



**Postpone time to dialysis  
for patients with  
Diabetic Kidney Disease**

**Up for Sale:  
Pipeline for Treatment of  
Diabetic Kidney Disease**

# Company Information

## Serodus in brief...

### Company

- Serodus AS is a private Norwegian company
- Drug Development activities are managed by Serodus ApS in Copenhagen

### Eva Steiness, CEO Serodus ApS

- Eva Steiness, MD, D.Sci. professor clinical pharmacology
- Lundbeck Pharma A/S, EVP R&D 1989-1999, Zealand Pharma A/S Founder and CEO 1999-2008
- Founding and CEO of Phlogo (2008), CEO Serodus ASA (2011), CEO Serodus ApS (2023)

### Shareholders

- Largest shareholder (54,10%) together with the CEO & closest network (14,2%) make up two thirds of the shares – these shareholders are Danish

### Focus

- Development of new drugs with a strategic focus on Diabetic Kidney Disease

### Staff, Serodus ApS

- Currently 1 CEO, 2 part-time consultants (CFO, BD/Documentation)
- Staff can be available during transition

# The Problem

## Diabetic Kidney Disease

- Diabetic Kidney Disease prevalence is increasing as a result of increasing prevalence of diabetes
- Diabetic Kidney Disease is a “silent” disease and often underdiagnosed
- Elevated blood sugar triggers inflammatory processes that damage kidneys
- Urinary albumin is a strong biomarker of Diabetic Kidney Disease
- Urinary albumin is recognized by FDA\* and EMA\*\* as a valid biomarker
- Loss of kidney function ↑ morbidity and ↑ cardiovascular mortality
- Treatment of “End Stage” renal disease is either chronic dialysis or kidney transplant

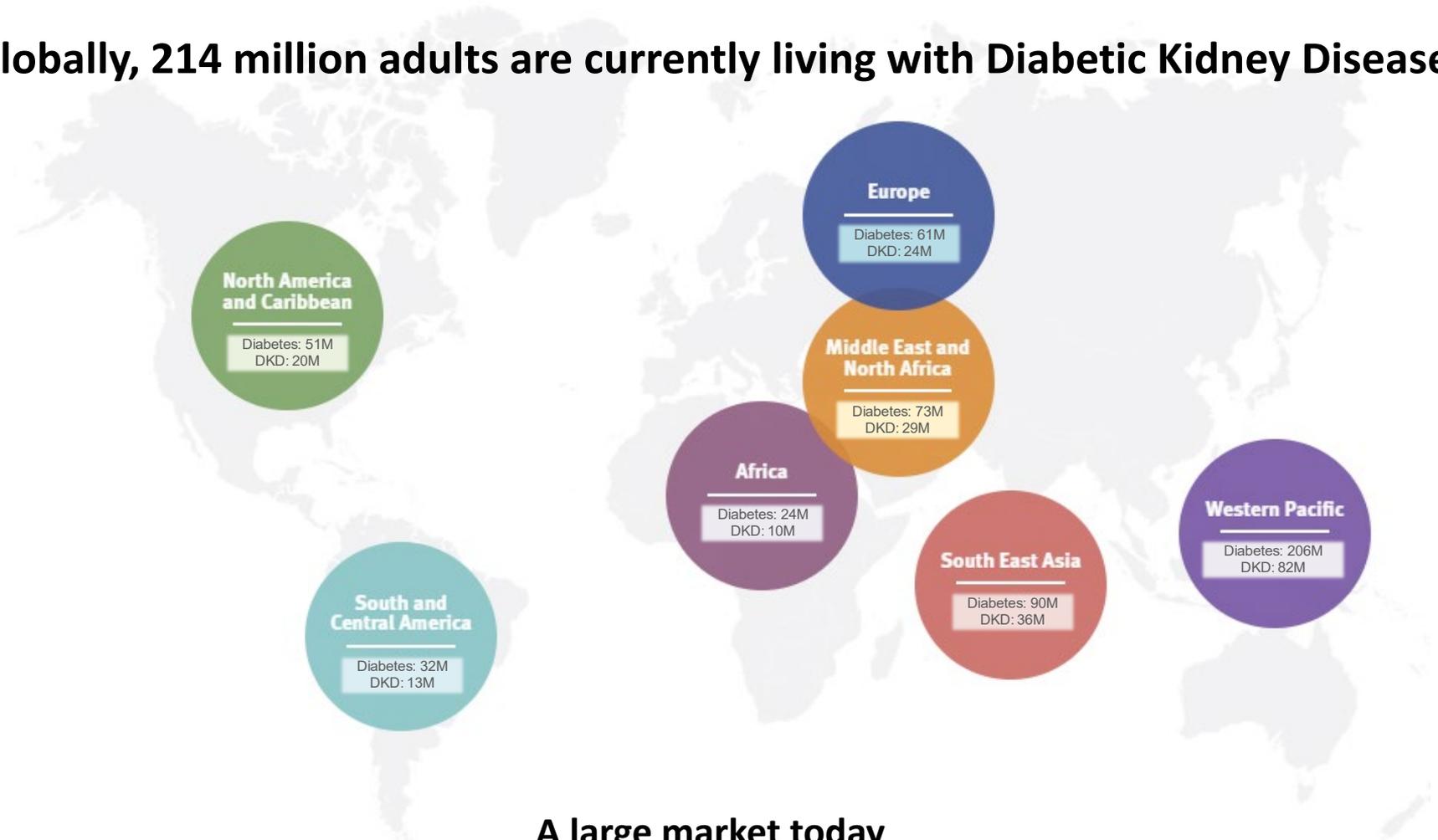
\*) Thompson 2019, Change in Estimated GFR and Albuminuria as End Points in Clinical Trials: A Viewpoint From the FDA

