Redefining Kidney Disease Treatment with A1M Therapies

Non-confidential summary

October 2025

GUARD THERAPEUTICS

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GUARD THERAPEUTICS – DEVELOPING A1M PROTEIN THERAPEUTICS TO PROTECT KIDNEY FUNCTION

RMC-035 for kidney protection in open-heart surgery

- **Phase 2b POINTER study** – **topline results in Q4 2025** (enrollment completed, 170 patients)
- **Clinical proof-of-concept** in Phase 2a AKITA study with 177 patients
  - 59% risk reduction vs placebo (MAKE, regulatory endpoint)
- **FDA Fast Track Designation** (kidney protection in open-heart surgery); eligible for Breakthrough Therapy Designation
- **First-to-market potential** in open-heart surgery; >USD 1 billion market – no approved therapies

Additional opportunities with RMC-035 & GTX peptides

- **Phase 3-ready sepsis program** with additional expansion opportunities (>USD 5 billion market)
- **Preclinical GTX peptides** with broad opportunities in late-stage & orphan chronic kidney diseases (>USD 8 billion market)

Company & Ownership

- Listed on Nasdaq First North Growth Market (Stockholm: GUARD)
- Strong institutional shareholders including Industrifonden & Swedbank Robur

GUARD THERAPEUTICS

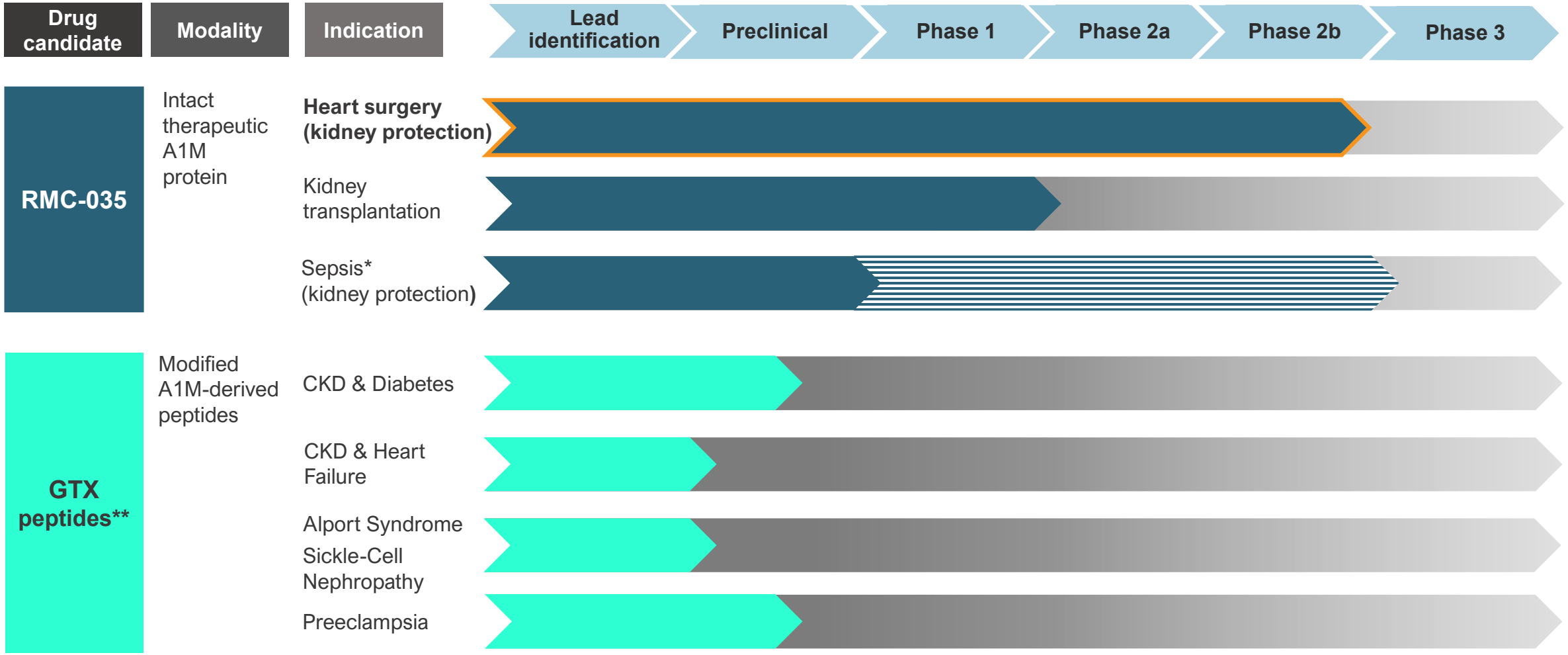
A1M, alpha-1-microglobulin; MAKE, major adverse kidney events

EXPERIENCED MANAGEMENT TEAM

– STRONG AND PROVEN TRACK RECORD IN DRUG DEVELOPMENT

NAME / POSITION	EXPERIENCE	NAME / POSITION	EXPERIENCE
 **TOBIAS L. AGERVALD** **CEO** MD, PhD	**+15** years in industry astellas	 **KARIN BOTHA** **CFO** MSc	**+25** years in industry NOVARTIS, SmithKline Beecham, GlaxoSmithKline
 **MICHAEL REUSCH** **CMO** MD	**+30** years in industry Fujisawa, astellas	 **PETER GILMOUR** **CSO/Head of Preclinical** MSc, PhD	**+20** years in industry AstraZeneca, astellas
 **TORBJÖRN LARSSON** **Head of CMC** BSc	**+30** years in industry Medivir, aprea therapeutics, Pharmacia & Upjohn	 **SARA THURESSON** **Head of Clinical Operations** MSc	**+20** years in industry oncopeptides, WILSON THERAPEUTICS, IQVIA, Medivir

BUILDING A DIFFERENTIATED PIPELINE ON A1M'S UNIQUE BIOLOGY



* Opportunity to initiate pivotal Phase 3 study in sepsis following results in ongoing Phase 2b study (POINTER) in open-heart surgery.

