

## **FY 2024: Financial Results & Operational Update**

**A year marked by positive kidney function data and progress in advancing varoglutamstat in kidney disease**

April 29, 2025

Vivoryon Therapeutics N.V.

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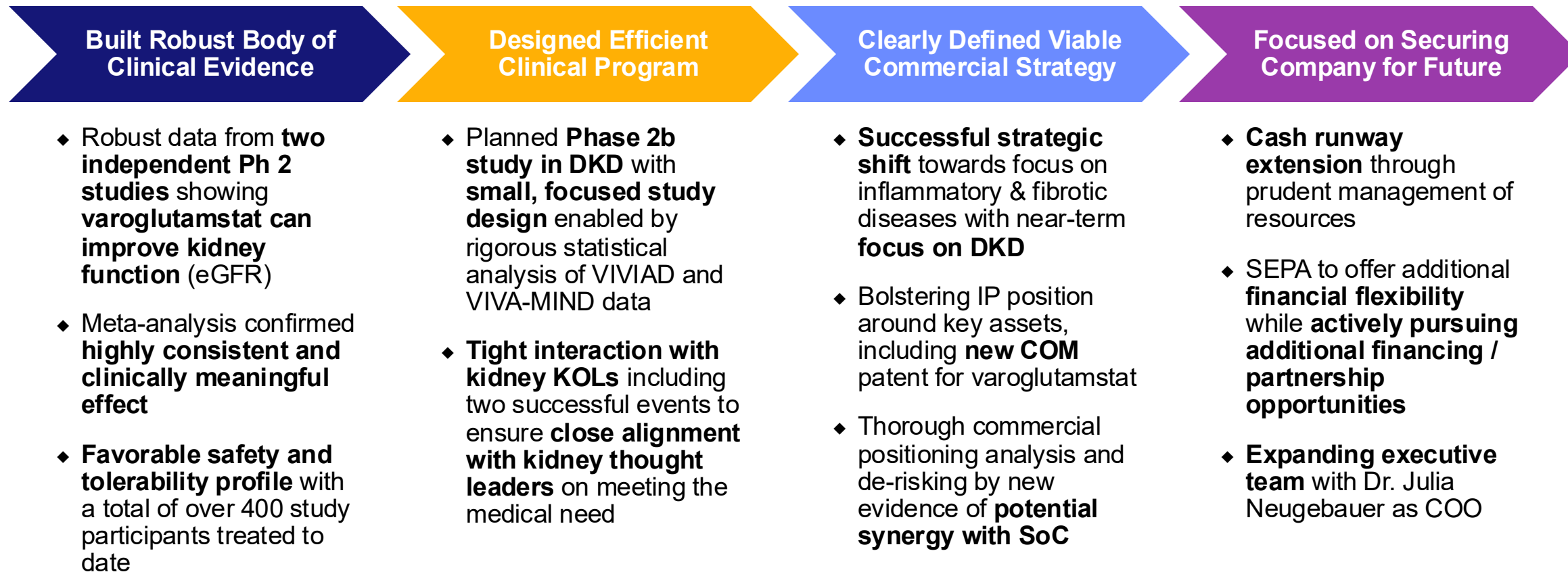
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# Shaping the future of Vivoryon in kidney disease: 2024/2025 YTD progress



**Underpinned by strong foundational science & compelling data**



COM: composition of matter; DKD: Diabetic kidney disease; SoC: standard of care; SEPA: Standby Equity Purchase Agreement; COO: Chief Operating Officer

# Robust body of evidence generated for varoglutamstat in kidney supports strategic shift towards advancing varoglutamstat in DKD

YTD

Q1

## Topline VIVIAD data in early AD disappointing

- ◆ Did not meet primary and secondary efficacy endpoints in early AD
- ◆ Generally well-tolerated

Q2

## Exciting kidney function data observed in VIVIAD Phase 2b study

- ◆ Statistically significant improvement in kidney function (eGFR) vs. placebo
- ◆ Clinical biomarker data confirms target engagement

Q3

## Kidney effect larger in diabetes subgroup; plan to do Phase 2 study in DKD

- ◆ Substantially larger treatment effect in diabetes subgroup
- ◆ Additional health benefits observed in diabetes subgroup
- ◆ Intense dialogue with kidney experts
- ◆ Ph 2 study planned to confirm results in patients with Stage 3b+ DKD

Q4

## Data presented at ASN Kidney Week; confirmed in second Phase 2 study

- ◆ KOL event hosted outlining varoglutamstat's opportunity in kidney disease
- ◆ Outstanding VIVIAD data selected for late-breaking oral presentation at ASN Kidney Week; high enthusiasm from medical / scientific community
- ◆ Topline VIVA-MIND Ph 2 data reported corroborating VIVIAD results

2025

## Meta-analysis data support consistent effect and high response rates

- ◆ Responder analysis showed eGFR predominantly improved / stabilized in active vs. decline in placebo group
- ◆ Observed treatment effect size enables tailored Ph 2 study with ~90 patients
- ◆ R&D update with KOLs underscored quality, and consistency of data, potential to transform kidney outcomes
- ◆ Pre-clinical evidence showing potential synergistic effect with current SoC
- ◆ Meta-analysis data accepted for oral presentation at ERA in June 2025



eGFR: estimated glomerular filtration rate; DKD: Diabetic kidney disease; SoC: Standard of Care; ERA: European Renal Association



# 2024 Financial Results & Corporate Updates

*Anne Döring, CFO*

# Prudent spending allowed us to achieve strategic turnaround towards kidney disease while reducing cash utilization

In €k	Twelve months ended Dec. 31, 2024	Twelve months ended Dec. 31, 2023
Revenue	0	(3,620) <sup>^</sup>
Research & Development expenses	(14,058)	(17,637)
General & Administrative expenses	(6,903)	(8,600)
Net loss for the period	(20,586)	(28,576)

In €k	Dec. 31, 2024	Dec. 31, 2023
Cash & cash equivalents	9,365	18,562 <sup>*</sup>
Financial assets	63	10,165 <sup>*</sup>

- ◆ In 2024, R&D expenses continued to capture meaningful clinical costs for the Phase 2 VIVIAD and VIVA-MIND studies, as well as reallocation of investments to support advancing the kidney program
- ◆ Costs from VIVIAD and VIVA-MIND are largely completed; spending continues to occur on pre-clinical studies and kidney strategy



# Cash runway extended into January 2026; SEPA with Yorkville provides financial flexibility beyond updated guidance

## Improved outlook - cash runway now into January 2026\*

- ◆ Successfully managed 2024 challenges
- ◆ Existing cash sufficient to finance operations for the full year 2025 and **into January 2026**
- ◆ Continue to **support kidney disease strategy, expand pipeline** and **strengthen IP** with limited cash utilization
- ◆ Initiation of the Phase 2b DKD study remains a key priority – start of the study subject to further additional funding and/or partnership

## SEPA is one piece of our financial strategy towards starting our Phase 2b DKD study

- ◆ Standby Equity Purchase Agreement (SEPA) with Yorkville Advisors, provides access to additional capital of up to EUR 15 million over 36 months
- ◆ Facility can be utilized **at our discretion**: mechanisms in place that provide a **level of control** over amount and timing of tranches; program can be **stopped at any time**; no restrictions on additional fundraising activities
- ◆ Gives us financial flexibility while pursuing optimal solution to fund Phase 2b study