\*\*\*) Holtkamp 2020, Change in Albuminuria and Estimated GFR as End Points for Clinical Trials in Early Stages of CKD: A Perspective From European Regulators

# Market Size (2021)\*

Diabetic Kidney Disease prevalence is ~40% in Diabetics\*\*

Globally, 214 million adults are currently living with Diabetic Kidney Disease



A large market today

DKD: Diabetic Kidney Disease

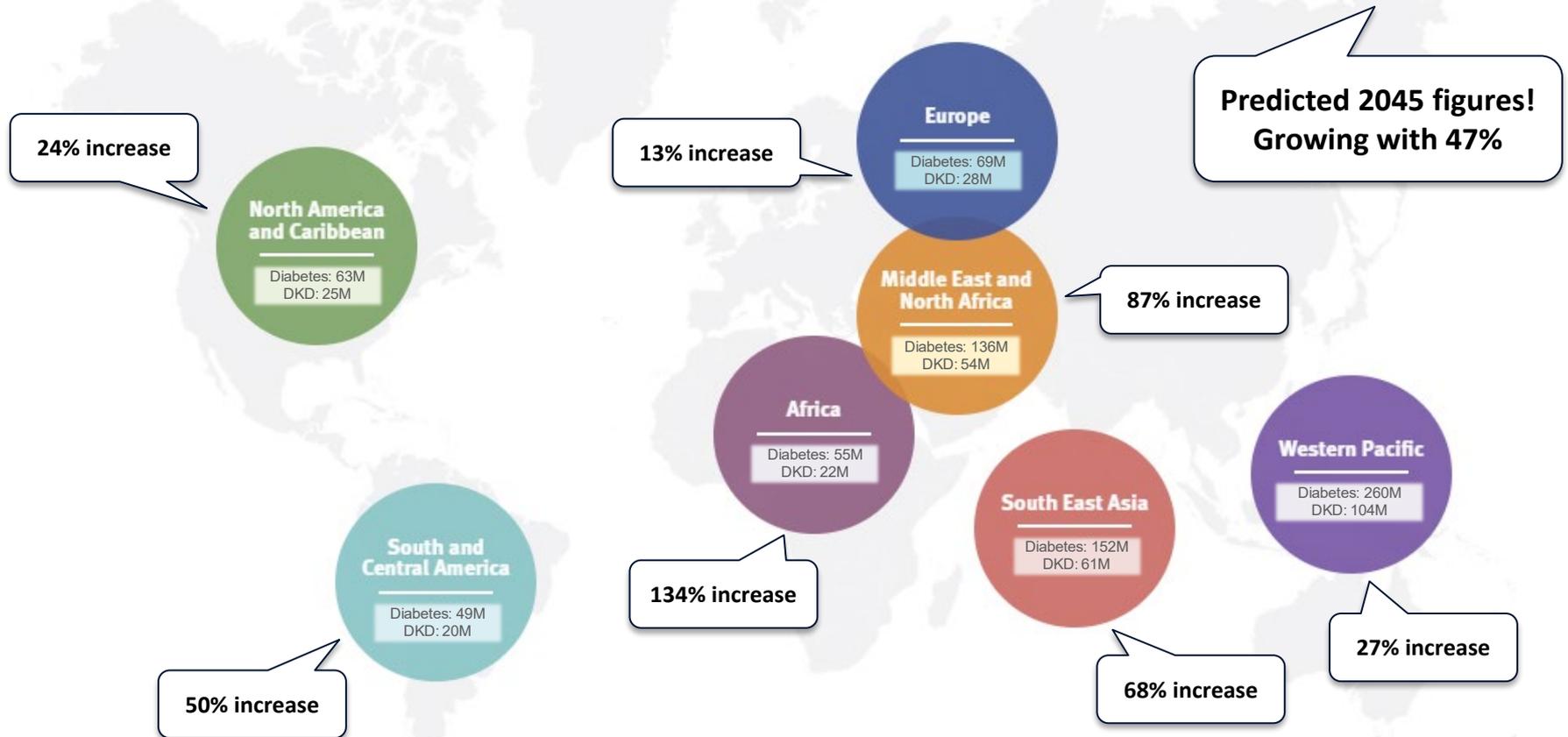
\*) IDF: International Diabetes Federation ([www.diabetesatlas.org](http://www.diabetesatlas.org))

