

Improving KIDNEY TRANSPLANTATION OUTCOMES through better CMV prevention

MAY 2025



www.synklino.com

INVESTMENT CONSIDERATIONS

Summary



SYN002 is the only drug of its kind

- Unique MoA places SYN002 alone in entirely new space: Treating donor kidneys ex vivo - before transplantation



Short duration, de-risked development path

- SYN002 could be on the market already in 2030
- Ex vivo MoA offers smaller, de-risked trials to market approval
- Possibility for orphan drug designation, conditional early approval



Significant advantages over current SoC

- SYN002 offer single-application solution eliminating the need for long-term systemic antiviral treatment
- Positioned against letermovir (Prevymis®), suggesting advantages in safety, patient adherence, and administration simplicity
- SYN002 targets peak sales > 2 bUSD per year



Significant health economic benefits

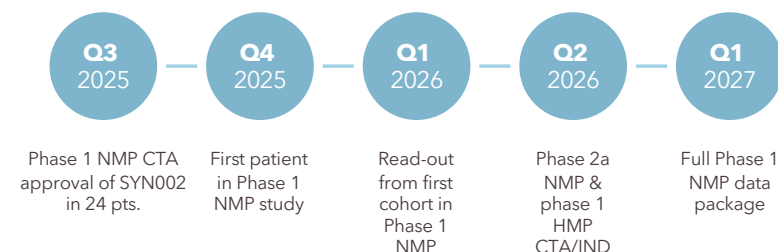
- Kidneys constitute largest transplantation market worldwide
- Attractive US reimbursement pathway for SYN002 available through Medicare Part A



PROPOSED FINANCING ROUND

- ✓ **Aim is to raise 20 mEUR by Q2 25**
 - Phase 1 NMP clinical safety study in the UK
 - DS process optimization
 - Phase 2a NMP & phase 1 HMP CTA/IND filings
- ✓ **Expandable to 40 mEUR**
 - Phase 2a NMP clinical efficacy study EU/UK & US
 - Phase 1 HMP clinical safety study
 - Prepared for pivotal trials
- ✓ **Soft commitment from Asahi Kasei CVC for 5 mUSD**
 - Subject to terms, further due diligence
- ✓ **In final stage of potential 10 mEUR EIC grant/equity award**
- ✓ **Existing shareholders expected to participate**

NEAR TERM MILESTONES INCLUDE



THE CMV LATENT RESERVOIR IS LIFE-LONG AND DRIVES THE RISK OF POST-TRANSPLANTATION CMV REACTIVATION



Most of us will never know we are infected



In latency, CMV does not replicate, and the viral genome is maintained in a quiescent state

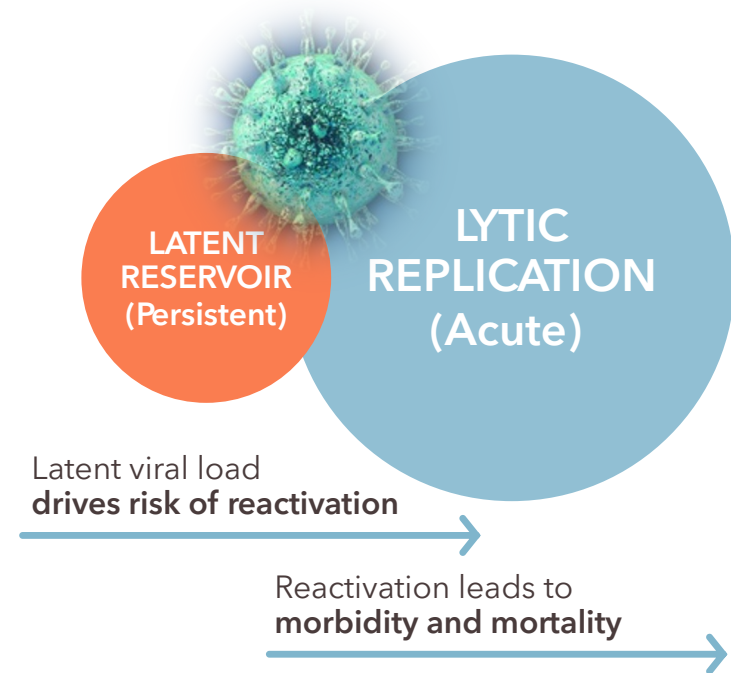


During latency, the virus hides in rare CD14+ monocytes and CD34+ myeloid progenitor cells