# Strengthening a seasoned senior management team

## Management

**Frank Weber, MD**  
*Chief Executive Officer*



**Anne Doering, CFA**  
*Chief Financial Officer*



**Michael Schaeffer, PhD**  
*Chief Business Officer*



**Joining May 1, 2025**

**Julia Neugebauer, PhD**  
*Chief Operating Officer*



## Non-executive Directors

**Erich Platzer, MD, PhD**  
*Chairman of the Board*

**Charlotte Lohmann**


**Claudia Riedl, PhD**  
*Chair Audit Committee*

**Samir Shah, MD**

- ◆ Julia Neugebauer, PhD, joining as Chief Operating Officer May 1, 2025, and will take on responsibility for IR, market analysis and other corporate functions
- ◆ Formerly VP, Global Head of IR & Sustainability at MorphoSys AG, a biotech company previously dual-listed on the Frankfurt Stock Exchange and NASDAQ
- ◆ ~20 years experience in the biotech industry and strong track record in executing IR strategies, building long-term relationships with the investment community, managing the IR aspects of financial reporting and ensuring compliance with capital market regulations
- ◆ Extensive R&D background with >10 years of experience in antibody engineering and development; PhD from Ludwig-Maximilians-Universität München, Germany; Certified Investor Relations Officer (CIRO)



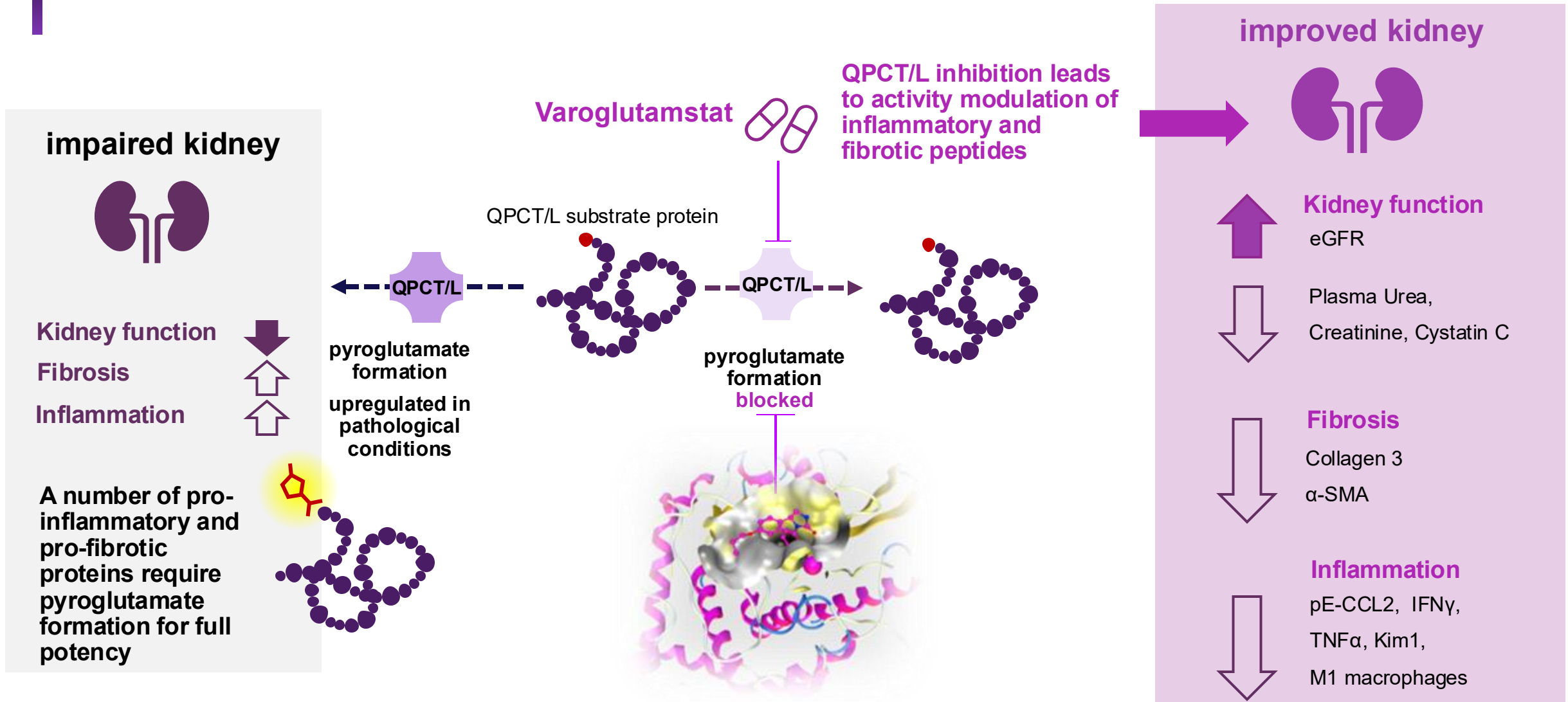




Varoglutamstat has a novel MOA  
with new pre-clinical evidence  
showing potential synergistic  
effect with current SoC

*Michael Schaeffer, CBO*

# Groundbreaking discovery: Inhibition of QPCT/L reduces kidney inflammation and fibrosis, and improves pathophysiology and kidney function



# SGLT-2 Inhibitors are now standard of care for patients with CKD (KDIGO 24)

## **KDIGO 2024 recommends SGLT2i for patients with**

- ◆ Type 2 diabetes, CKD, and an eGFR  $\geq 20$  mL/min/1.73 m<sup>2</sup>
- ◆ Adults with CKD eGFR  $\geq 20$  mL/min/1.73 m<sup>2</sup> with urine ACR  $\geq 200$  mg/g or heart failure, irrespective of level of albuminuria
- ◆ Adults with eGFR 20 to 45 mL/min/1.73 m<sup>2</sup> with urine ACR  $< 200$  mg/g

## **The medical need for patients with CKD remains high**

- ◆ SGLT-2 inhibitors reduced the risk of kidney disease progression by **34%**
- ◆ No differences observed in death due to kidney disease ( $P = 0.182$ ) or events of eGFR  $< 15$  mL/min/1.73 m<sup>2</sup> ( $P = 0.202$ )

Understanding the additional benefit of QPCT/L inhibitors on top of SGLT2i is essential for development and commercial success



# Evaluation of varoglutamstat in ADI-CKD model of CKD

- ◆ ADI-CKD – established animal model for CKD; CKD is induced by an adenine-rich diet in rat/mice<sup>1</sup>
- ◆ High doses of adenine lead to accumulation and crystallization of a metabolic product (2,8-DHA), which induces kidney inflammation - a major mechanism of CKD
- ◆ 3-week treatment: SGLT2i dapagliflozin once daily w/o and w/ varoglutamstat on top, either once daily or twice daily dosing
- ◆ Broad panel of blood parameters and IHC (immunohistochemistry) markers in kidney samples for analyses of inflammatory and fibrotic events and kidney function



# Impressive synergistic effects of dapagliflozin plus varoglutamstat - pronounced modulation of inflammatory and fibrotic mechanisms in CKD mouse model

## Results pave the development path of QPCT/L inhibitors in combination with SGLT-2 inhibitors

- ◆ Efficacy observed on top of SGLT-2 inhibitors derisk the DKD / CKD clinical development program substantially
- ◆ Magnitude of effect of QPCT/L inhibition together with SGLT-2 inhibition shows trend towards normalization of pathological findings across multiple outcome parameters
- ◆ Once daily similar efficacy vs. twice daily in pre-clin models supports investigation of once daily in clinical trial
- ◆ Ideal combination partner for patients treated with SGLT-2 inhibitors with strong synergistic effect observed
- ◆ Due to outstanding effect observed we have filed patents for combination of QPCT/L inhibitors with SGLT-2 inhibitors