\*\*\*) Simit 2017 Diagnosis and Management of Type 2 DKD

# Market Size (2045)\* PREDICTED by IDF

Diabetic Kidney Disease prevalence is ~40% in Diabetics\*\*

Globally, 314 million adults will be living with Diabetic Kidney Disease in 2045



- with significant growth predictions

# Health Economics

## Postponing time to dialysis

### In the US:

786.000 people are living with ESRD

39% of these are Diabetics = 306.540 \*

*Estimated annual dialysis cost: USD 90K x 306K = ~USD 27 billion\*\**

(not including reduced tax payment, managed care, transplantation cost, etc.)

### Potential savings

Postponing time-to-dialysis with 3 years in average: ~USD 27 billion x 3 = ~USD 81 billion

With a market penetration of 10%, diabetic related dialysis cost saving equals ~USD 8 billion

DKD: Diabetic Kidney Disease

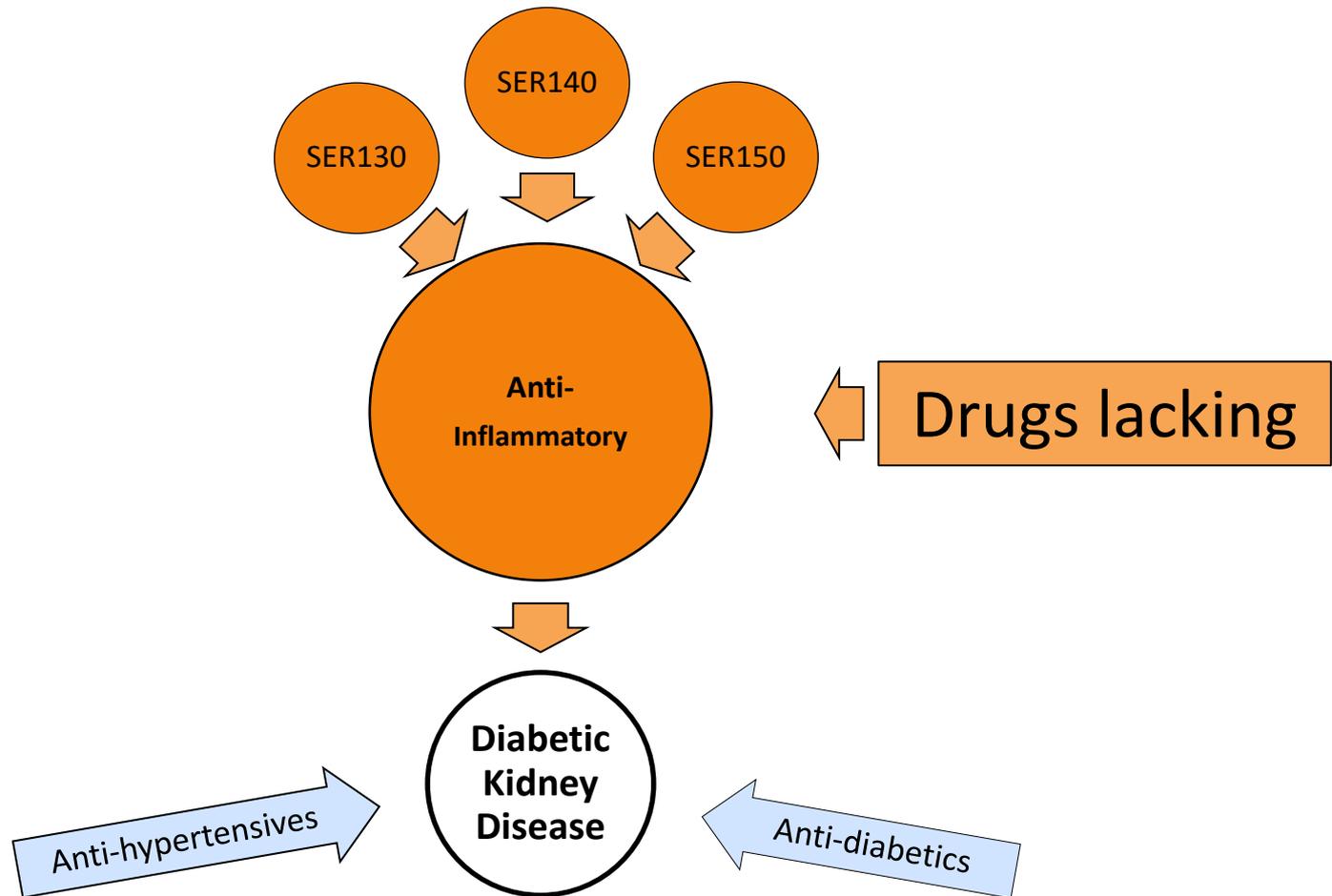
ESRD: End Stage Renal Disease

\*) CDC, Chronic Kidney Disease in the United States, 2021

\*\*\*) UCFS 2018, The Kidney Project, <https://pharm.ucsf.edu/kidney/need/statistics>