Initial infection

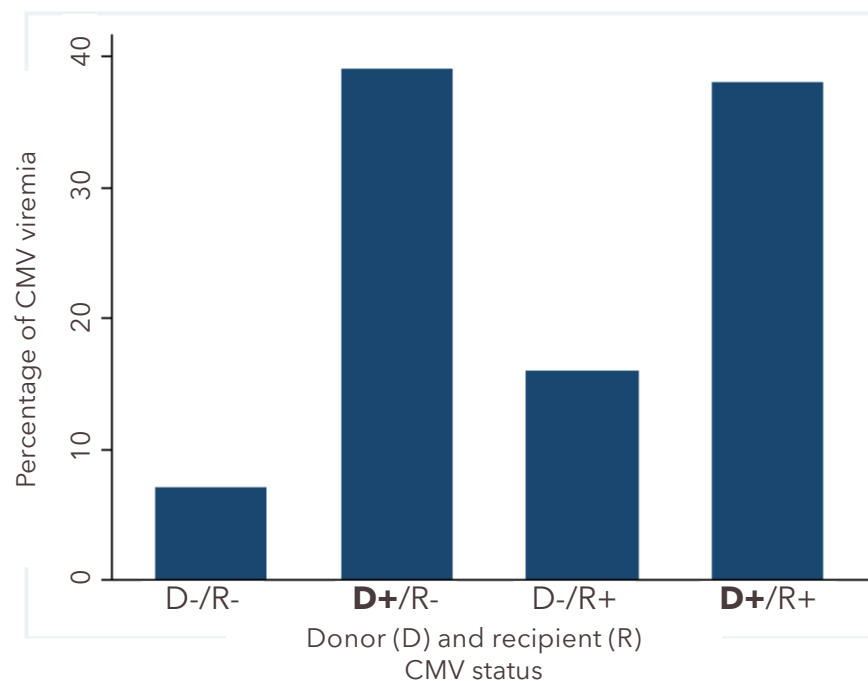


The CMV lifecycle



DONOR ORGAN CMV STATUS IS THE KEY DRIVER OF VIREMIA AFTER TRANSPLANTATION

Impact of CMV status on the risk of CMV reactivation

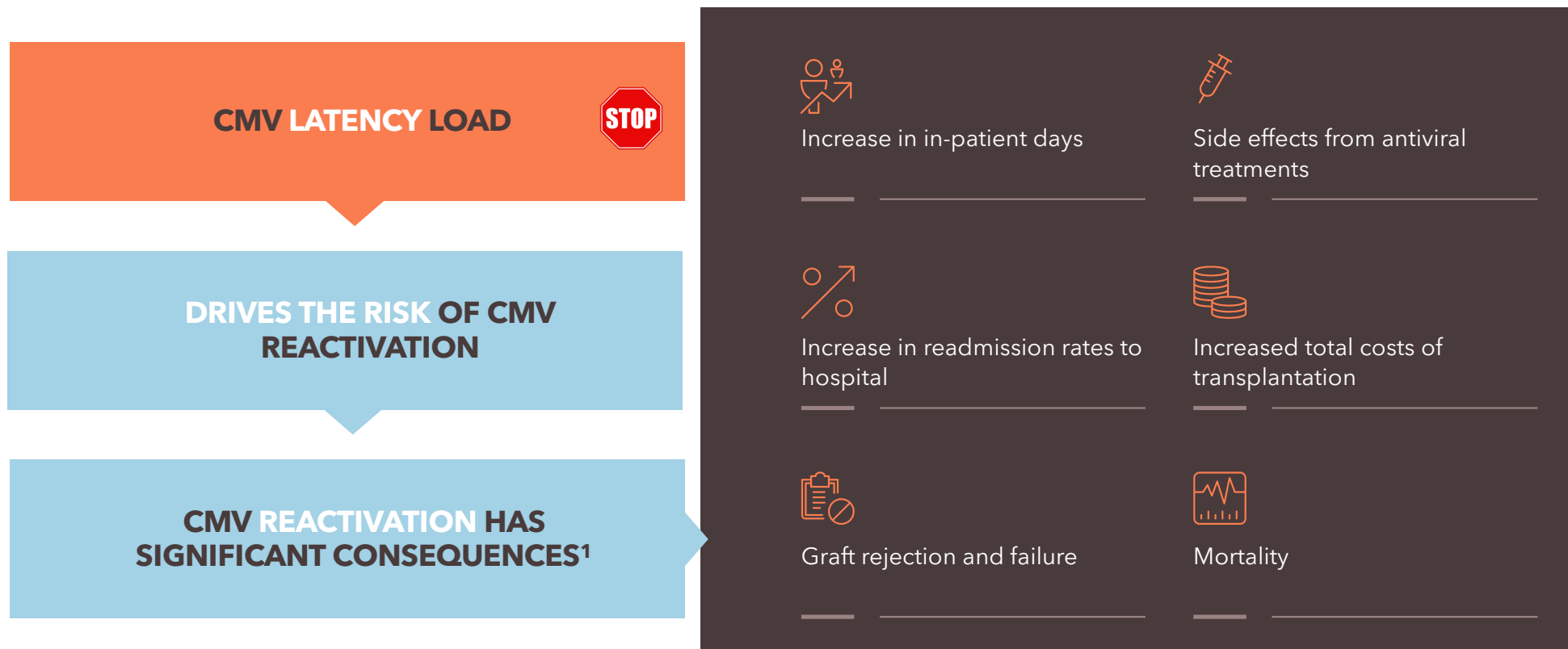


Donor (D) organ CMV status is driving CMV reactivation risk independent on recipient (R) CMV status