** Multiple GTX peptides fulfill criteria for candidate drug nomination. GTX-86 at nomination stage.

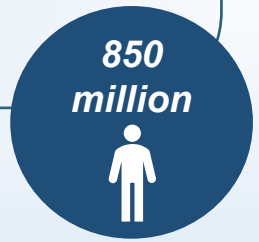
A1M, alpha-1-microglobulin

CHRONIC KIDNEY DISEASE & KIDNEY FAILURE

– A GLOBAL HEALTH CONCERN

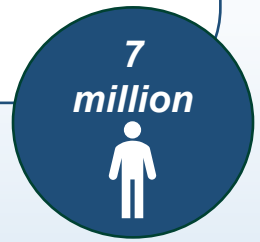
Chronic Kidney Disease

- Severe complications, including cardiovascular disease and kidney failure
- Years of life lost from CKD expected to soon surpass diabetes



Kidney failure

- Requires dialysis or kidney transplantation – poor outcomes and high cost
- High annual mortality rate (15-20%), worse than many cancers



Significant healthcare costs for kidney failure

~7% of Medicare budget, ~1% of Medicare population

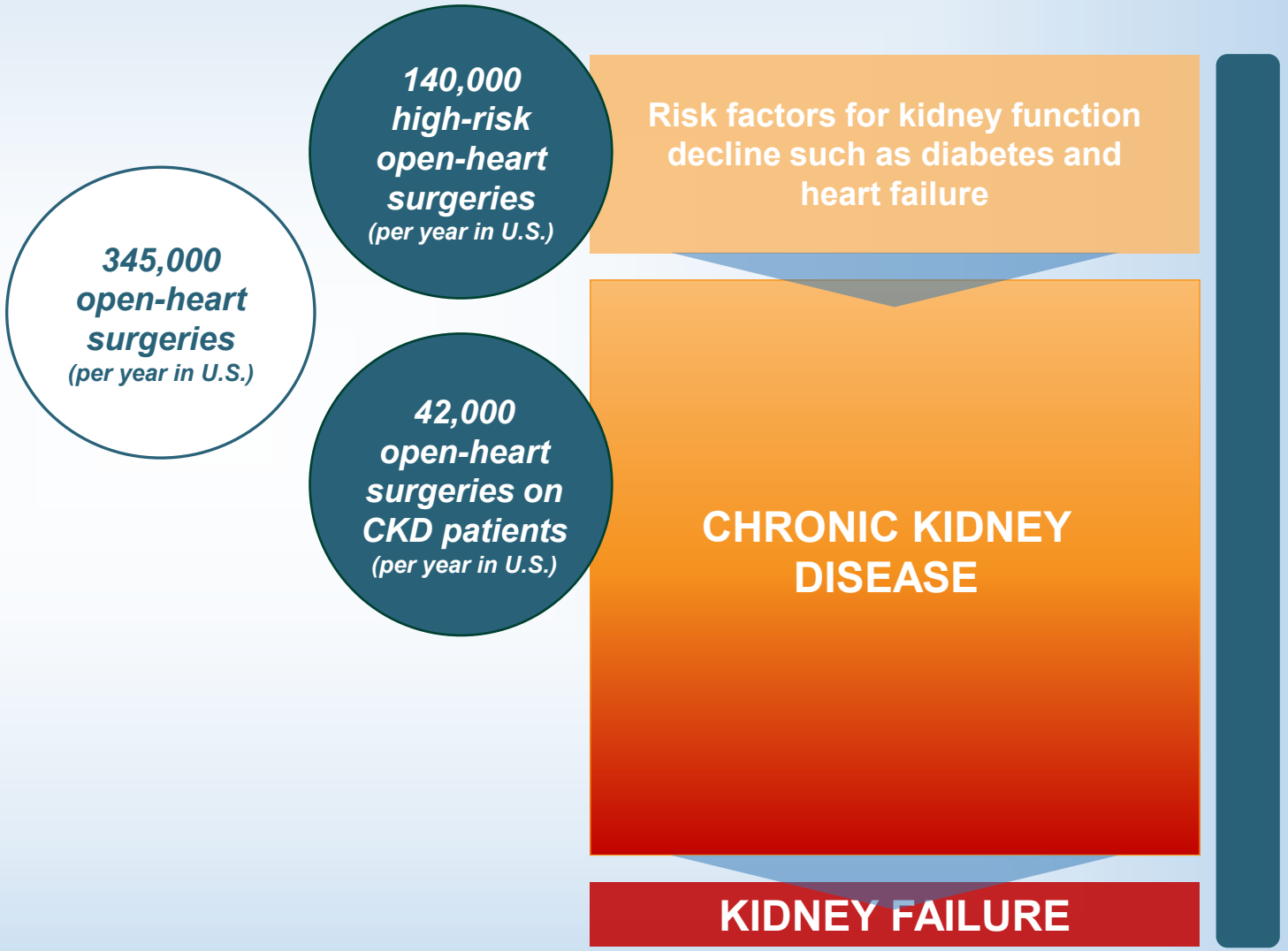
>USD 50 billion in Medicare annual spend

Sources: Francis et al, Nature Reviews Nephrology 2024, P Stenvinkel and TE Larsson, Am J Kidney Dis, 2013 Aug;62(2):339-51
2021 USRDS Annual Data Report July 2024 Data Book: Health Care Spending and the Medicare Program – MedPAC
GBD Chronic Kidney Disease Collaboration; Volume 395, Issue 10225 p709-733 February 29, 2020

HEART SURGERY AND THE LASTING BURDEN OF KIDNEY DISEASE

Open-heart surgery poses a high risk for irreversible loss of kidney function –

Protecting the kidneys during open-heart surgery will reduce the burden of Chronic Kidney Disease

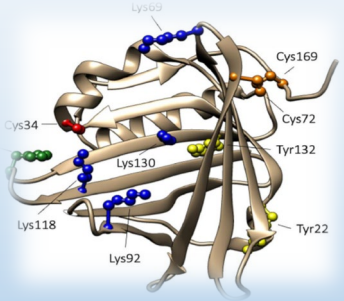


Numbers for open-heart surgery performed on-pump (cardiopulmonary bypass)