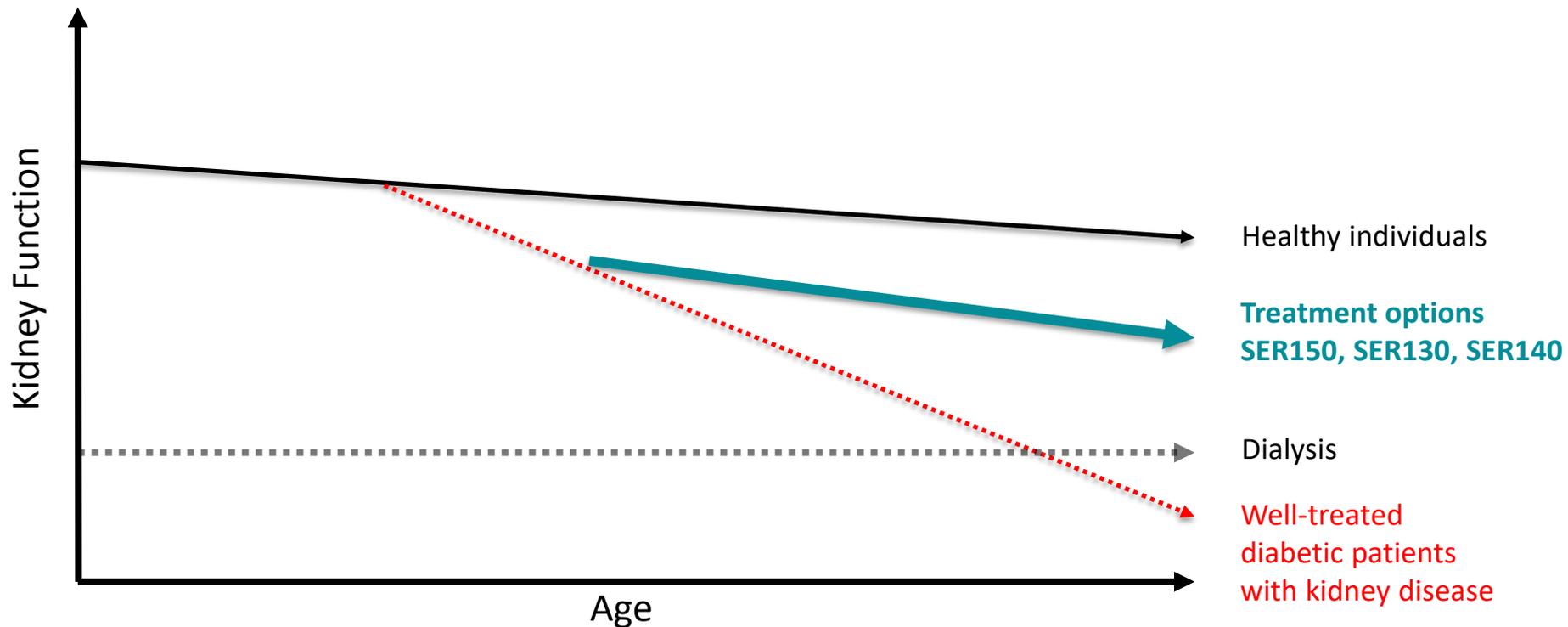
# Filling a treatment gap

## A novel approach to treatment of Diabetic Kidney