Pullerits K et al. Viruses 2022

PROPRIETARY AND CONFIDENTIAL

BY REDUCING CMV LATENT LOAD WE BREAK THE CHAIN



¹Hakimi Z et al. Transplant Infectious Diseases 2017

SYN002 DESIGN

DOCKING

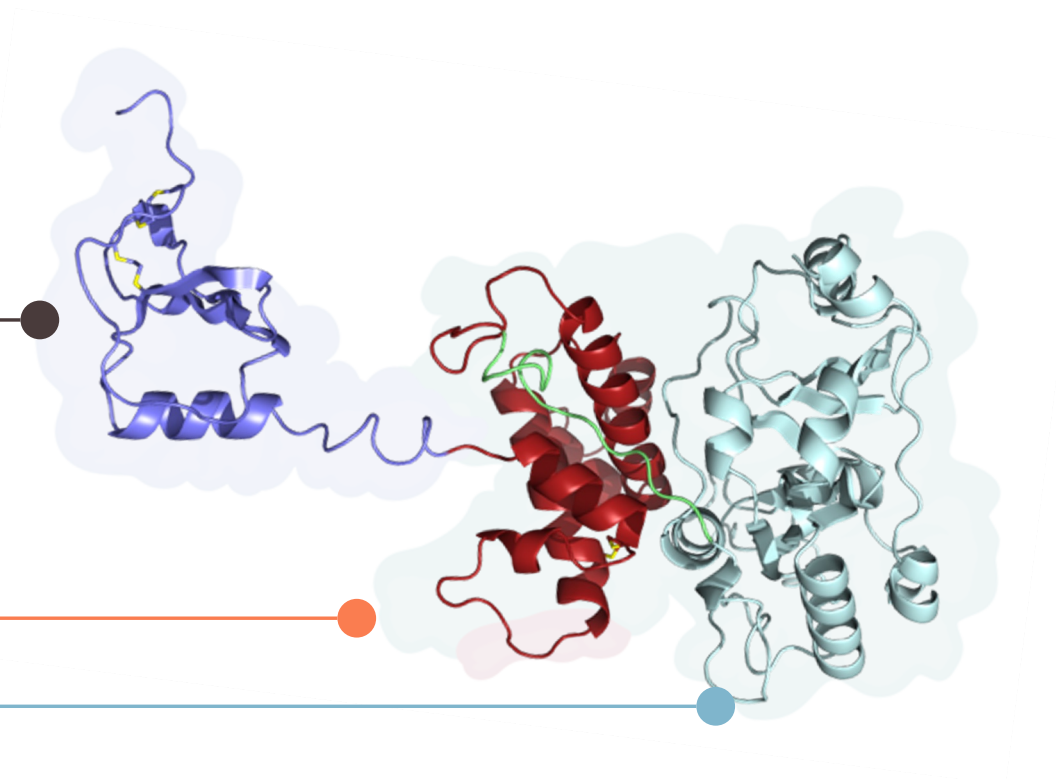
Chemokine scaffold optimized for selective binding to CMV US28
Enables internalization of SYN002 in all CMV infected cells

ACTIVATOR

Furin cleavage site
results in intracellular release

EFFECTOR DOMAIN

Catalytic domain of pseudomonas exotoxin
Blocks protein synthesis, driving CMV-infected cells to undergo apoptosis

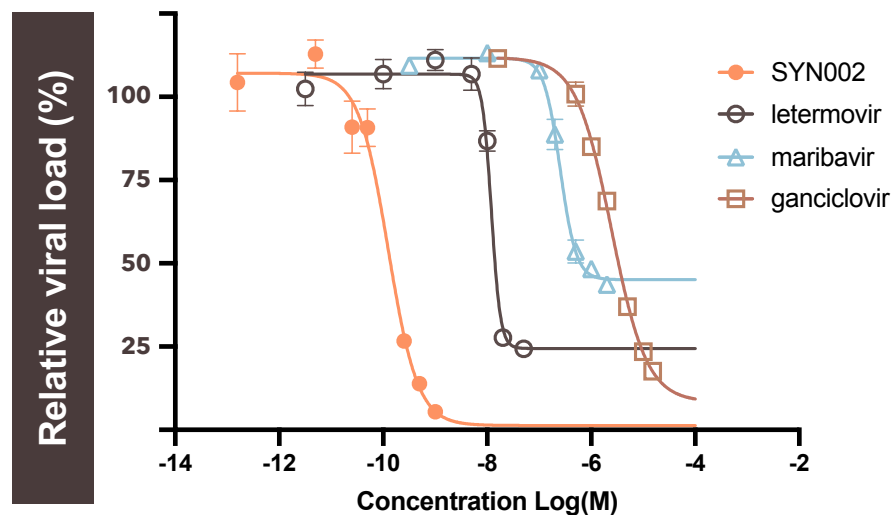


Selectively eliminate infected cells without impacting organ function

Simple single polypeptide protein design and microbial manufacturing process

SYN002 EFFICACY AND ANTIVIRAL CELL-KILLING POTENCY

Superior efficacy and potency of SYN002 compared to SOC in lytic infected cells



Wild Type CMV

Drug	SYN002	Letermovir	Ganciclovir	Maribavir
IC50 (nM)	0.13	8.8	1800	230

SYN002 is 14,000 times more potent than ganciclovir and **1,800 times more potent** than maribavir, and **68 times more potent** than letermovir

SUPERIOR POTENCY OF SYN002 COMPARED TO SOC – ON WILD TYPE AND RESISTANT STRAINS

SYN002 demonstrates superior and unaltered potency on resistant CMV strains (lytic infection)

Resistant strain

CMV Strain	ganciclovir (GCV)		foscarnet (FOS)		letermovir (LMV)		SYN002	
	IC50 (nM)	Resistance index	IC50 (nM)	Resistance index	IC50 (nM)	Resistance index	IC50 (nM)	Resistance index
Wild Type (KL7)	2500	1	39000	1			0.08*	1
KL7 GCV resistant strain	52000	21					0.16*	1
KL7 FOS Resistant strain			79000	2			0.10*	1
Wild Type (RV-HG)					9.6	1	0.09*	1
RV-HG LMV resistant strain					44000	4600	0.08*	1

