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Oxidative stress

- Surgical procedures
- Chemotherapy
- Transplantation
- Infections, sepsis

Acute Kidney Injury

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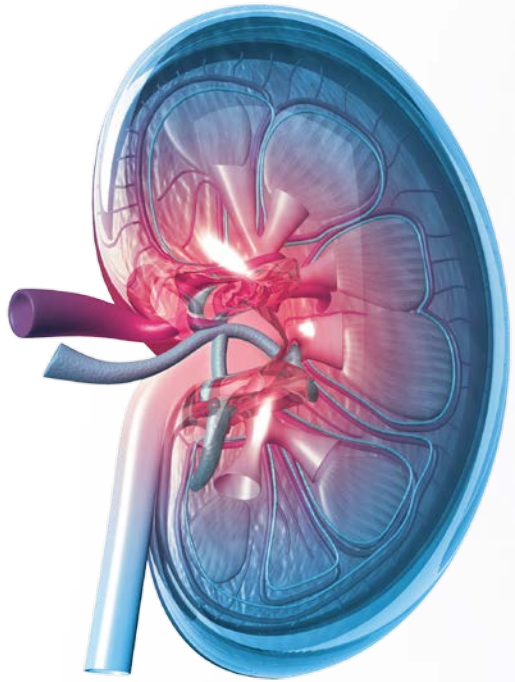
Acute kidney injury (AKI)



- 13 million individuals per year
- High morbidity and mortality
- Dialysis treatment (severe AKI)
- Reduced Quality of Life

→ No specific drug treatments available

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New A1M Pharma team

TOBIAS AGERVALD, CEO

MD, PhD, Ass Professor, board certified specialist physician in internal medicine and nephrology, former Senior Medical Director Astellas Pharma Global Dev

RONNY RENFURM, CMO

MD, MBA, former Executive Director Astellas Pharma Global Development

MAGNUS GRAM, CSO

PhD, former preclinical lead A1M Pharma Co-founder A1M Pharma

FREDRIK LEHMANN, CMC lead

PhD, currently also Head of CMC & Research Oncopeptides

ELISABETH AUGUSTSSON, RA lead

MSc, currently also Head of Regulatory Affairs Oncopeptides

Scientic concept of ROSgard™

- ROSgard mimics one of the **body's own most powerful and universal protection** against oxidative stress
- ROSgard treatment aims to **augment the endogenous defense system** in acute conditions that are driven by severe oxidative stress
- Significant advantages to leverage an endogenous and evolutionary conserved system
  - Increased likelihood that preclinical proof-of-pharmacology translates into clinically relevant effects in humans (e.g. similar to anti-diabetic drugs like insulin and GLP-1 analogues)
  - Lower risk for unexpected adverse events and safety signals
  - De-risk of clinical development program

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ROSgard™ mode of action

ROSgard™ is a recombinant variant of the endogenous protein alpha-1 microglobulin (A1M)

Three way mechanism:

Protecting against injury caused by free radicals/oxidants

Cleaning oxidants, e.g. ROS and heme

Repairing damaged tissue and mitochondria

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Innovative treatment

”Not just another anti-oxidant …”

- Multiple mechanisms which individually and synergistically contribute to its positive effect **(protecting, cleaning, repairing)**
- 10-fold higher capacity to bind and neutralize radicals as compared to e.g. vitamin C and E
- Does not constitute an oxidative threat once its targets are neutralized
- Natural **”homing mechanism”** to kidneys, which reinforces the focus on AKI as an important target indication

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AKI in cardiac surgery

- Patient pool easily identified
- Fast read-out of study results
- Short treatment duration
- Clinical endpoints are well defined