Sources: Global Data (2025); Real-world data (Cerner database, internal data on file)

A1M TARGETS CORE MECHANISMS OF KIDNEY INJURY IN OPEN-HEART SURGERY

Injury type	*Molecular action*	*Protective effect*
Ischemia – reperfusion	Reductase activity* Radical scavenging**	Reduces oxidative injury Preserves tissue integrity
Hemolysis	Heme-binding & neutralization***	Reduces heme-driven cell injury
Mitochondrial dysfunction	Cytochrome C binding & stabilization	Improves mitochondrial function & respiration



Each A1M molecule:

* Reduces 5-6 free radicals
** Traps 3-4 radicals
*** 2 heme-binding sites

A1M, alpha-1-microglobulin

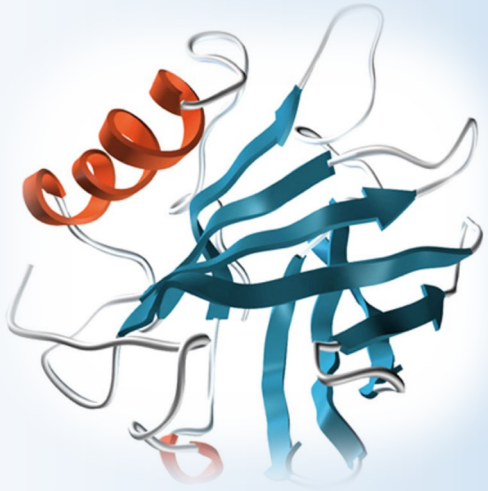
Source: Bergwik et al., Front Physiol 2021

RMC-035* – A RECOMBINANT VARIANT OF ENDOGENOUS HUMAN A1M

Harnessing endogenous A1M defense
Protects kidney function at the core mechanism of injury

Protein replacement therapy
Clinically validated concept with first-in-class potential

Simple hospital delivery
Short-term IV infusion, seamlessly integrated into standard care

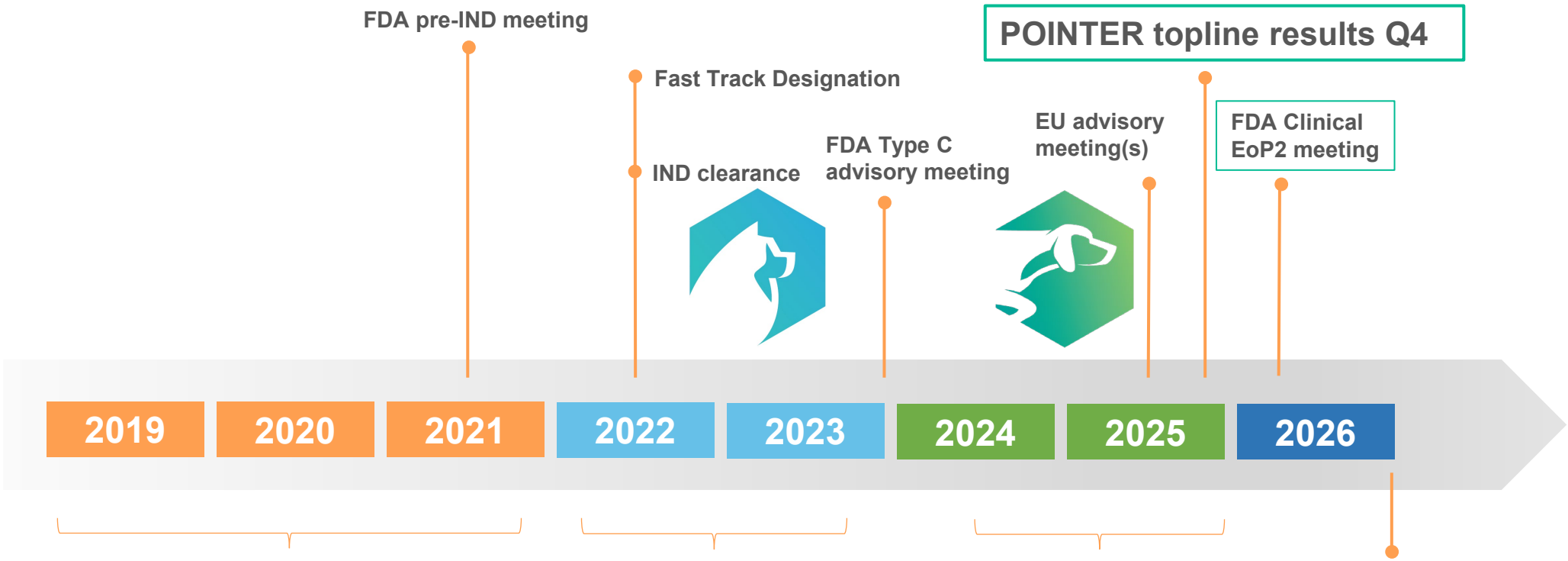


***Patent protection (composition of matter) until 2037 in all major regions including U.S., EU, Japan and China**

A1M, alpha-1-microglobulin

Source: Bergwik et al., Front Physiol 2021

SUCCESFULLY DELIVERING ON CLINICAL & STRATEGIC PLAN



Clinical Phase 1 program

- ✓ ROS-01 (single dose, healthy subjects)
- ✓ ROS-02 (multiple doses, healthy subjects)
- ✓ ROS-03 (renal impairment study)
- ✓ ROS-04 (safety/PK study in heart surgery)

Phase 2a *AKITA* study

- ✓ ROS-05 (proof-of-concept, heart surgery)

Phase 1b study

- ✓ ROS-06, kidney transplant

Phase 2b *POINTER* study

ROS-07 (dose-finding)

Phase 3 study start (open-heart surgery)

Optional Phase 3 study (sepsis)