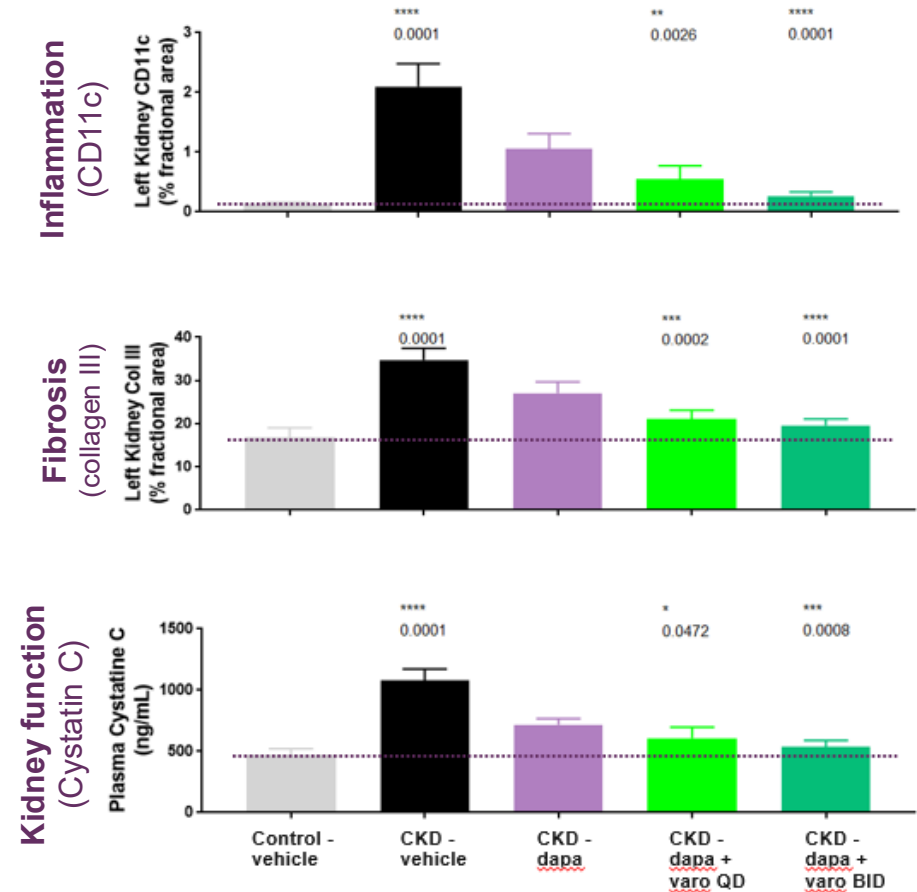


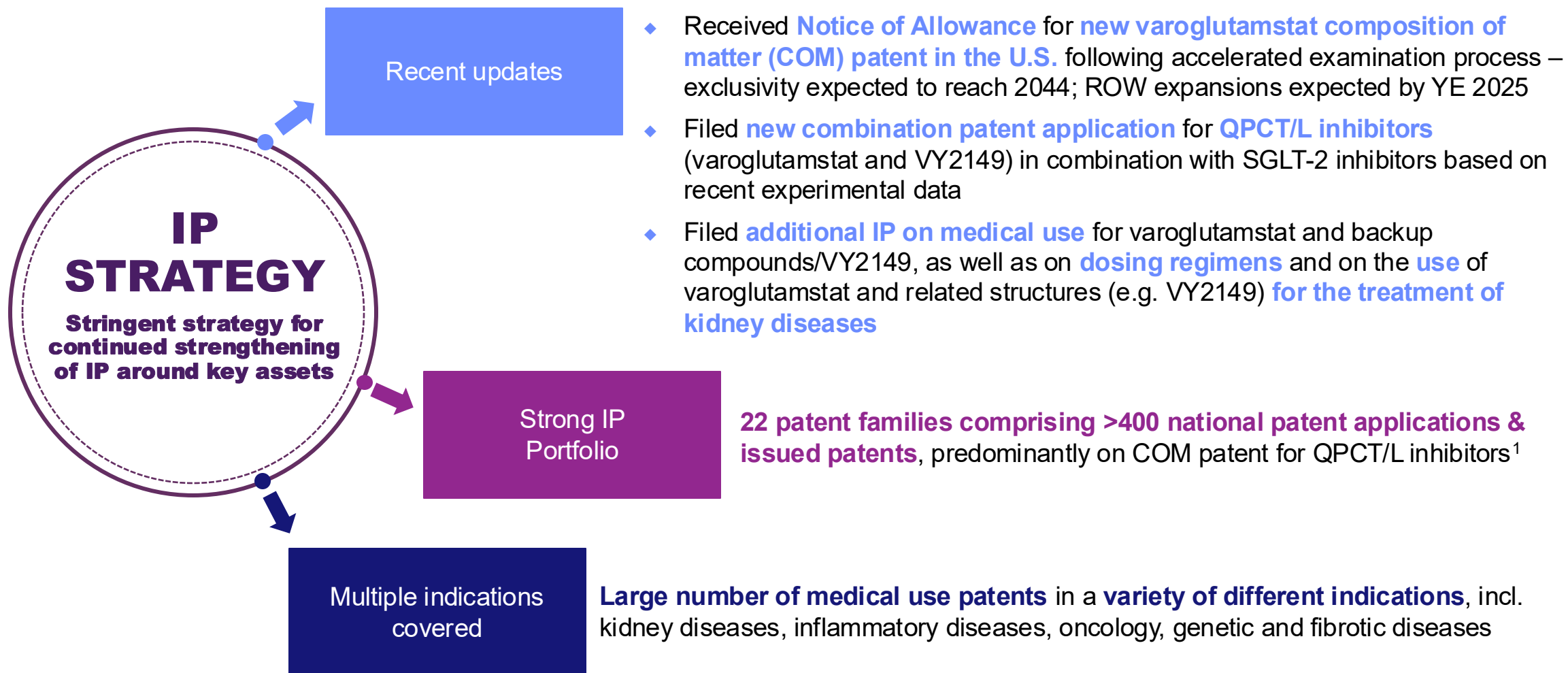
Chart data: Values expressed as mean  $\pm$  95%CI, N = 8 to 16 per group, Dunnett's Test, comparison to CKD - Dapagliflozin group; QD: once daily; BID: twice daily; varo: varoglutamstat; dapa: dapagliflozin