Disease



# The Solution

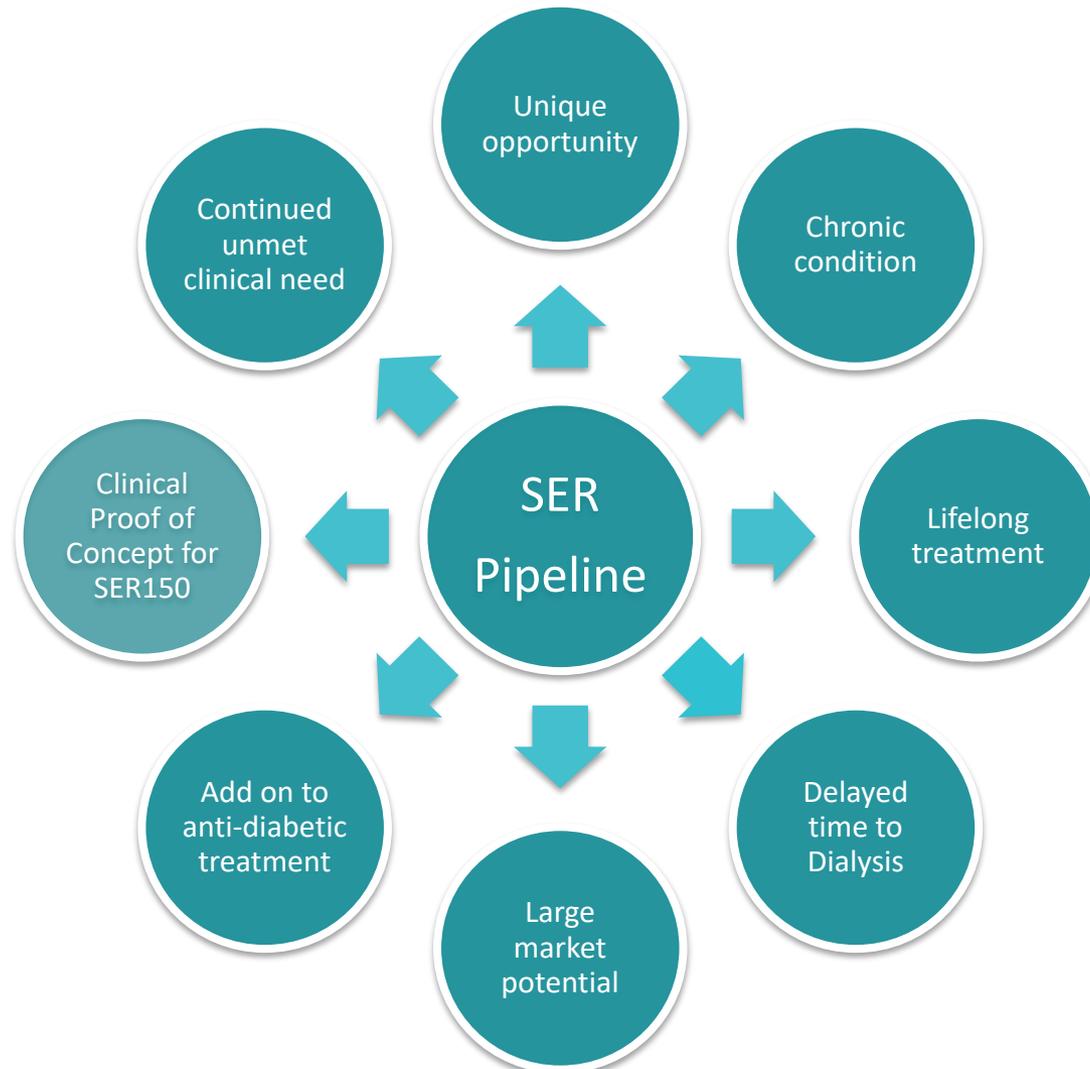
## Loss of Kidney Function in Healthy and Diabetics