PROMISING EFFICACY DATA IN PHASE 2a *AKITA* STUDY

Placebo-controlled, 177 patients undergoing open-heart surgery

Statistically significant & clinically meaningful improvement of kidney function (90 days after surgery)

eGFR benefit vs placebo

4.3 mL/min (total population)

7.9 mL/min (CKD subgroup)

MAKE* Relative Risk Reduction

59%

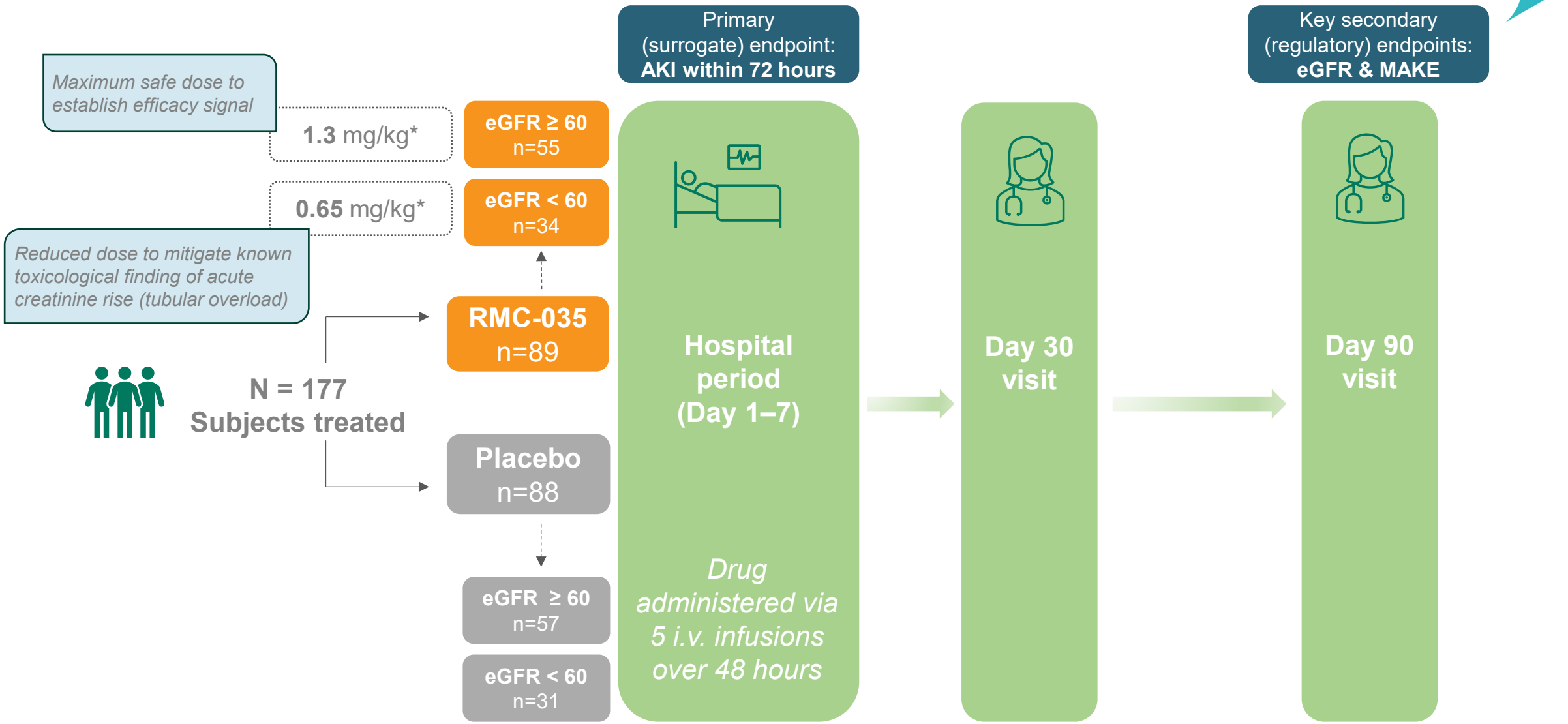
→ Phase 3 endpoint for market approval

Robust kidney protection profile – positions RMC-035 for late-stage clinical development