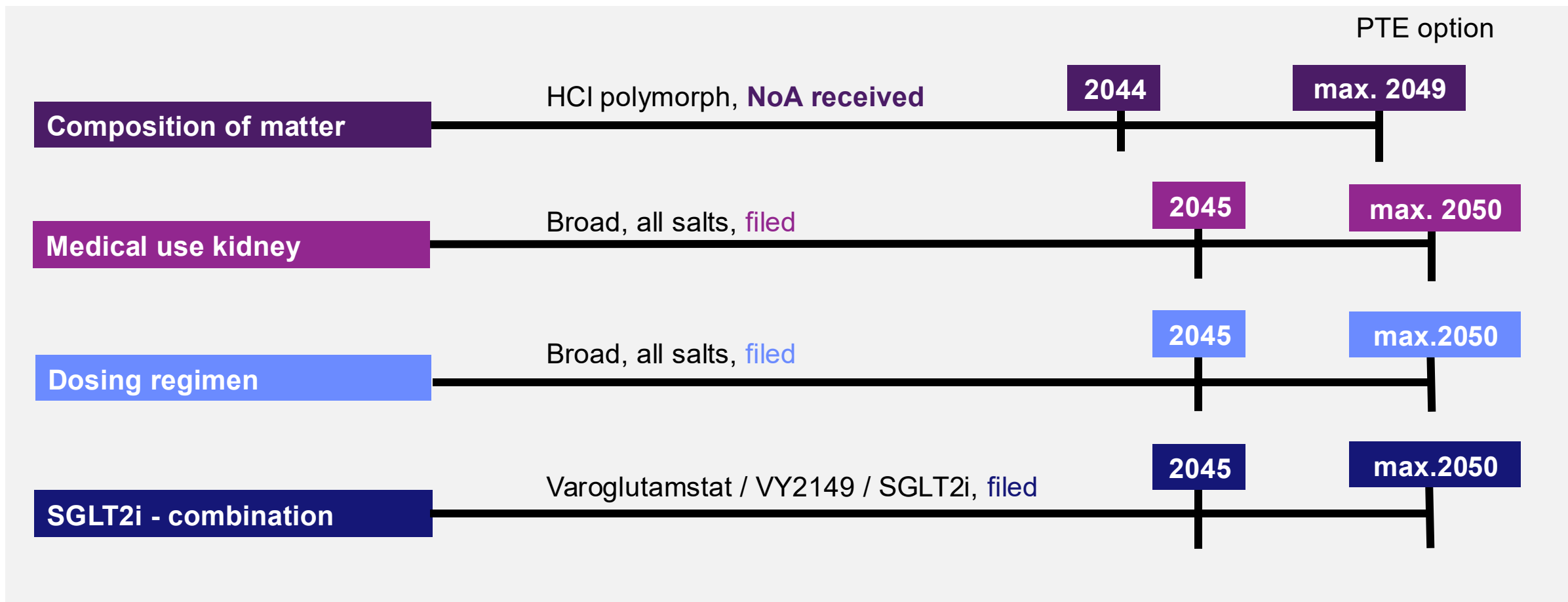


Continuing to evolve IP  
strategy based on scientific  
evidence

# Bolstering IP portfolio on multiple levels: Solid IP strategy spanning composition of matter and indication / dosing patents



# Our IP-strategy in the US aims to generate exclusivity for varoglutamstat up until at least 2044, with potential for further extensions



NoA: Notice of Allowance; PTE: patent term extension (potential for Hatch-Waxman extension of up to 5 years)



# A convenient new treatment option to fill the existing gap in kidney diseases

Product profile demonstrates varoglutamstat has the potential to stabilize/counteract continuous decline in kidney function as single agent and in combination with SoC



Single agent oral compound, in addition pre-clinical evidence for highly synergistic effect on top of SGLT2i



First-in-class mechanism of action addressing key pathways in inflammation / fibrosis



Statistically significant and clinically meaningful improvement of eGFR in two independent double-blind placebo-controlled studies. Effect size substantially larger in diabetes vs. non-diabetes population



Clearly differentiated profile with >70% patients showing improvement or stabilization of eGFR in diabetes subgroup




Excellent safety profile consistent across two years of study duration



Composition of matter protection in US until 2044 (2049 with potential PTE)<sup>1</sup>; expansions to ROW due end 2025



<sup>1</sup>Notice of Allowance received; PTE patent term extension (potential for Hatch-Waxman extension of up to 5 years)



Varoglutamstat's unique and  
beneficial effect on kidney  
function

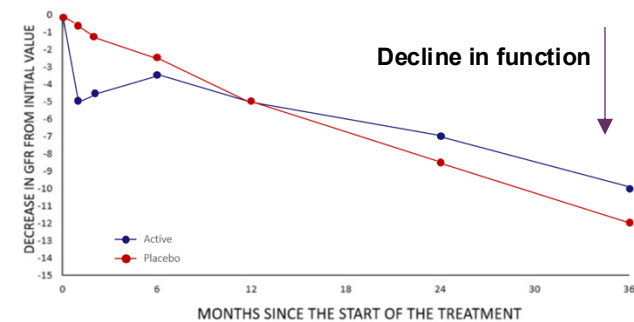
*Frank Weber, CEO*

# Novel therapies are needed to address the rising global health challenge of kidney disease

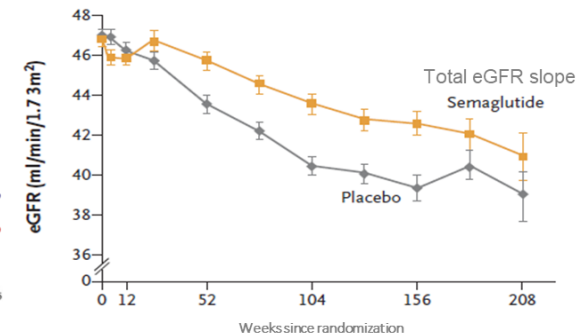
Vivoryon's varoglutamstat has potential to transform kidney outcomes

- ◆ Chronic Kidney Disease (**CKD**) is a **rising global health problem** and is set to become the fifth leading cause of years of life lost by 2040
- ◆ CKD manifests as a **progressive decline in kidney function** and can lead to significant disability and/or premature death
- ◆ **Diabetes is a major risk factor** for CKD and Diabetic Kidney Disease (**DKD**) is a **leading cause of end stage kidney disease**
- ◆ **Treatments** for CKD/DKD have advanced but **still do not halt or reverse kidney function decline** which will likely increase as the population ages
- ◆ **Inflammation is a key underlying pathway** in driving progression of DKD and other kidney disorders

Current therapies do not halt or reverse the progressive decline in kidney function characteristic of chronic kidney disease



SGLT2i effect on kidney function (eGFR ;compiled data)<sup>1</sup>

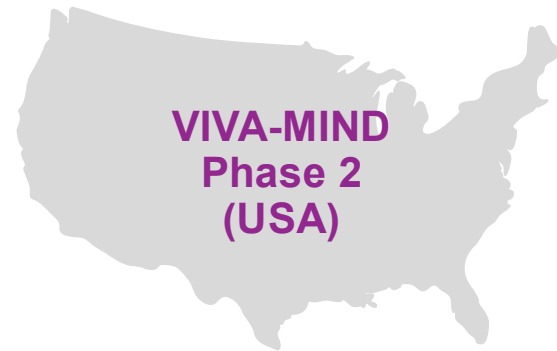


Semaglutide effect on kidney function (FLOW trial eGFR)<sup>2</sup>

Vivoryon is well-positioned with varoglutamstat to address the unmet medical need in kidney disease



Vivoryon has evaluated varoglutamstat's effect on kidney function in two independent randomized double-blind placebo-controlled Phase 2 studies



## Similarities and differences between VIVIAD & VIVA-MIND

Parameter	VIVIAD (Europe)	VIVA-MIND (U.S.)
Patient selection	Mild AD, mean age 68 yrs	Mild AD, mean age 72 yrs
No. of patients treated	n=259	n=109
Varoglutamstat dose	300 and 600 mg BID	600 mg BID
Dose escalation period	Slow: 600 mg start week 13	Fast: 600 mg start week 9
Treatment duration	76 wks (mean) / 96 wks (max.)	46 wks (mean) / 72 wks (max.)
eGFR <sup>1</sup> sampling	Every 12 weeks plus week 4	Every 12 weeks plus weeks 4, 8, 16
No. of patients with diabetes	n=32 (12.4%)	n=16 (14.7%)

*Kidney function, measured using eGFR, was a pre-specified safety / exploratory endpoint*