**Postpone time to dialysis for patients with Diabetic Kidney Disease**

# SER pipeline

- a unique addition to a company's portfolio



# Serodus' pipeline vs development stage

Three different modes of action - three development stages

Discovery Preclinical Phase 1 Phase 2 Phase 3 Approval

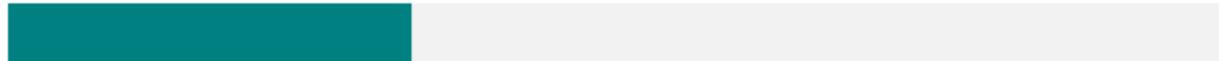
## SER150

Diabetic Kidney Disease in T2D



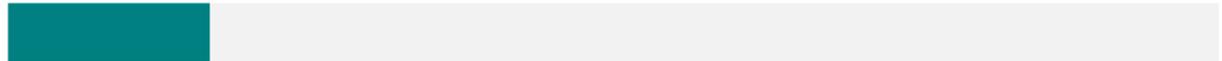
## SER130

Diabetic Kidney Disease in T2D



## SER140

Diabetic Kidney Disease in T2D



# SER150, SER130, SER140 – in Diabetic Kidney Disease

## Mode of Action & Scientific References

### SER150

MoA: Thromboxane receptor antagonist, thromboxane synthase inhibitor

References:

- *Steiness 2018, SER150: Low dose anti-thromboxane reduces urinary albumin in patients with Diabetic Kidney Disease*
- *Richardson 2013, Single ascending oral dose pk and pd study of EV-077: the specific inhibitor of prostanoid- and isoprostane-induced cellular activation*
- *Sakariassen 2012, EV-077 in vitro inhibits platelet aggregation in type-2 diabetics on aspirin*

### SER130

MoA: IL-4 partial receptor agonist

References:

- *Klementiev 2013, Antiinflammatory properties of a peptide derived from interleukin-4 (cells, Wistar rat)*

### SER140

MoA: IL-1 selective receptor antagonist

References:

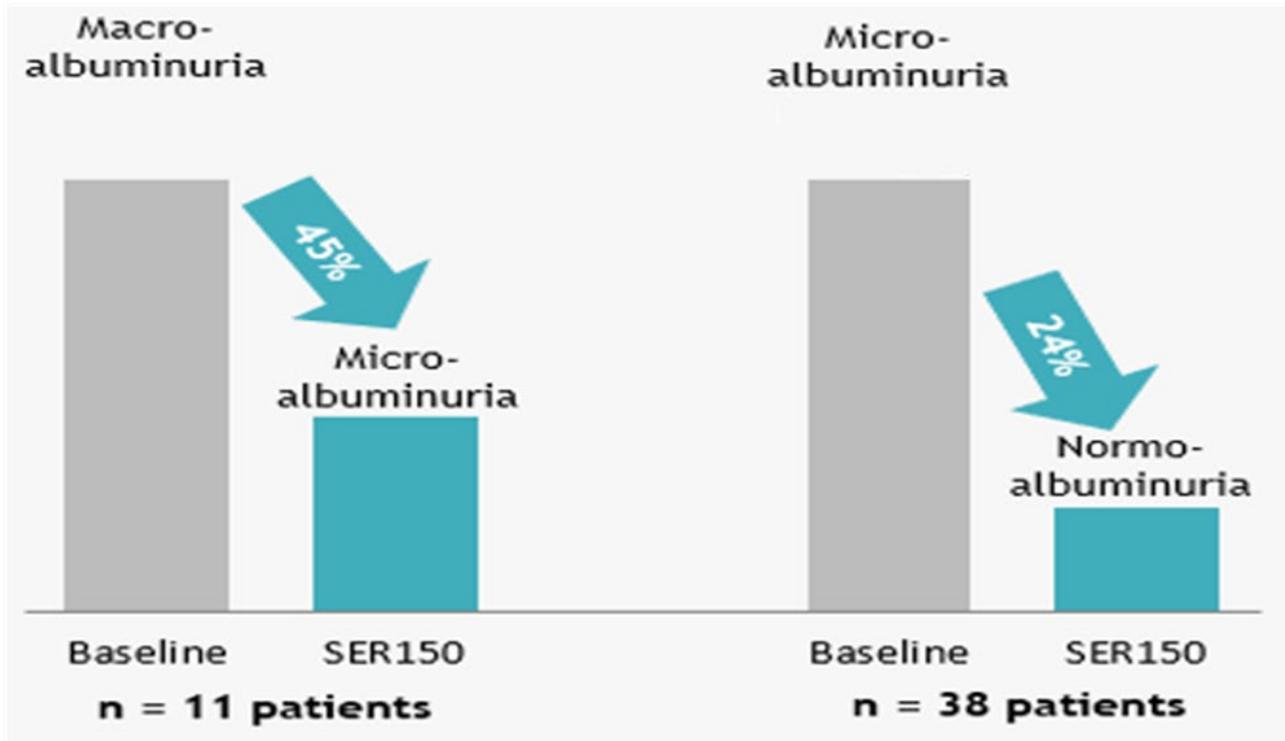
- *Klementiev 2014, Anti-inflammatory properties of a novel peptide interleukin 1 receptor antagonist (Wistar rat)*
- *Cucak 2016, The IL-1 $\beta$  Receptor Antagonist SER140 Postpones the Onset of Diabetes in Female Nonobese Diabetic Mice*

# SER150

# SER150 – Clinical Proof of Concept

## Induces remission in patients with Diabetic Kidney Disease

SER150 Dose 15 or 30 mg BID for 4 weeks, Phase 2 study results



>300 mg/g cr:  
Macroalbuminuria

≥ 30 < 300 mg/g cr:  
Microalbuminuria

<30 mg/g cr:  
Normoalbuminuria

cr=creatinine

No safety or tolerance issues

# SER150 – in Diabetic Kidney Disease

## Characteristics, Status & Plan

### Molecule Characteristics

- Small molecule, low-cost API
- PO administration, minitablets in capsules

### Development Status

- Clinical Proof of Concept (study SER150 CL-007, Phase 2)
- Safety and toxicological studies finalized
- Plasma half-life (steady state dosing) is ~9 hours
- No drug-drug interactions are expected
- Ongoing Phase 2/3 study, 6 months dosing clinical study in Australia & New Zealand

### Development plan

- Finalizing the ongoing clinical Phase 2, perhaps improving number of patients to 3-500
- End of Phase 2 meeting: Pursue Breakthrough Therapy Designation for SER150
- Design of phase 3 study shall be discussed with the pipeline acquirer

API: Active Pharmaceutical ingredient  
eGFR: Estimated Glomerular Filtration Rate  
MA: Marketing Authorization  
PO: Per os (orally)

# SER130 & SER140 – in Diabetic Kidney Disease

## Characteristics, Status & Plan

### SER130

#### Molecule Characteristics

- Peptide, low-cost API is expected
- Derived from human IL-4 receptor alpha helix C
- No IL-13 receptor binding, low respiratory site effects expected
- Antagonize IL-6 and IL-1 induced TNFalpha production

#### Development Status

- Pharmacological Proof of Concept, diabetic nephropathy
- Single IV safety and tox studies finalized, no findings

#### Development plan

- 1<sup>st</sup> step: IMP for SC development

### SER140

#### Molecule Characteristics

- Peptide, low-cost API is expected
- Derived from the human IL-Ra N-terminal domain involved in interactions with IL-1RI
- Inhibit IL-1 $\beta$ -induced NF- $\kappa$ B activation

#### Development Status

- Pharmacological Proof of Concept, diabetic nephropathy

#### Development plan

- 1<sup>st</sup> step: IMP for SC development

API: Active Pharmaceutical Ingredient  
IMP: Investigational Medicinal Product  
IV: Intravenous  
SC: Subcutaneous

# Scientific and Regulatory Advisor



**George Bakris, MD, Hon. DSc, FASN, FNKF, FAHA**

Professor University of Chicago, IL, US

*Specializes in treatment of kidney disease, specifically diabetes-related kidney disease.*

Professor Bakris has assisted Serodus in meetings with the FDA in 2017 and 2021. At both meetings, a development strategy for SER150 and Breakthrough Treatment Designation was discussed.