**MAKE = major adverse kidney event*
*Composite of **death, dialysis, or ≥ 25% eGFR decline***

Source: Zarbock et al. eClinicalMedicine, 2024 Sep 16:76:102830

PHASE 2a *AKITA* STUDY DESIGN – OVERVIEW

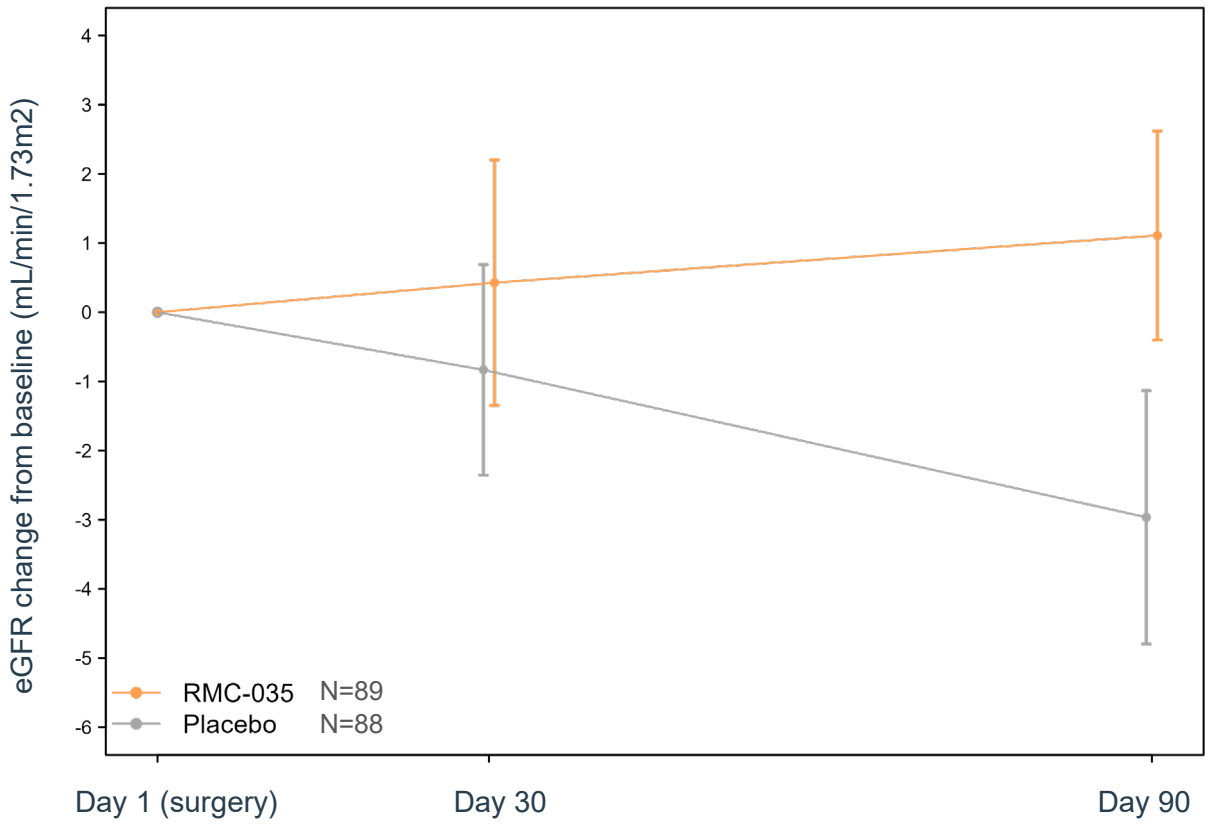


***eGFR subgroup ≥ 60: 1.3 mg/kg for Dose 1 and 2. 0.65 mg/kg for Dose 3 to 5; eGFR subgroup < 60: 0.65 mg/kg for all five doses. Time of dosing: during surgery (0 h), 6, 12, 24, 48h**

AKI, acute kidney injury; eGFR, estimated glomerular filtration rate; MAKE, major adverse kidney events

RMC-035 PREVENTS LOSS OF RENAL FUNCTION AFTER OPEN-HEART SURGERY – eGFR ENDPOINT

Modified intent-to-treat population
(i.e., all patients randomized and who received at least one dose of study drug)



eGFR endpoint at Day 90 met

Placebo-adjusted difference:
*4.3 mL/min
P = 0.06

Pre-defined two-sided alpha is 0.1
P-values < 0.1 are statistically significant

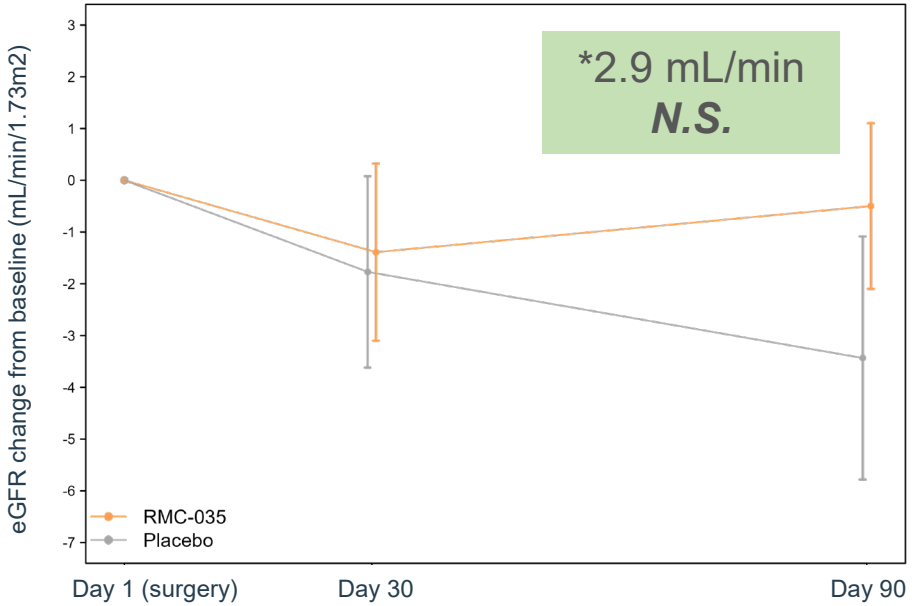
Error bars indicate mean +/- Standard Error; *eGFR change assessed by a Mixed Model of Repeated Measures

Source: Study 21-ROS-05 CSR, Table 14.2.3.3.3

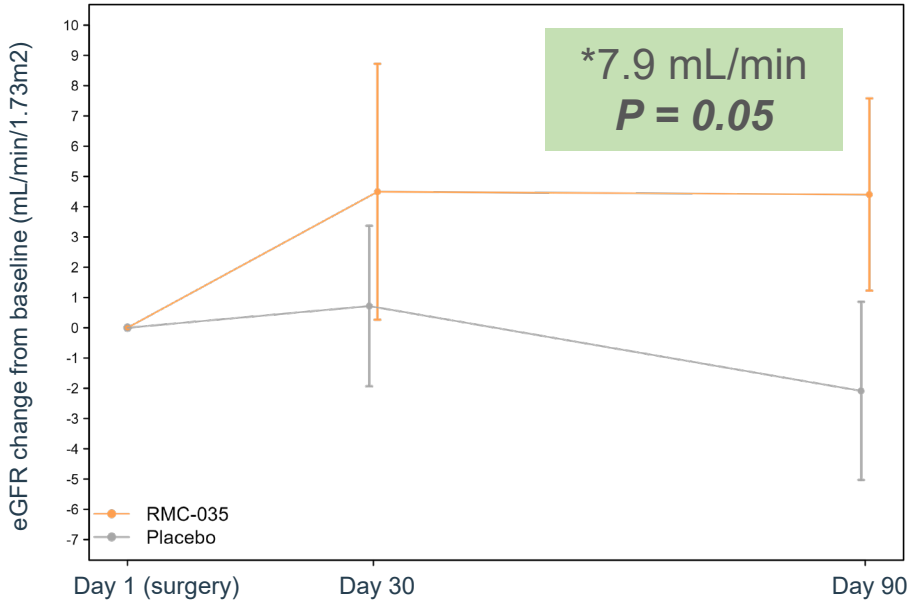
RMC-035 PREVENTS LOSS OF RENAL FUNCTION AFTER OPEN-HEART SURGERY – eGFR SUBGROUP ANALYSIS

