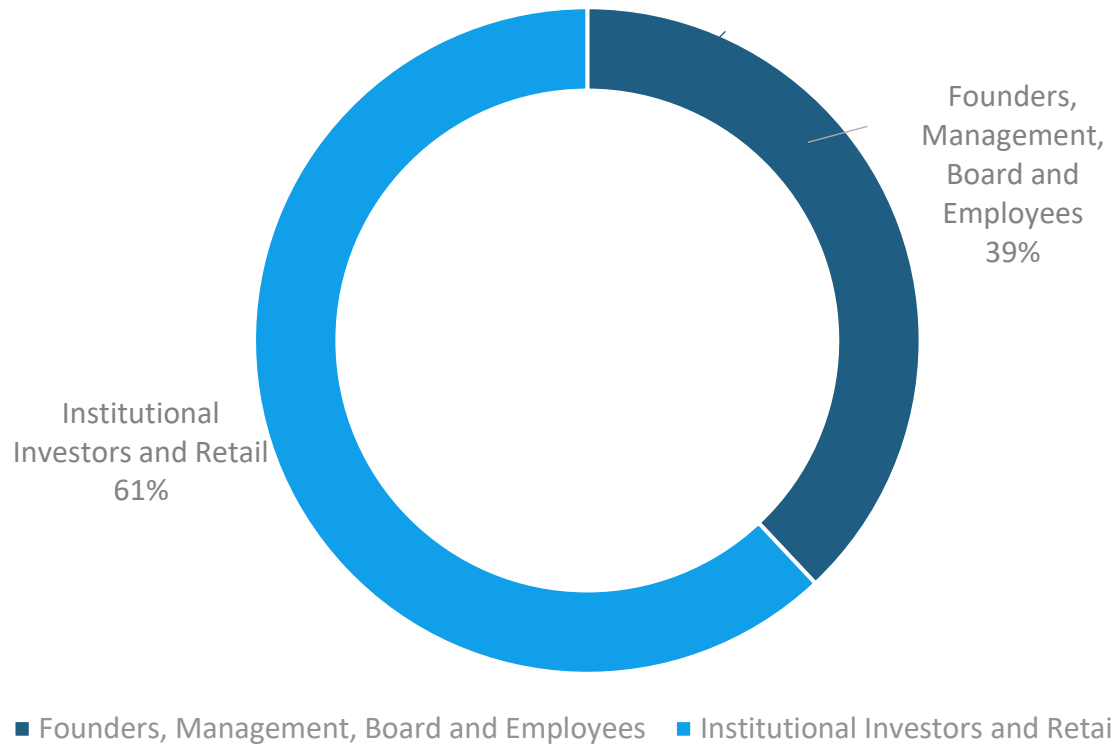
Position BI 765063 on the CD47 landscape in solid tumors together with its partner
Boehringer Ingelheim to address unmet needs in ICI resistant cancers

Proprietary early-stage assets with 3 programs to enter the clinic in 2022-23 in
blockbuster indications

Strong partnerships with Boehringer Ingelheim, Servier and Veloxis generating substantial
revenues to reduce cash burn and risk

Financial Visibility and Capital Structure

Shareholding structure



Financial visibility and share price

Number of outstanding shares : 18,285,038

Share price November 15th 2021 : 9.15 Euros

Financial visibility until Q3 2022



Immuno-Oncology And Autoimmune Diseases

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