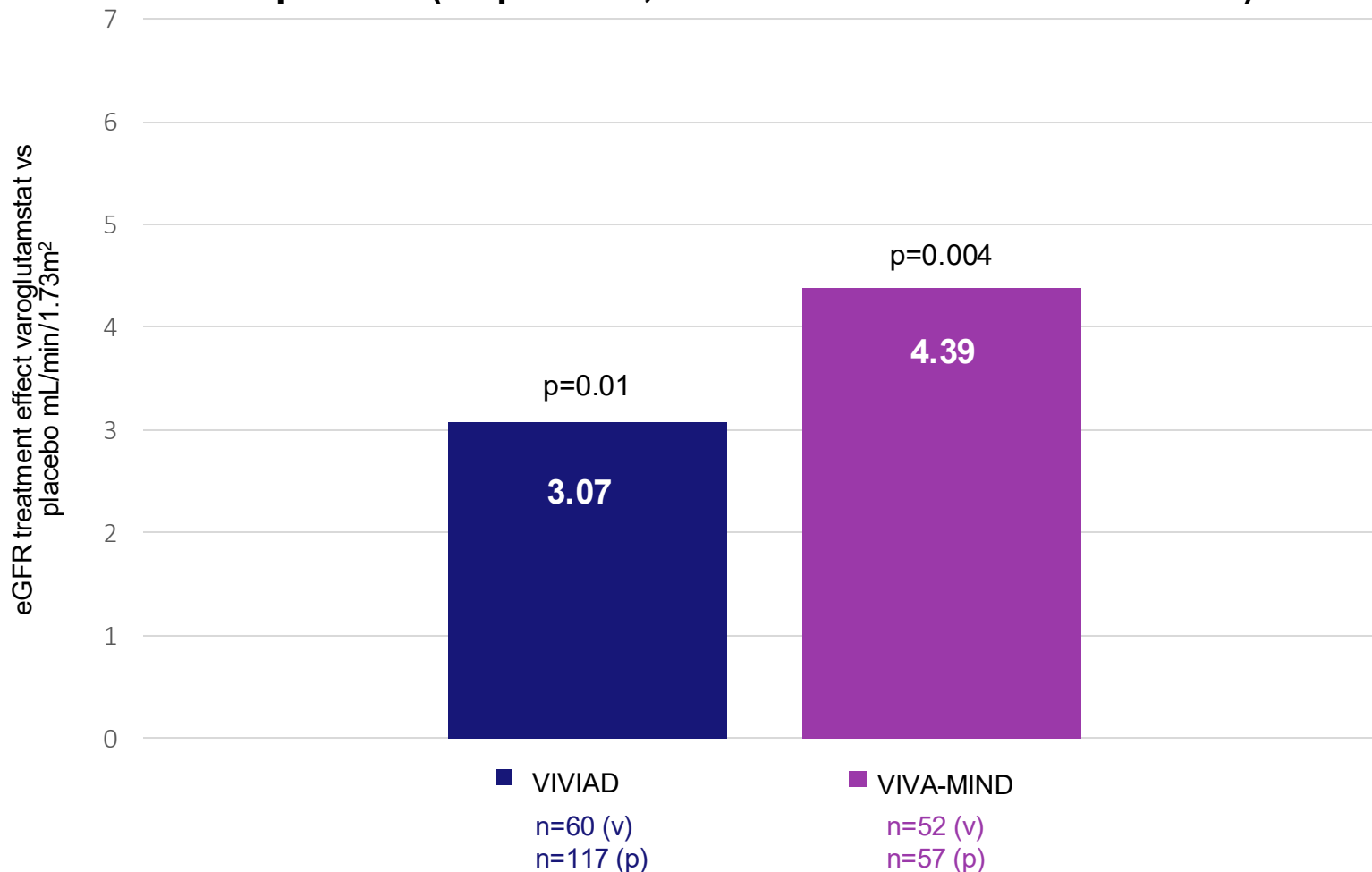


VIVIAD: ClinicalTrials.gov IDNCT04498650; VIVA-MIND: ClinicalTrials.gov IDNCT03919162; BID: twice daily; eGFR: estimated glomerular filtration rate, based on serum creatinine samples and calculated using the modification of diet in renal disease (MDRD) method; AD: Alzheimer's disease; Diabetes subgroup defined as patients having at baseline either medical history of diabetes (type 1 or 2, and glucose tolerance impaired, hyperglycaemia in VIVA-MIND) and/or comedication with drugs used in diabetes and/or untreated with a HbA1c > 6.5%.

# Beneficial kidney function effect consistently observed in both VIVIAD and VIVA-MIND

Two independent studies confirm statistically significant and clinically meaningful improvement in eGFR

LSmean difference of eGFR between varoglutamstat 600mg BID and placebo (all patients, all visits with eGFR assessment)



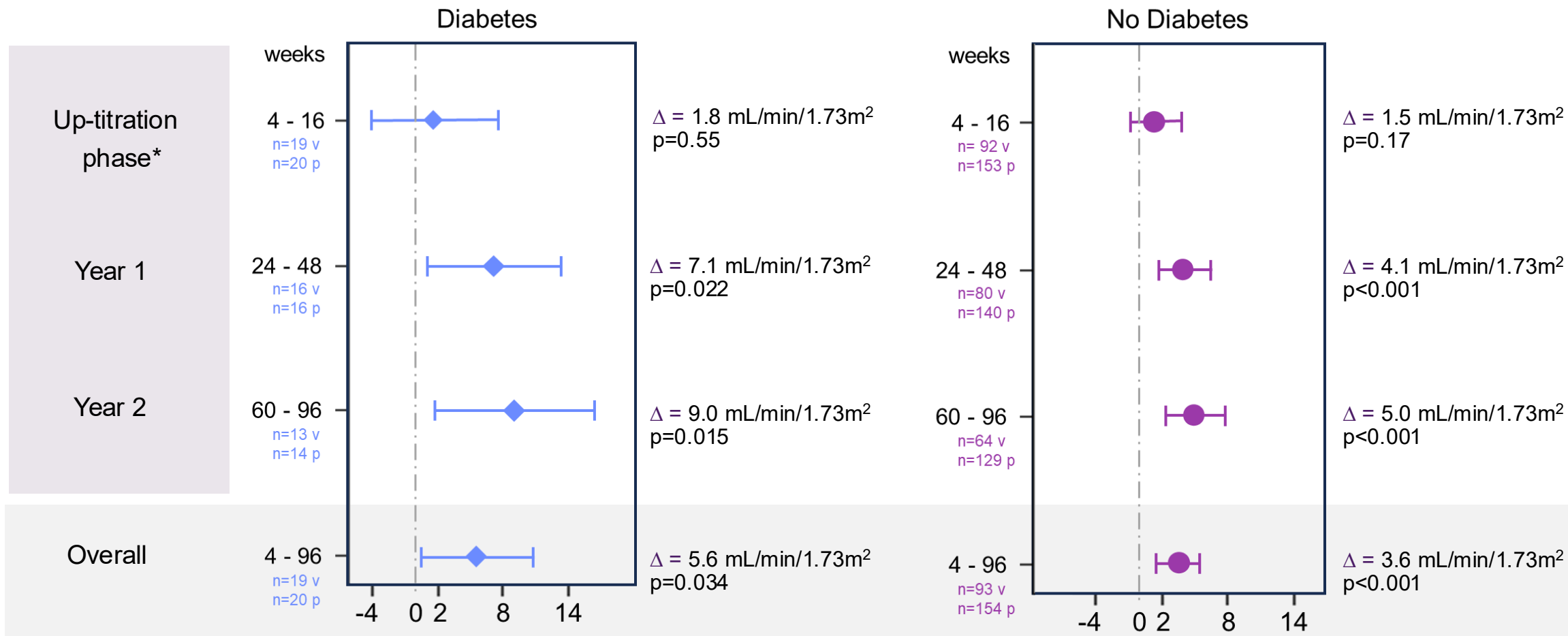
Effect size approximately 3x higher compared to SGLT2i or GLP-1 agonists



eGFR: estimated glomerular filtration rate, based on serum creatinine and calculated using the modification of diet in renal disease (MDRD) method. eGFR data were analysed over time using MMRM (mixed model for repeated measures) modelling including fixed effect terms for treatment, visit window and treatment-by-visit interaction as well as additional co-variables same as used for the respective primary endpoints as defined in the SAP using data from patients randomized to 600 mg BID and placebo of all visits on treatment, for VIVIAD (4 – 96 weeks) and VIVA-MIND (4 – 72 weeks).