→ Attractive indication for clinical development

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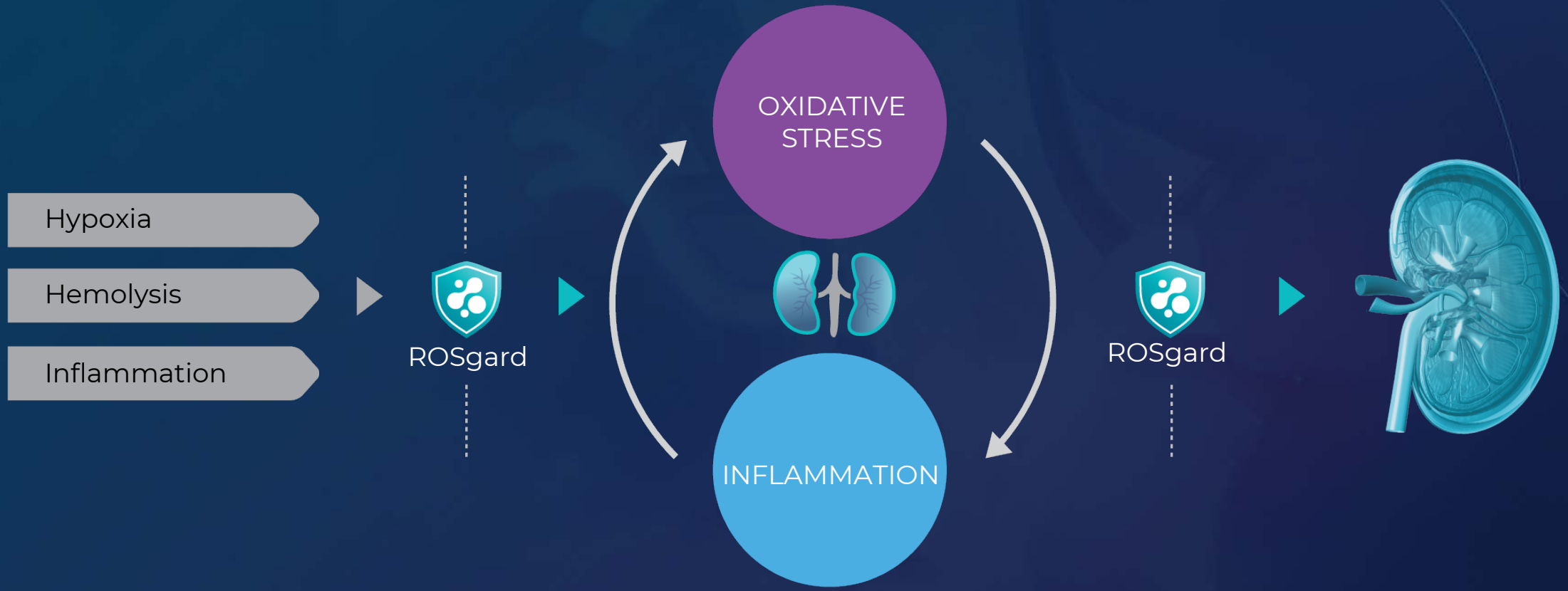
ROSgard™ protection in cardiac surgery