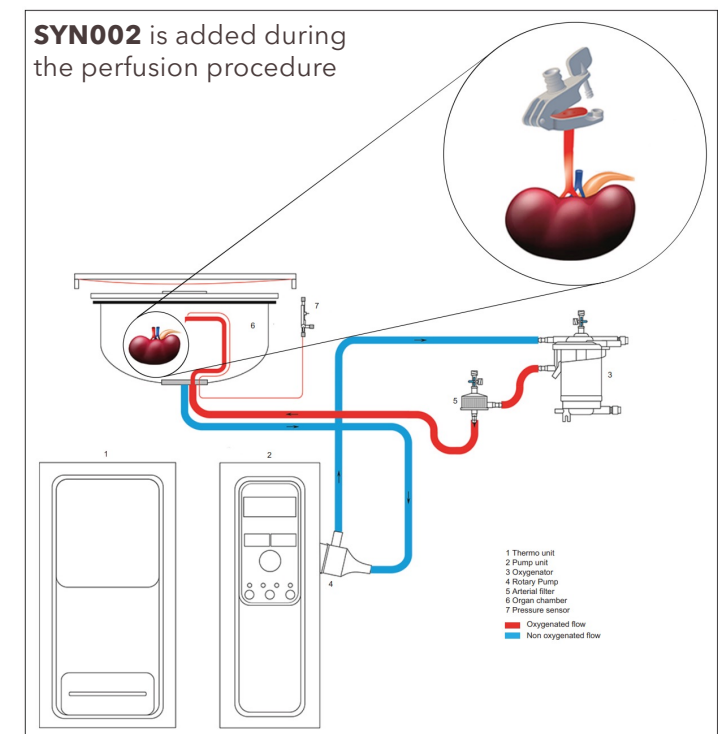
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* SYN002 IC50 values are within the error margin of one another

KIDNEY PRESERVATION PRIOR TO TRANSPLANTATION

Ex vivo machine perfusion is used to preserve and recondition/repair organs

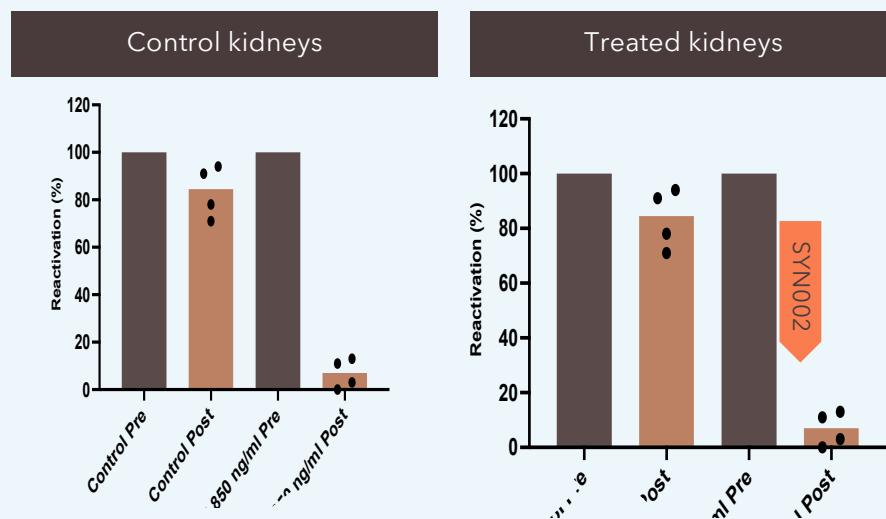
- Kidneys harvested for transplantation are preserved by **cold storage** or **machine perfusion**
- Organs that are perfused during preservation have a reduced incidence of delayed graft function, an overall improved graft survival, and an increased rate of use



Perfusion circuit of the XVIVO Kidney Assist
(Rijkse et al., Int J Surg Protoc., 2021)

SYN002 IS HIGHLY EFFICACIOUS AND WELL TOLERATED IN A HUMAN KIDNEY EX VIVO MODEL

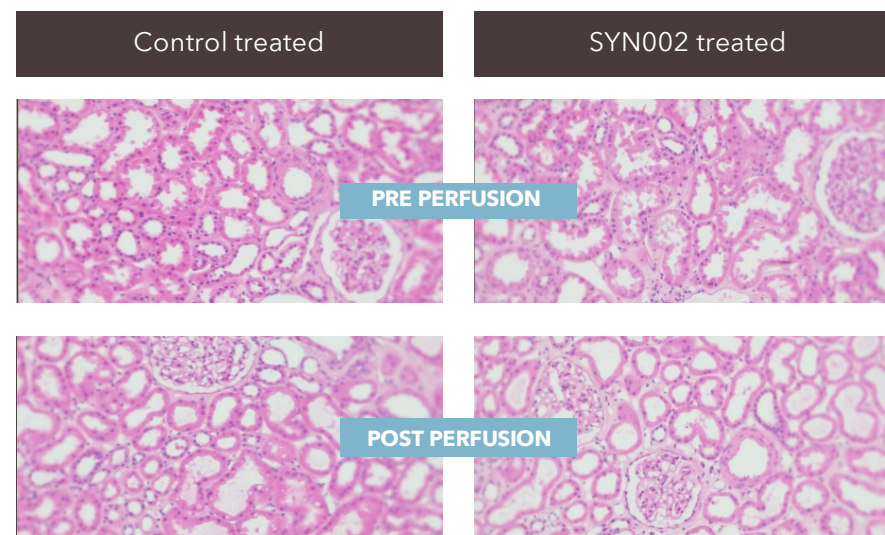
Latent CMV infection is **reduced by >90%** after single, 4-hour treatment



The preclinical ex vivo studies conducted at the University of Cambridge recapitulate the approach that will be used in the Phase 1 study and significantly derisk the outcome of the study