# VIVIAD and VIVA-MIND: Meta-analysis confirms a robust treatment effect and a larger effect size in diabetes versus non-diabetes patients

Difference of change from baseline between varoglutamstat (v) and placebo (p) of eGFR (MDRD)



Treatment effect and 95% confidence intervals (mL/min/1.73m<sup>2</sup>)

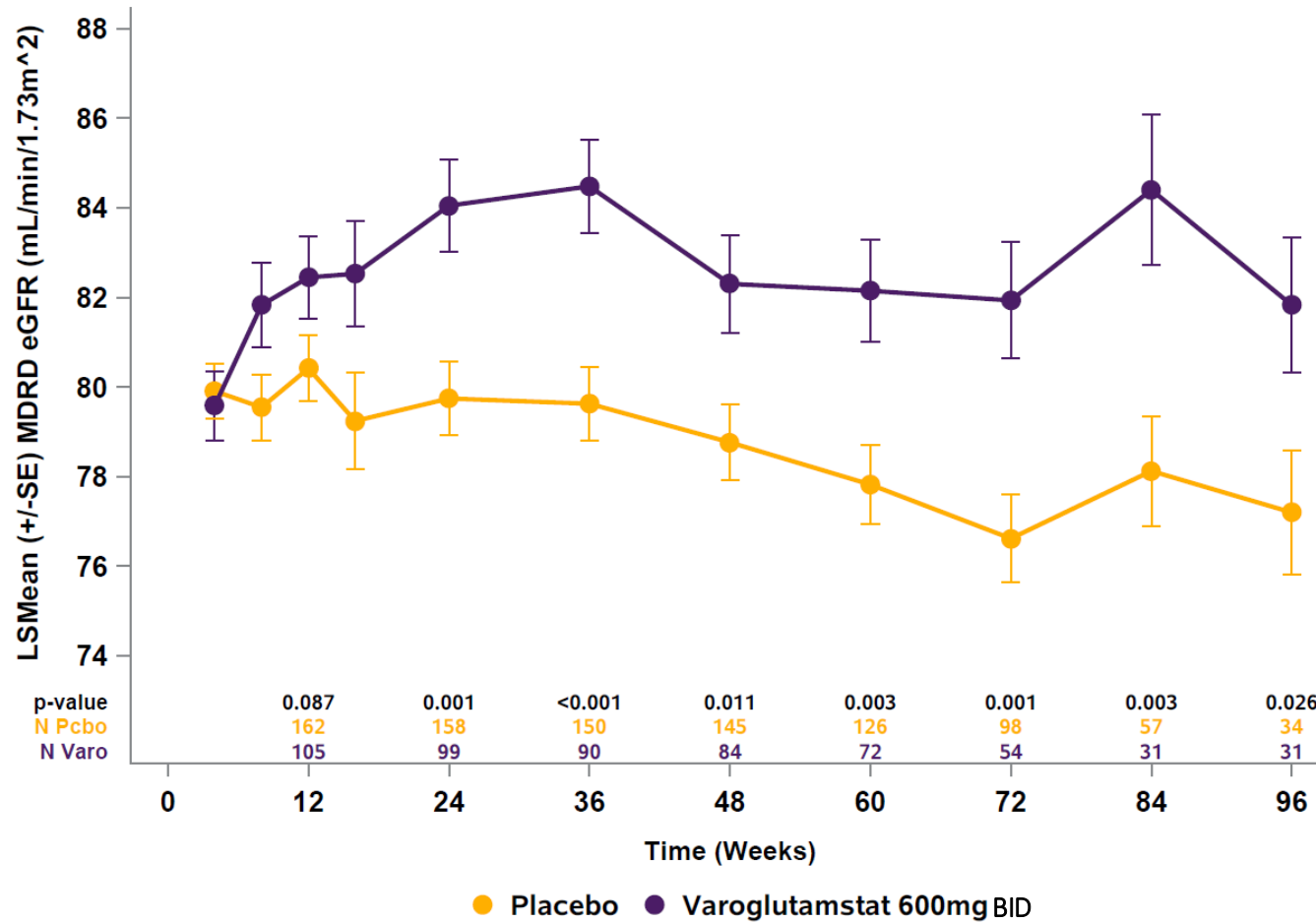
0: No treatment effect; > 0: Improvement of eGFR (MDRD);

n: Number of patients in the varoglutamstat (v) and placebo (p) group with a least one data point in the indicated time span



VIVIAD Phase 2b in early AD included investigation of kidney function (eGFR) over up to 96 weeks; VIVA-MIND Phase 2 study in early AD included investigation of kidney function (eGFR) over up to 72 weeks; eGFR: estimated glomerular filtration rate based on serum creatinine, calculated using modification of diet in renal disease (MDRD) method; Meta analysis of change from baseline (MMRM) in varoglutamstat-treated patients vs. placebo; \* Up-titration phase: includes weeks 4, 8 (DE only), 12 in VIVIAD, weeks 4, 8 in VIVA-MIND, full-dose weeks 12, 16 in VIVA-MIND

# Change in eGFR over time; pooled data from VIVIAD and VIVA-MIND (MMRM); **All subjects**; 600mg BID varoglutamstat



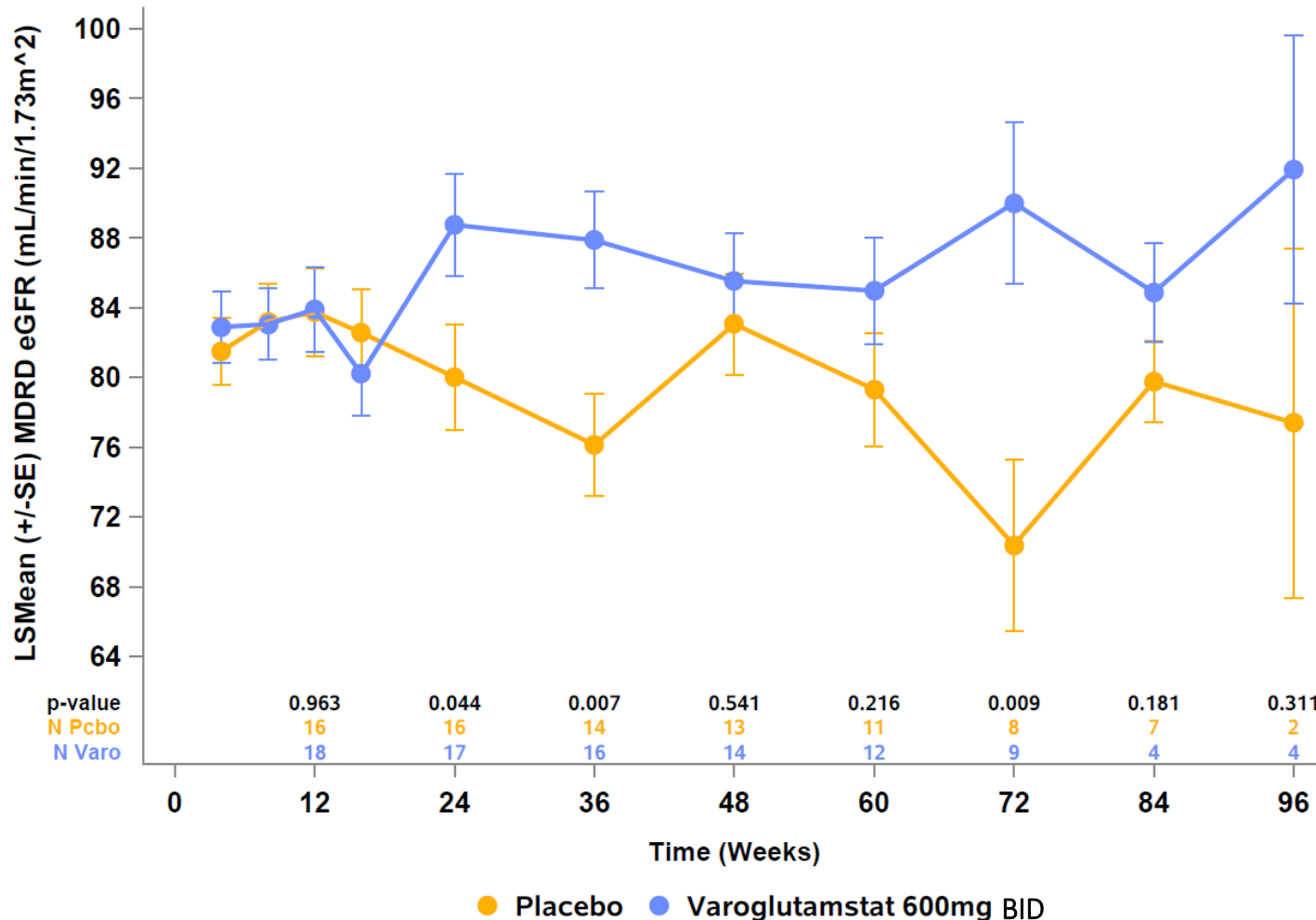
## Varoglutamstat

- ◆ Clear and consistent separation after 24 weeks
- ◆ Effect stable and maintained above baseline for 2 years
- ◆ Placebo patients decline mildly