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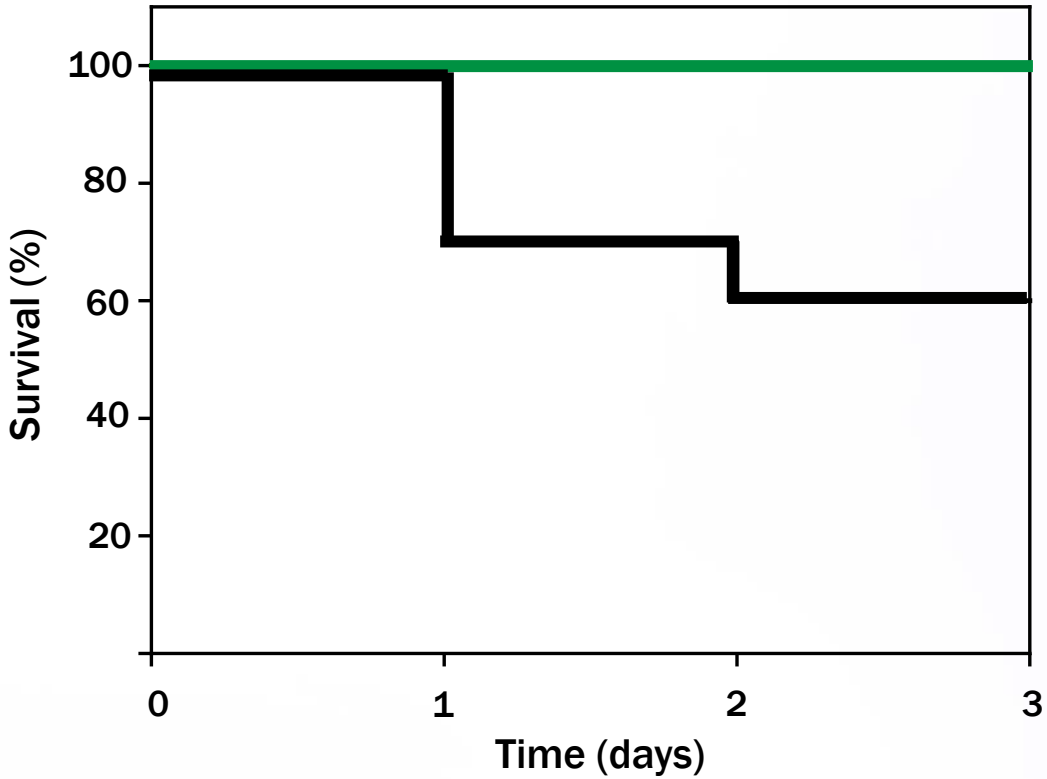
ROSgard™ reduces mortality in a mouse AKI model



- Control – 1 dose before and after renal insult (n=10)
- ROSgard – 1 dose before and after renal insult (n=10)

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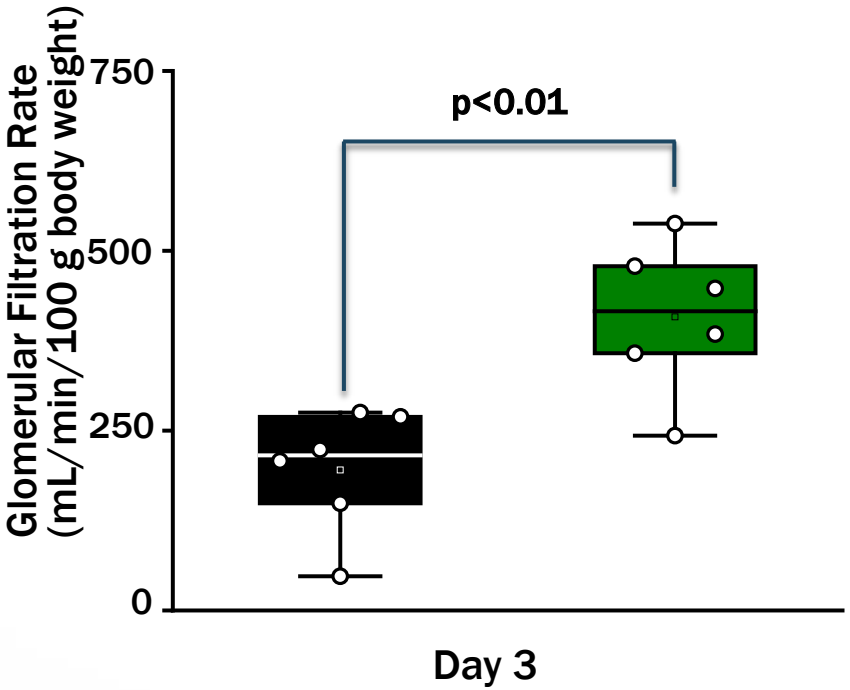
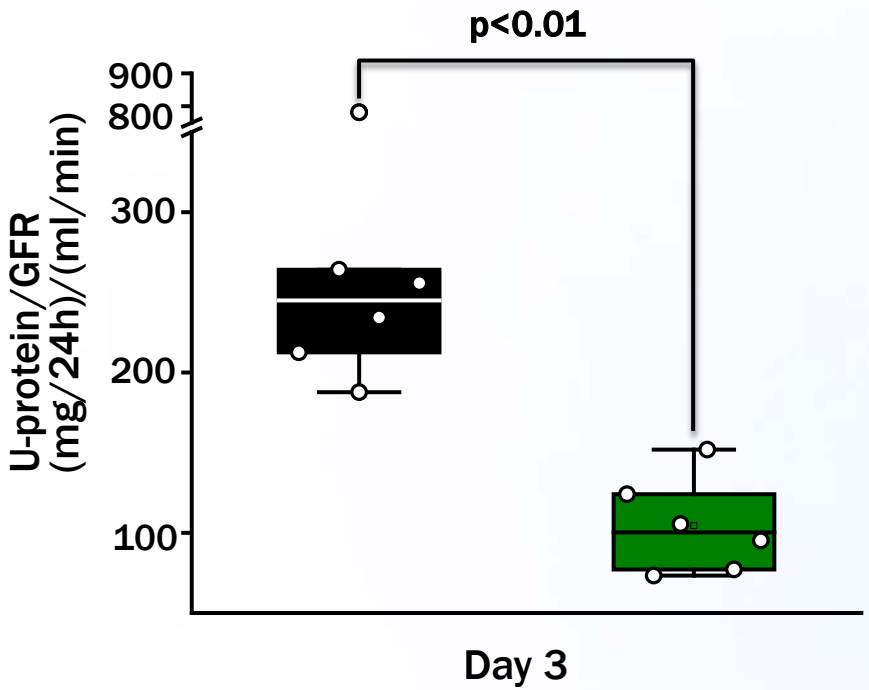
ROSgard™ improves renal function and proteinuria