Pre-specified eGFR subgroups based on dose and kidney injury risk

eGFR ≥ 60 (dose 1.3 mg/kg)
n=112



eGFR < 60 N=65 (dose 0.65 mg/kg)
n=65



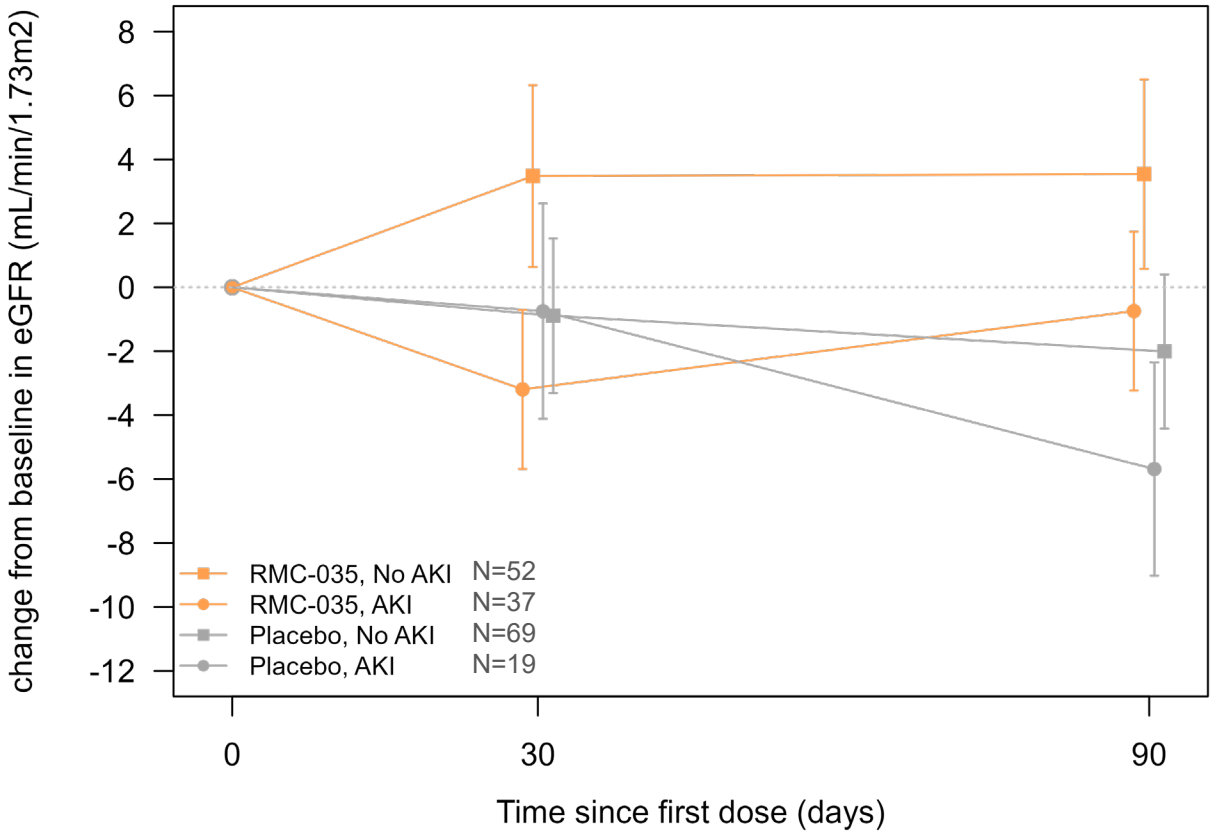
eGFR endpoint met in subgroup eGFR < 60

Modified intent-to-treat population
(i.e., all patients randomized and who received at least one dose of study drug)

Error bars indicate mean +/- Standard Error; * Placebo-adjusted difference; eGFR change assessed by a Mixed Model of Repeated Measures

Source: Study 21-ROS-05 CSR, Tables 14.2.3.3.3.1, 14.2.3.3.2

eGFR ENDPOINT – STRATIFIED BY PRESENCE OF AKI



Patients without AKI
5.5 mL/min
P = 0.019

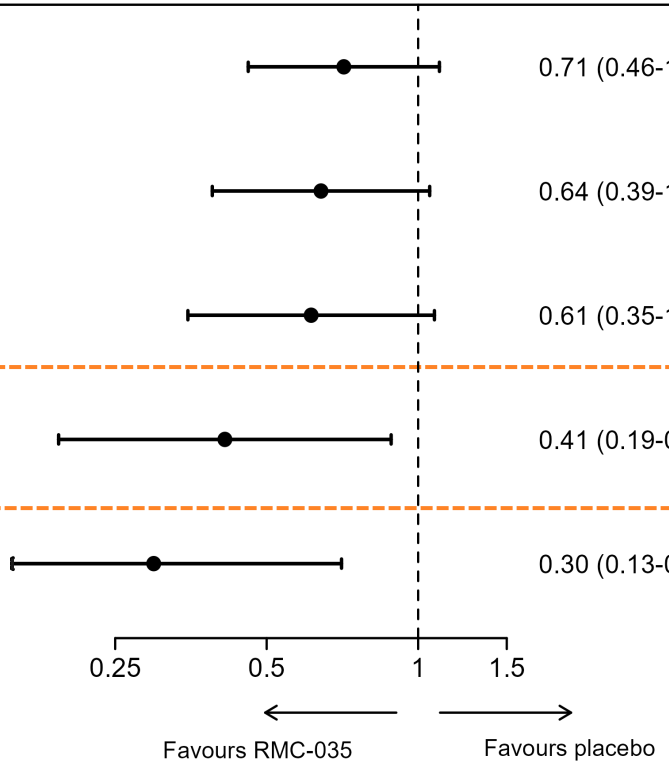
Patients with AKI
4.9 mL/min
P = 0.056

Results are stratified by treatment group and by the post-operative occurrence of AKI (acute kidney injury). Data are presented as least-squares mean change in eGFR from baseline to Day 90, estimated using a mixed model for repeated measures (MMRM). Error bars represent 90% confidence intervals.