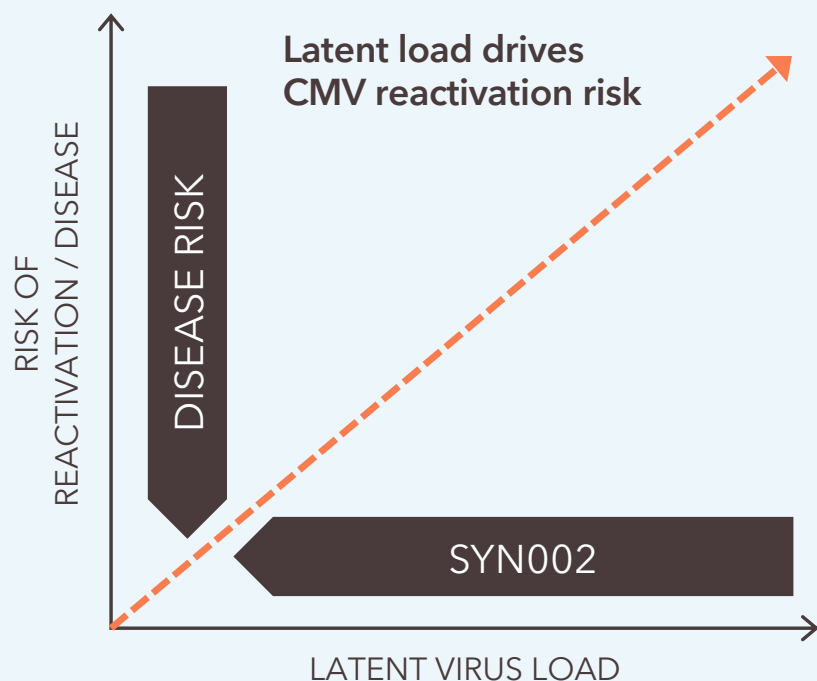
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No acute histopathological changes after SYN002 treatment

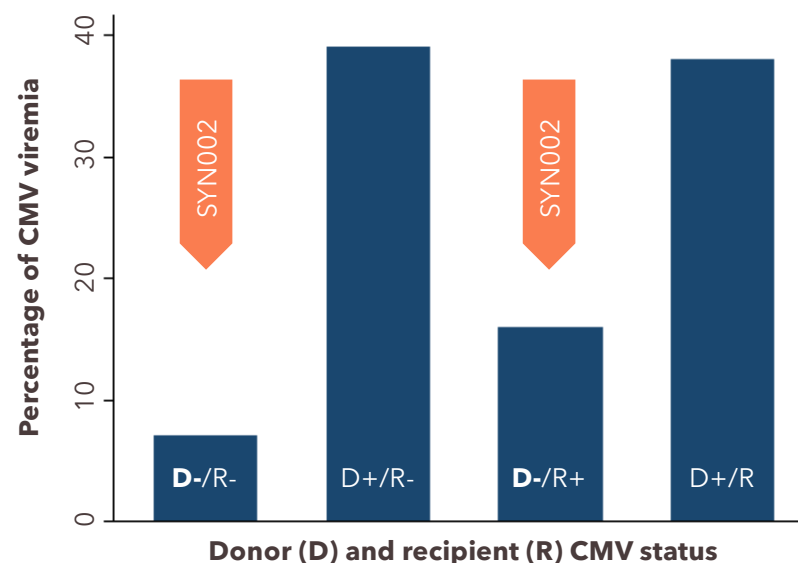


SYN002 ELIMINATES LATENTLY INFECTED CELLS, DRIVING DOWN RISK FOR REACTIVATION, AND DISEASE

SYN002 targets the main CMV reactivation risk driver - the donor organ latency pool



SYN002 will drive down risk of CMV reactivation



SYN002 ENJOYS STRONG SUPPORT FROM TRANSPLANT KOLs

Synklino used world-class KOL board to help design clinical program for SYN002



Lead Coordinating Principal Investigator

Professor Michael Nicholson
(Cambridge, UK)

"Ex vivo perfusion offers a unique window of opportunity to administer tailored treatments to donated organs. This CMV antiviral study is an extremely relevant clinical innovation that parallels our team's ongoing research and dedication to bringing more healthy organs to more transplant patients"

Prof. Michael Nicholson

Michael Nicholson (Cambridge, UK) - World-renowned leader in transplantation surgery, organ perfusion, preservation, and transplantation techniques. Pioneer in normothermic perfusion

Nassim Kumar (Toulouse, France) – Leading authority in transplant immunology and recipient outcomes

Marcus Pereira (New York, USA) – Renowned expert in infectious diseases in transplantation

Atul Humar (Toronto, Canada) – Pioneer in transplant virology and post-transplant care