eGFR: estimated glomerular filtration rate, based on serum creatinine and calculated using the modification of diet in renal disease (MDRD) method. eGFR data were analysed over time using MMRM (mixed model for repeated measures) modelling including fixed effect terms for study, treatment, visit window and treatment-by-visit interaction as well as baseline and study using data from patients randomized to 600mg BID and placebo of all visits on treatment, for VIVIAD (4 – 96 weeks) and VIVA-MIND (4 – 72 weeks). Within subject error modelled using an unstructured covariance matrix.

# Change in eGFR over time; pooled data from VIVIAD and VIVA-MIND (MMRM); Diabetes subgroup; 600mg BID varoglutamstat



## Varoglutamstat

- ◆ Clear and consistent separation after 24 weeks
- ◆ Large and stable effect maintained above baseline for 2 years
- ◆ Larger treatment effect in diabetes patients\*
- ◆ Placebo patients decline as expected

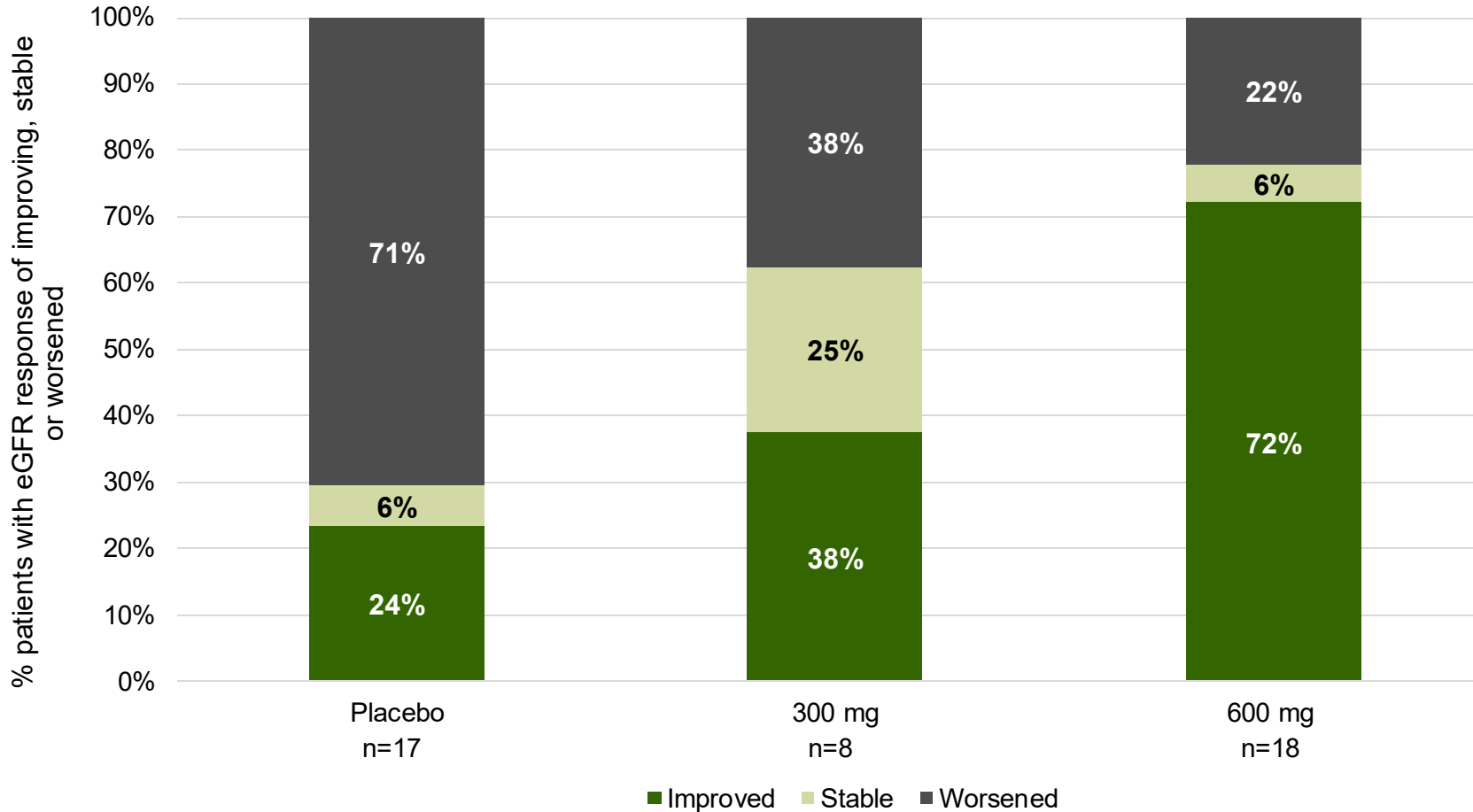


eGFR: as defined per prior slide, MDRD method. eGFR data were analysed over time using MMRM modelling including fixed effect terms for study, treatment, visit window and treatment-by-visit interaction, and baseline using data from patients randomized to 600 mg BID and placebo of all visits on treatment, for VIVIAD (4 – 96 weeks) and VIVA-MIND (4 – 72 weeks). Diabetes subgroup defined as patients having at baseline either medical history of diabetes (type 1 or 2, and glucose tolerance impaired, hyperglycaemia in VIVA-MIND) and/or comedication with drugs used in diabetes and/or untreated with a HbA1c > 6.5%. Within subject error modelled using an AR(1); \*y-axis scale different from all population graph



# Responder analysis: kidney function predominantly improved or stabilized in varoglutamstat treated patients compared to a decline in the placebo group

Diabetes patients pooled VIVIAD & VIVA-MIND



### Classification of eGFR response (change vs. baseline, mL/min/1.73m<sup>2</sup>)

- Improved:  $\geq 2$  mL above baseline
- Stable:  $\geq 0 - < 2$  mL above baseline
- Worsened:  $< 0$  mL below baseline