- Control – 1 dose before and after renal insult (n=6)
- ROSgard – 1 dose before and after renal insult (n=6)

Statistical comparison between groups; Mann Whitney

Solid platform for clinical studies

Robust efficacy in AKI models

- Reduced mortality
- Improved AKI biomarkers
- Improved renal function (GFR)
- Reduced tissue damage
- Reduced proteinuria

In general

- Safety profile well documented
- Large-scale production established (GMP)
- Administered as intravenous infusion
- Solid IP protection (composition of matter and medical use patents)

First dose administration in humans in April 2019

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Target product profile

INDICATION	Reduction of Major Adverse Kidney Event (MAKE) in patients undergoing cardiac surgery
PATIENT SEGMENT(S)	Patients undergoing open-chest cardiac surgery (Coronary Artery Bypass Graft (CABG) and/or valve surgery) with predisposing AKI risk factors
EFFICACY	At least 30% reduction of MAKE (composite endpoint) defined by: - sustained reduction of renal function (30% reduction in GFR) at 90 days - new dialysis - death
DOSING REGIMEN	Final dose and posology TBD. Tentatively 3-5 dose administrations: - immediately prior to surgery - every 12-24 hours after surgery until 48 h

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Early clinical dev plan

	Phase 1a	Phase 1b
DESIGN	• Single ascending doses (SAD) • Multiple ascending doses (MAD)	• Repeated dose administrations up to 48 hours post-surgery
OBJECTIVES	• Primary: safety and tolerabiliy • Secondary: pharmacokinetics under various dosing conditions	• Primary: safety and tolerability • Secondary: pharmacokinetics • Exploratory: early signs of efficacy (PD markers) and posology
INDIVIDUALS	• Healthy subjects	• Patients undergoing open-chest cardiac surgery with use of heart-lung machine
CONTROLS	• Placebo (double blind)	• Placebo (double blind)