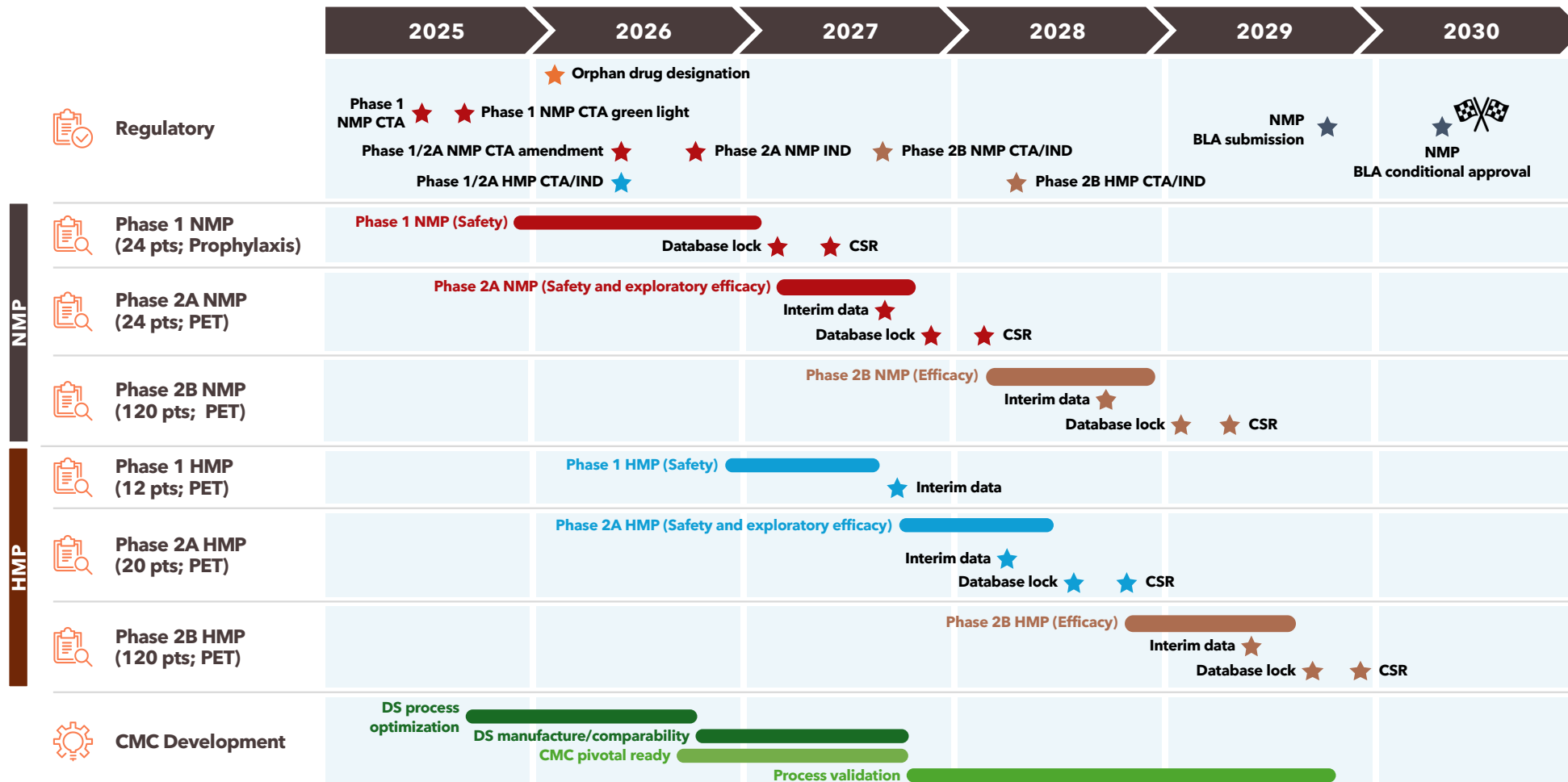
Dan Brennan (Baltimore, USA) – Specialist in transplant nephrology and long-term graft survival

Camille Kotton (Boston, USA) – International leader in transplant infectious diseases and immunosuppression management

Vassilios Papalois (London, UK) – Renowned authority in organ transplantation and surgical excellence










Chris Callaghan (London, UK) – Key expert in kidney transplantation and organ preservation

DEVELOPMENT STRATEGY (2025-2030)



SYN002 IS READY FOR CTA FILING AND INITIATION OF PHASE 1



Area 	Milestones	Status 
CMC	SYN002 drug product ready for clinical supply	
Non-clinical	<i>In vitro</i> safety pharmacology	
Non-clinical	GLP toxicology studies (NHP and rodent)	
Regulatory	EU (DK and ES) scientific advice meetings	
Regulatory	MHRA / UK scientific advice meeting	
Non-clinical	CTA enabling Studies	
CMC /non-clinical	Compatibility / Suitability study	
Regulatory	CTA writing and filing	Ongoing
Clinical	Phase 1 - ex vivo treatment of kidneys for transplantation (UK)	Planned

REGULATORY ALIGNMENT IN SUPPORT OF PHASE 1 CTA

Phase 1 planned to take place in UK - agreement with MHRA on non-clinical conclusions and clinical plan



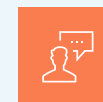
No additional in vivo toxicology studies needed



Alignment on preclinical conclusions



Support for Phase 1 plan



Positive response to overall development path to registration

FAVORABLE PRICING AND REIMBURSEMENT DYNAMICS IN THE US FOR KIDNEY TRANSPLANTS



SYN002 is to be used during organ acquisition where reimbursement will be under **Medicare A**

01



CMS/Medicare **reimburses all organ acquisition costs** that are deemed "reasonable and necessary" for transplantation.

02



SYN002 is expected to have a **significant positive effect** on transplantation outcome

03

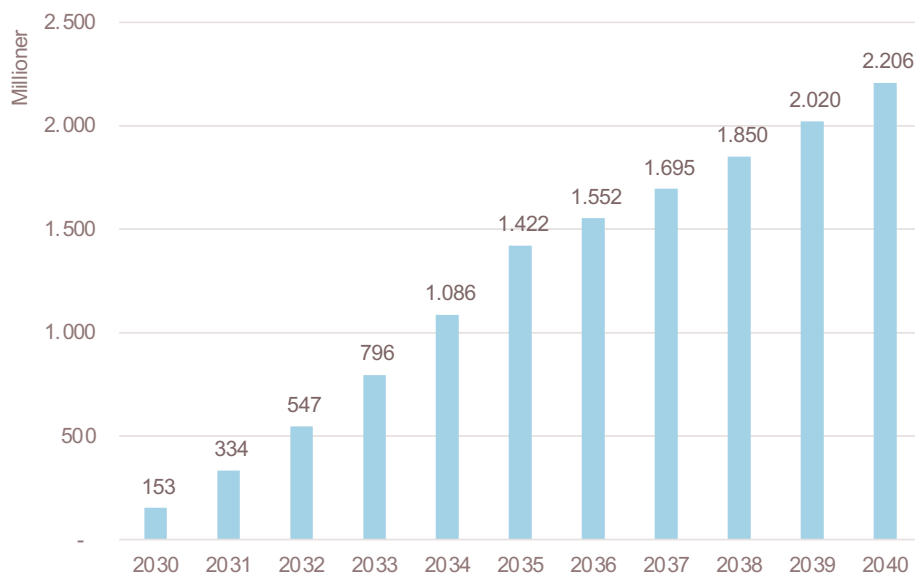


Pricing could be at parity to prophylactic drugs such as PREVYMIS® - **around \$57,000** - for a treatment course