### Response analysis (proportional odds)

300 mg vs placebo  
2.91, 95% CI (0.55, 15.53), p=0.2106

600 mg vs. placebo  
9.20, 95% CI (2.14, 39.50), p=0.028

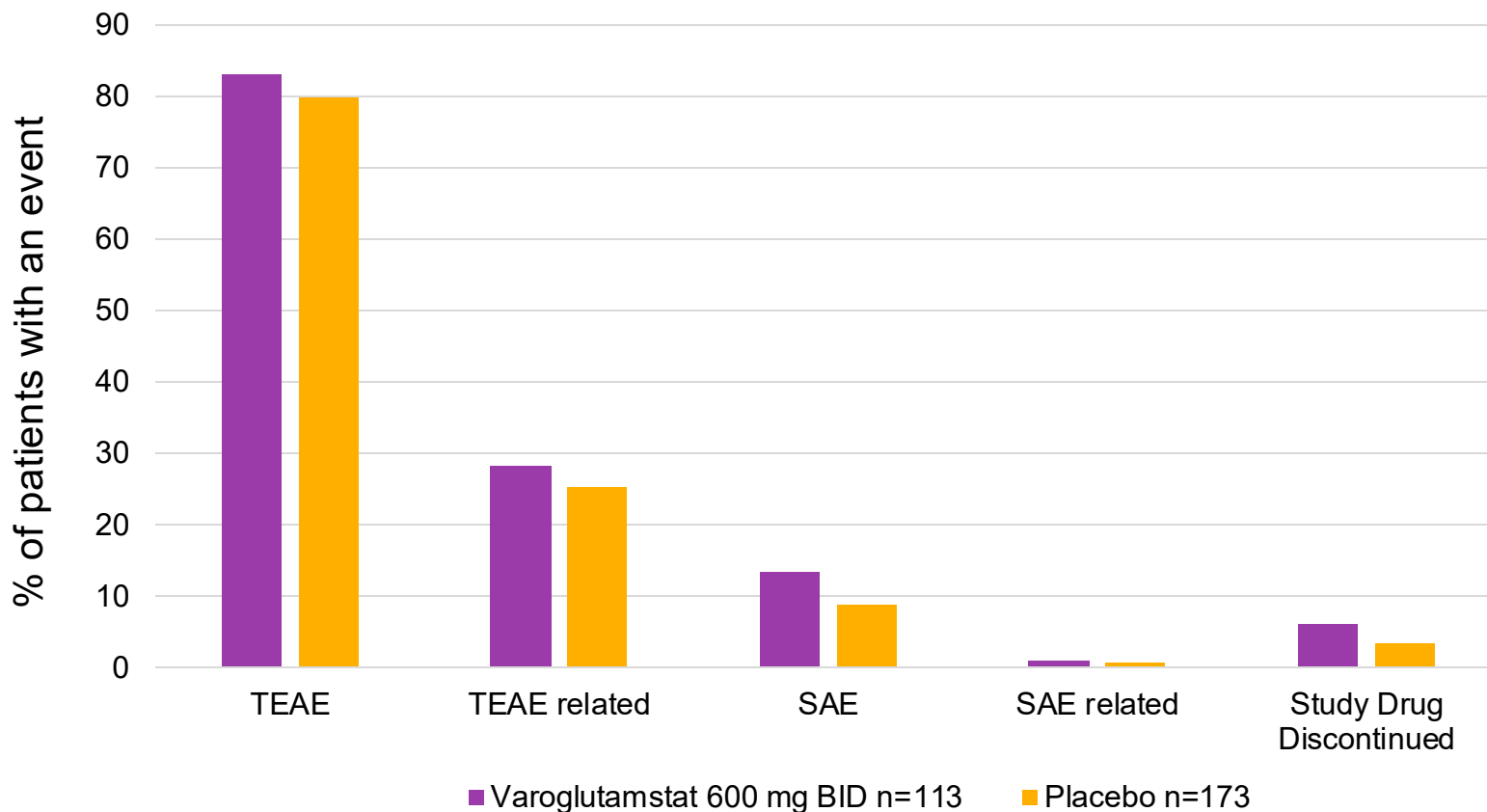


Data based on mean eGFR (week 12 – EOT) vs. baseline; combined data from VIVIAD and VIVAM-MIND studies by dose; average treatment duration in VIVIAD was 76 weeks (70 weeks in the diabetes subgroup) and in VIVA-MIND was 46 weeks; diabetes subgroup as defined on slide 9; CI: confidence interval; Some figures do not sum to 100% due to rounding

# Varoglutamstat was well tolerated in VIVIAD & VIVA-MIND

Pooled safety analysis; 600mg varoglutamstat dose

All patients randomized to 600mg varoglutamstat BID and placebo



## Extensive safety package (# / duration)

### Pharmacology / Phase 1

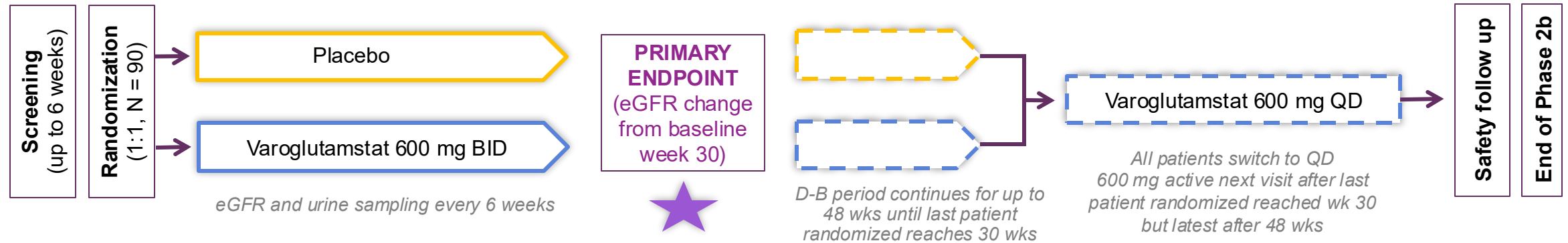
- ◆ Phase 1 study: large trial with 205 subjects
- ◆ Human ADME / mass balance study completed

### Phase 2 double-blind, placebo-controlled

- ◆ Phase 2a study: 120 patients, 12 weeks
- ◆ VIVIAD Phase 2b study: 259 patients, mean treatment duration 76 weeks
- ◆ VIVA-MIND Phase 2 study: 109 patients treated, mean treatment duration 46 weeks



# Robust evidence supports move into Phase 2b study: double-blind placebo-controlled study in patients with T2DM and CKD stages 3b+ on top of SoC<sup>1</sup>



## Patient characteristics

- ◆ T2DM patients with Stage 3b+ CKD; all patients on standard of care medicines (SoC)

## Endpoints

- ◆ **Primary:** eGFR change from baseline to last visit
- ◆ **Secondary:** UACR (albuminuria)
- ◆ **Exploratory:** Inflammatory, metabolic and fibrotic biomarkers liver transaminases, liver ultrasound (fibroscan)

## Stratification

- ◆ By CKD severity
- ◆ Patients with SGLT-2 versus no SGLT-2
- ◆ Patients with GLP-1 versus without GLP-1

## Estimated timeline to topline readout



<sup>1</sup>Draft trial design; study subject to additional financing / partnership. Baseline: average of two measurements during screening / baseline 6 weeks apart; BID: twice daily; QD: once daily; T2DM: type 2 diabetes mellitus; CKD: Chronic Kidney Disease; GLP-1: Glucagon-like peptide-1; SGLT-2: sodium-glucose co-transporter-2





Conclusions

## Create value and robust evidence for QPCT/L inhibitors in improving kidney function in patients with CKD

### 2024

- ◆ Deliver two high quality Phase 2 studies: VIVIAD and VIVA-MIND
- ◆ Provide robust evidence of efficacy for an improvement in kidney function
- ◆ Design a dedicated Phase 2b study in patients with Stage 3b+ diabetic kidney disease

### 2025 and beyond

- ◆ Ensure the commercial viability of varoglutamstat with novel composition of matter IP
- ◆ File additional dosing and medical use patents
- ◆ Derisk future development by showing substantial benefits on top of SGLT-2 inhibitors
- ◆ Provide a novel fast follower compound - VY2149



# The future of Vivoryon: Improving kidney outcomes



## Strong scientific foundation

- Novel MoA
- Robust evidence of a long-term effect
- Excellent safety package
- Strong benefit on top of SoC
- QPCT/L inhibitor pipeline



## Clearly defined commercial strategy

- Large population with high unmet medical need
- Unique product profile with simple oral administration
- Long IP runway expected to 2044 and beyond<sup>1</sup>
- Attractive time to market mid stage clinical program



## Securing value creation in the future

- SEPA is a part of financial strategy offering additional flexibility
- Actively pursuing additional financing / partnership opportunities
- Enhancing management capabilities and breadth





Q&A



## **Vivoryon Therapeutics N.V.**

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