Source: Study 21-ROS-05, post-hoc analyses (manuscript in submission)

RMC-035 PREVENTS LOSS OF RENAL FUNCTION AFTER OPEN-HEART SURGERY – MAKE90 ENDPOINT

eGFR cutoff	RMC-035 (n=89) Rate (90% CI)	Placebo (n=88) Rate (90% CI)	Risk ratio (90 % CI)	p-value
10 %	20.2 (13.2-27.2)	28.4 (20.5-36.3)	0.71 (0.46-1.10)	0.200
15 %	15.7 (9.4-22.1)	25.0 (17.4-32.6)	0.64 (0.39-1.05)	0.138
20 %	12.4 (6.6-18.1)	20.5 (13.4-27.5)	0.61 (0.35-1.08)	0.150
25 %	6.7 (2.4-11.1)	15.9 (9.5-22.3)	0.41 (0.19-0.88)	0.047
30 %	4.5 (0.9-8.1)	15.9 (9.5-22.3)	0.30 (0.13-0.70)	0.010



MAKE90 endpoint met

25% decline in eGFR = FDA-endorsed threshold for MAKE90 and pre-specified secondary endpoint in the AKITA trial

MAKE, major adverse kidney events ("kidney equivalent" to MACE in CV outcomes studies); eGFR, estimated glomerular filtration rate
Source: Study 21-ROS-05 CSR Table 14.2.3.9.1 & post-hoc analyses

PHASE 2b *POINTER* STUDY – RESULTS IN Q4 2025

Key Design Elements

- 170 patients enrolled (EU & Canada)
- Two RMC-035 dose groups (30 & 60 mg) and placebo (2:2:3 randomization)
- Three doses administered over 24 hours
- Primary endpoint: change in renal function (eGFR) from pre-surgery to Day 90
- Powered to detect eGFR difference of 5 mL/min with two-sided alpha of 0.1

Key milestones achieved

- ✓ Patient enrollment completed in 9 months – ahead of plan
- ✓ Independent interim safety reviews with positive outcome
- ✓ Data collection near completion

Topline results expected in Q4

KEY VALUE DRIVERS AHEAD OF PIVOTAL TRIAL

Q4 2025 → **H1 2026**

POINTER results

- **Breakthrough Therapy Application**
- **Clinical End-of-Phase 2 FDA meeting** (end-of-Q1)
- **Phase 3 preparations & BD opportunities**

PHASE 3 STUDY – KEY DESIGN ELEMENTS

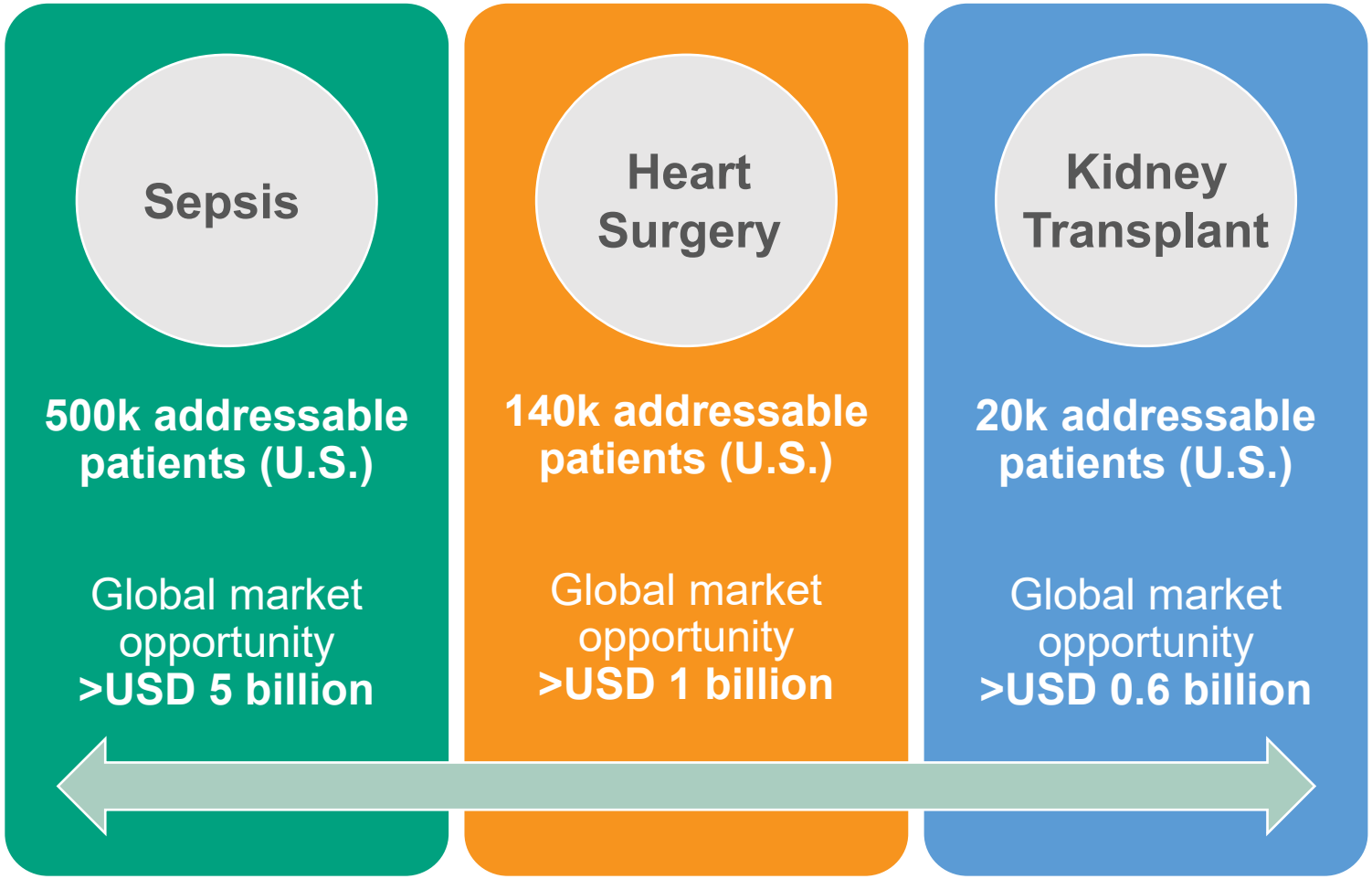
- **Single pivotal Phase 3 trial** designed to support BLA/MAA submission
- **Same high-risk patient population** as in Phase 2 AKITA and POINTER studies
- **Primary endpoint:** MAKE at Day 90 after surgery
- **Potential for accelerated approval** to be explored, based on **interim eGFR analysis** at Day 90
- **~600 patients in total**, with **~300 patients** contributing to the interim (accelerated approval) analysis
- **Enrollment period:** ~2 years (15 months to interim analysis)