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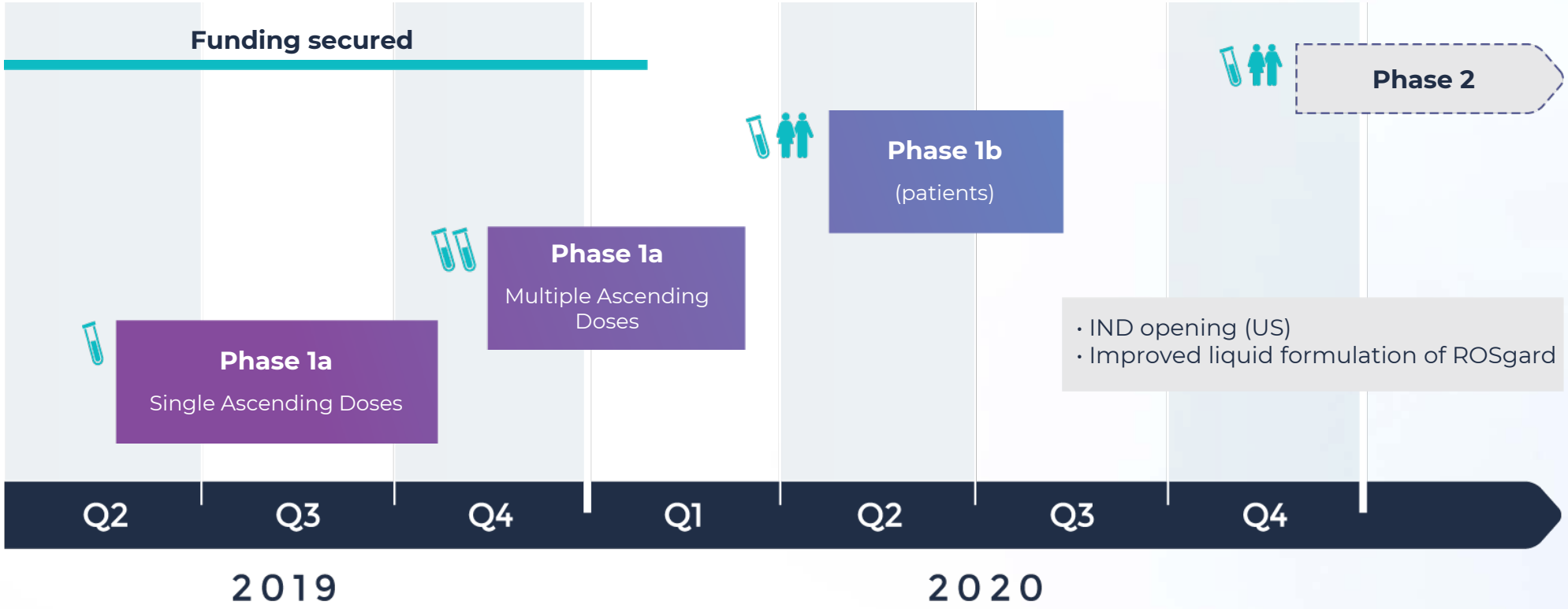
Accelerated timelines



Start of **Phase 1 MAD** requires a separate regulatory approval by MPA in Sweden

Start of **Phase 1b** (first patient study in cardiac surgery) requires a separate regulatory approval (Country TBD; probably single-site in Germany)

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Phase 2 study

Proof-of-concept before initiation of late phase program

- Major value inflection point
- Positive results provide a solid framework to explore additional indications and broaden the clinical development program
- Rapid execution – approximately 1 year
- Attractive time point to enter a licensing agreement with a development partner
- Difference design choices – strategic decision

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AKI market

Global AKI market estimated to more than 2.6 billion USD with an annual growth rate of 11%

- Peak sales for primary indication (prevention/treatment of AKI in cardiac surgery) estimated to more than 7 billion SEK per year
- Healthcare costs in Great Britain estimated to 4.4 – 6.4 billion SEK per year (more than total healthcare cost for breast, lung – and skin cancer combined)
- 2-3% of total healthcare budget in EU/US allocated to patients with end-stage kidney disease (ESKD)
- Attractive competitive landscape – no approved drugs, only one competitor in late phase (QPI-1002, Quark Pharmaceuticals, different mode of action)

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New A1M Pharma moving forward

- Strenghtened organization
- Attractive primary indication
- Robust clinical development plan
- Phase 1 study ongoing

Final results of Phase 1 study (SAD) expected early Q4

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