SYN002 REPRESENTS A SIGNIFICANT MARKET OPPORTUNITY

SYN002 market uptake will be driven by the risk associated with transplanting a CMV infected organ

SYN002 US sales forecasts | Base case



Key assumptions



- Market share at peak sales
 - 90% for deceased D+/R-
 - 45% for deceased D+/R+
 - 45% for living D+/R-
 - 23% for living D+/R+
- Assumes continuous growth of deceased/living kidney transplants - based on growth from 2013
- Pricing : \$57,000 + 3% increase per year

EXCLUSIVITY SCENARIO

Significant market protection for SYN002 until 2045

Estimated marketing entry 2030



Data Protection

5-10 years from MA

Orphan Drug Protection

7-10 years from MA

PTE WO 2021/043863 - **US** (2-5 years from patent expiry; max 14 years from MA)

SPC* WO 2021/043863 - **EU** (5 years from EP patent expiry; max 15 years from MA)

Patents derived from WO 2021/043863

Patents derived from WO 2022/184825

Estimated market entry 2030



EU



EU/US

2020

2025

2030

2035

2040

2045

AFR

: Patent term adjustment (awarded due to prosecution delay at the USPTO)

PTE

: Patent term extension (awarded due to regulatory delay at the FDA; max 14 years from MA and max 5 years from original expiry of patent)

SPC

: Supplementary protection certificate (awarded due to regulatory delay at the EMA; max 15 years from MA and max 5 years from original expiry of patent)

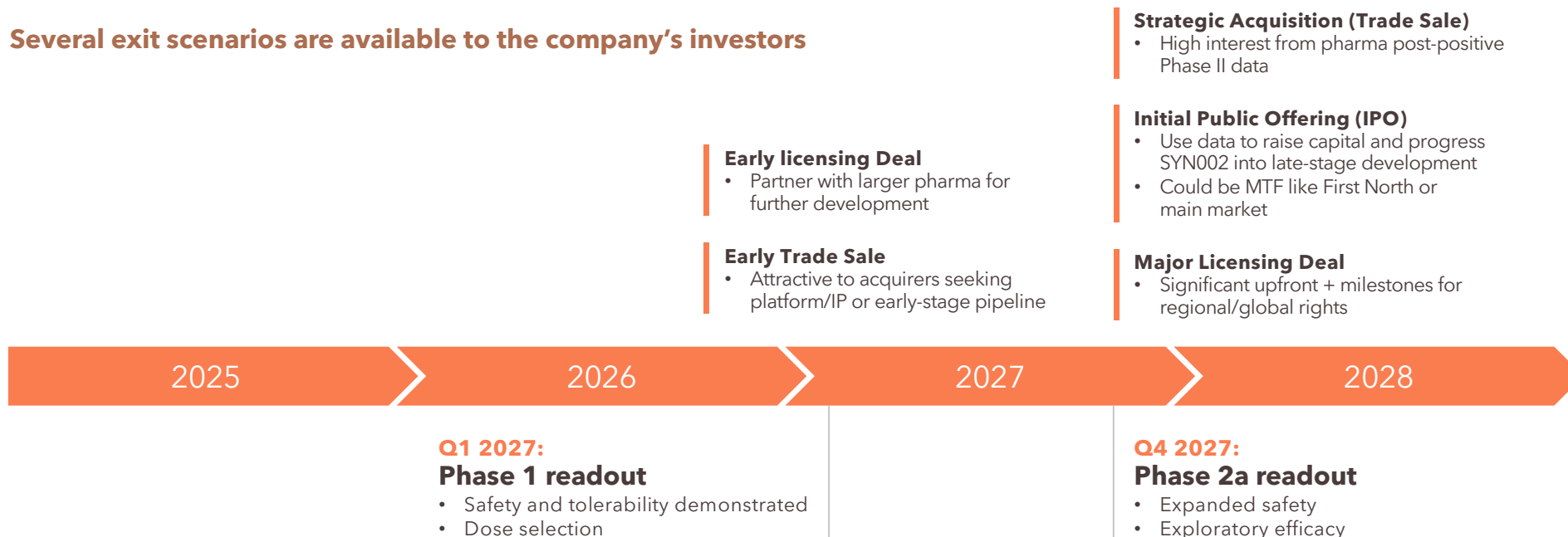
MA

: Marketing approval

HØIBERG
EUROPEAN PATENT ATTORNEYS

EXIT SCENARIOS

Several exit scenarios are available to the company's investors



Important considerations

Phase I: Validates safety and clinical viability – enables early licensing M&A but may not capture full value potential for Synklino's investors

Phase II: Demonstrates early efficacy – unlocks higher valuations and broader exit options, including an IPO and the possibility of taking SYN002 through phase III before a partner is sought

Exit strategy should match risk appetite, capital needs, and strategic vision

POTENTIAL ACQUIRERS/PARTNERS

Includes pharma companies active in antiviral space as well as MedTech in the machine perfusion space