BLA, biologics license application; MAA, market authorization application

FIRST-TO-MARKET POTENTIAL – NO APPROVED THERAPIES

COMPANY (DRUG)	PHASE	MECHANISM	EFFICACY DATA IN HEART SURGERY	COMMENT
Guard Therapeutics (RMC-035)	**2b**	**A1M analogue**	**Yes**	eGFR & MAKE benefit in Phase 2 AKITA study Phase 2b POINTER results expected Q4 2025
AM Pharma (Ilofotase alpha)	2	ALP analogue	-	Study start Q4 2023, expected completion Q3 2025
AstraZeneca / Alexion (Ultomiris)	3	Complement 5 inhibitor	-	Study start Q2 2023, expected completion Q1 2027
Genentech (GDC-8264)	2a/b	RIP-1 inhibitor	-	Study start Q1 2025, expected completion Q4 2027
Novartis (TIN-816)	2a	Human CD39 enzyme	-	Study recently stopped due to lack of efficacy
Renibus Therapeutics (RBT-1)	3	Iron sucrose + stannus protoporphyrin	-	Focus on acute outcomes. No efficacy on kidney endpoints in Phase 2

GLOBAL MARKET OPPORTUNITY POSITIONS RMC-035 FOR BLOCKBUSTER POTENTIAL



Sources: External analysis (September 2022) & interviews with Health Care Professionals & Hospital & Therapeutics Committee members.
Data from US Renal Data System (USRDS) & Organ Procurement and Transplantation Network (OPTN)
US CDC website
Rhee at al. Incidence and Trends of Sepsis in US Hospitals Using Clinical vs Claims Data, 2009-2014

GUARD THERAPEUTICS – DEVELOPING A1M PROTEIN THERAPEUTICS TO PROTECT KIDNEY FUNCTION

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GTX peptides –

Broadening the A1M Platform Beyond Acute Indications

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GTX PEPTIDES – NEXT GENERATION A1M PLATFORM

Expanding A1M Biology Into New Frontiers

Scientific foundation

- Novel A1M-derived peptides with preserved functionality, potency comparable to native A1M
- ~15–35 amino acids, synthetically manufactured
- Robust preclinical efficacy across diverse acute and chronic models

Strategic positioning

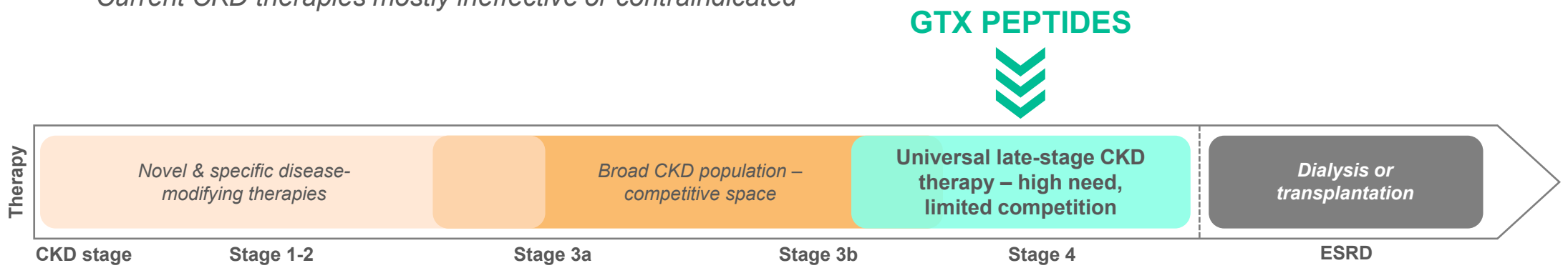
- Strong IP (composition of matter until 2044)
- Broad clinical development opportunity with unique positioning in CKD
- Significant optionality – strategy under refinement

Path to clinic

- Lead candidate GTX-86 at nomination stage
- ~2 years to IND filing

GTX PEPTIDES – SIGNIFICANT OPPORTUNITY IN LATE-STAGE CKD

- **A1M mechanism validated** in numerous disease models, e.g., kidney disease and preeclampsia
- **Broad impact across CKD,** including orphan diseases
  - *Robust efficacy in a wide range of preclinical kidney disease models*
- **Specific opportunity in late-stage CKD**
  - *Highest risk for progression to kidney failure (end-stage renal disease, ESRD)*
  - *Often excluded from clinical trials*
  - *Current CKD therapies mostly ineffective or contraindicated*



CKD classification based on Kidney Disease Improving Global Outcomes (KDIGO); CKD, chronic kidney disease