Professor George Bakris is an international well-known and highly respected clinical researcher, diagnostician and adviser in drug Development in Diabetes and Chronic Kidney Disease.

With close to 1000 publications, more than 236.000 citations and a h-index of 161, Professor George Bakris is a highly esteemed and valuable strategic capacity to Serodus.

<https://www.uchicagomedicine.org/find-a-physician/physician/george-bakris>

# Board of Directors, Serodus AS

## Curricula vitae

**Søren Elmann Ingerslev, Chairman** since 2017. Mr Ingerslev is an attorney and a partner in the Danish law firm Elmann Advokatpartnerselskab. He has extensive international experience and business acumen within mergers and acquisitions, company law, business development and international business agreements. He is head of Elmann's Corporate and M&A department and serves as a non-executive member of the board of directors of several listed and privately held companies, including Immudex ApS and Biostrip ApS.

**Viggo Gunnensen Harboe.** Mr Harboe has been a member since 2022. Mr Harboe joined DAKO A/S (now part of Aglient Technologies, Inc.) in 1972. In 1980, he founded DAKO's first subsidiary in the US and served as CEO in the US until 2002. He also founded DAKO's subsidiaries in Japan, Australia and Canada and served on the boards of these subsidiaries. He was a member of the board of directors of DAKO from 2002 until 2007, when the company was sold, and served as chairman of the Harboe Foundation from 2002 to 2019.

**Terri Sebree. Mrs Sebree has been a** member since 2014. Mrs Sebree is an experienced pharmaceutical and biotechnology entrepreneur who has successfully founded, financed, grown and taken public three biopharmaceutical companies. She was most recently President of Zynerva Pharmaceuticals (Nasdaq: ZYNE). Zynerva was acquired by Harmony Biosciences in October 2023. She co-founded NuPathe Inc. (Nasdaq: PATH) and served as its President from February 2005 to March 2014. Prior to NuPathe, she served as Senior Vice President, Development, of Auxilium Pharmaceuticals (Nasdaq: AUXL) from January 2000 to January 2005. Before joining Auxilium, she served in a variety of management roles with Abbott Laboratories and with IBAH, a global contract research organization. She holds a BSc from Texas A&M University, US.

# Management, Serodus ApS

## Curricula vitae

### **CEO, Eva Steiness**

- MD, D.Sci. professor clinical pharmacology
- Postgraduate 10 years at University Hospital in Aarhus, Jutland and Rigshospitalet in Copenhagen
- Dean at Medical Faculty, Copenhagen University 1981-85. Professor clinical Pharmacology Aarhus University 1985-1989
- Executive Vice President, Drug Discovery & Development Lundbeck Pharma A/S 1989-1999. Was a member of the Executive Board and instrumental in the pipeline development for the IPO in 1999. Today, Lundbeck Pharma A/S is a OMX C25 index member on the Copenhagen Stock Exchange
- Founder and CEO of Zealand Pharma A/S 1999-2008. The company went public in 2010 and is today a OMX C25 index member on the Copenhagen Stock Exchange
- CEO and co-founder of Phlogo ApS 2008-2013. Acquired by Serodus AS 2013
- CEO of Serodus AS from 2013 to 2023 and present the CEO of Serodus ApS which manage and develops a pipeline focused on Diabetic Nephropathy

### **CFO, Henrik Mordhorst**

- MSc Econ, Certified financial advisor UK/CH
- 30 years+ experience in finance, asset management and commercial real estate
- Founder and CEO of HeMo ApS

### **BD, Daniel Capion**

- MSc Pharm, Executive MBA, Diploma in Managing Medicinal Product Innovation (SIMI)
- +25 years of life science experience primarily within Regulatory Operations, R&D Data & Digital Strategies (Genmab, Ferring, LEO Pharma)
- Founder and CEO of Documizer ApS – specializing in documentation of R&D science assets

# Serodus – Addressing Diabetic Kidney Disease



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[\*\*www.Serodus.com\*\*](http://www.Serodus.com)