Company	Rationale for Acquisition/Partnership	Relevant Portfolio/Recent Moves
Merck (MSD)	<ul style="list-style-type: none"> Market leader in CMV with Prevymis Strong antiviral expertise 	<ul style="list-style-type: none"> Owns Prevymis Expanding transplant-related offerings
AstraZeneca (AZ)	<ul style="list-style-type: none"> Active in transplantation & immunology Synergy with infection prevention initiatives 	<ul style="list-style-type: none"> Imfinzi (immunosuppressive); Past M&A in infection & transplant
Asahi Kasei (Veloxis/Calliditas)	<ul style="list-style-type: none"> Strong presence in Transplant immunosuppression 	<ul style="list-style-type: none"> Owns Envarsus XR (extended-release tacrolimus) for kidney transplant patients Developing VEL-101 for transplant immunosuppression
Sanofi	<ul style="list-style-type: none"> Established transplant portfolio with immunosuppressive and antiviral therapies 	<ul style="list-style-type: none"> Thymoglobulin, Mozobil, Requrock in SOT and HSCT
Takeda	<ul style="list-style-type: none"> Active in antiviral therapies for transplant patients 	<ul style="list-style-type: none"> Developed Livtency (maribavir) for post-transplant CMV infection /disease Opportunistic in M&A
Sobi (Swedish Orphan Biovitrum)	<ul style="list-style-type: none"> Focus on specialty & rare disease therapies Recently expanded into organ transplant infection prevention 	<ul style="list-style-type: none"> Recent expansion into transplant infection prevention initiatives
Memo Therapeutics	<ul style="list-style-type: none"> Specializes in antibody-based therapies for viral infections in transplant patients Focuses on innovative therapeutic approaches to viral control in transplants 	<ul style="list-style-type: none"> Developing MTX-005, a monoclonal antibody for BK virus control Active R&D in viral infection & transplantation arenas
CareDX	<ul style="list-style-type: none"> Leader in transplant diagnostics and monitoring solutions 	<ul style="list-style-type: none"> Developed Allosure, a dd-cfDNA test for detecting organ transplant rejection
Fresenius	<ul style="list-style-type: none"> Active in the kidney care/dialysis area and therapeutic apheresis 	<ul style="list-style-type: none"> Provides products and services for dialysis as well as desensitization programs for solid organ transplantation
Paragonix Technologies	<ul style="list-style-type: none"> Leader in organ transport and preservation systems Strategic fit with ex vivo perfusion technology advancements 	<ul style="list-style-type: none"> Developed SherpaPak Developed LungGuard for hypothermic organ transport
TransMedics	<ul style="list-style-type: none"> Owner of the Organ Care System (OCS), a leading ex vivo perfusion system Positioned to integrate enhanced ex vivo organ treatment 	<ul style="list-style-type: none"> Acquired EVOSS (warm perfusion) and LifeCradle (cold perfusion) technologies from Bridge to Life
Xvivo	<ul style="list-style-type: none"> Owner of the Kidney Assist, Liver Assist and XPS, leading ex vivo perfusion systems Provide widely used STEEN Solution to the organ perfusion market 	<ul style="list-style-type: none"> Developed PERFADEX® Plus offer an organ recovery service on the US market

EXPERIENCED MANAGEMENT TEAM

EXECUTIVE



Thomas N. Kledal

Ph.D., MBA

25+ years in life science and biotech. Previous Head of Virology and Life Science Engineering at DTU, CEO at Inagen. Co-founder of Synklino

MEDICAL



Ian McGowan

M.D., Ph.D., FRCP

35+ years in managing Phase 1 through Phase 3 drug development. Previously Professor of Medicine, at the University of Pittsburgh.

FINANCE



Carit Jacques Andersen

M.Sc. B.A.

20 years as CFO in biotech and pharma. Experienced taking companies public and managing listed companies.

OPERATIONS



Jette Wagtberg Sen

Ph.D.

15+ years in development, operations and CMC. Previous Senior Director at Symphogen.

NON-CLINICAL



Johan Lantto

Ph.D.

20+ years in drug discovery and development in biotech and pharma. Previous Sr. Director at Symphogen/Servier.

PROJECTS



Fredrika Carlsson

Ph.D.

Experienced researcher, and project manager with experience from Alligator Bioscience. Previous postdoc at Scripps Research



Drug Development
SUCCESS



Transaction
EXPERIENCE



Financing & IPO
EXPERTISE



Significant ownership
INTEREST

BOARD AND ADVISORS

CHAIRMAN



John Haurum

M.D., D. Phil
Previously CEO of F-star, VP Eli Lilly, CSO at Symphogen

BOARD MEMBER



Morten Schrøder

Board member MC2 Therapeutics, Mermaid Care, MEQU and XO Care

BOARD MEMBER



Prof. Mette Rosenkilde

Ph.D., M.D.
Molecular and translational pharmacology
Co-founder of Synklino

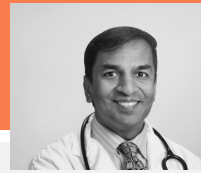
OBSERVER



Mark Hensley

Previous CEO at Veloxis. US commercial, market access, reimbursement, and healthcare strategy, focus on transplant medicine

CLINICAL ADVISOR



Prof. Atul Humar
M.D., M.Sc.

Senior Scientist, Toronto General Hospital Research Institute. World leading expert in the field of transplantation & infectious diseases

SCIENTIFIC ADVISOR



Prof. John Sinclair

Ph.D. Deputy Head of the Department of Medicine and Head of the Division of Infectious Diseases at Cambridge University

SCIENTIFIC ADVISOR



John Lambert

Ph.D.
Previous EVP, CSO, and Distinguished Research Fellow at Immunogen

THANK YOU FOR YOUR ATTENTION

Unique MoA in field
with vast unmet need

Near term milestones
and important value
inflection points

Significantly derisked
development, clear
and short path to
market

Multiple exit routes

Attractive market
opportunity,
blockbuster potential



Contact



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