Kerendia (Finerenone) - a new treatment option for CKD with T2D

Investor-Webinar
November 15, 2021

Christian Rommel, Head of R&D, Pharmaceuticals
Sebastian Guth, Head of Commercial Operations Americas, Pharmaceuticals
Agenda

1. Welcome
   Oliver Maier
   Head of Investor Relations

2. Prepared Remarks
   Christian Rommel
   Head of R&D, Pharmaceuticals
   Sebastian Guth
   Head of Commercial Operations Americas, Pharmaceuticals

3. Q&A
Cautionary Statements Regarding Forward-Looking Information

This presentation may contain forward-looking statements based on current assumptions and forecasts made by Bayer management.

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The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.
We laid the foundation for long-term growth at Pharma

Main building blocks of post LoE growth

<table>
<thead>
<tr>
<th>Late-stage Pipeline in CV &amp; WH</th>
<th>Oncology</th>
<th>Cell &amp; Gene Therapy Platform</th>
<th>External Innovation and BD&amp;L</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Verquvo</strong> (vericiguat tablets)</td>
<td><strong>NUBEQA</strong> (darolutamide)</td>
<td><strong>Kerendia</strong> (finerenone)</td>
<td><strong>Elinzanetant</strong> (KaNDy NT-814)</td>
</tr>
<tr>
<td>PSP ~ €0.5bn</td>
<td>PSP ≥ €1bn</td>
<td>PSP ≥ €1.0bn</td>
<td>PSP ≥ €1.0bn</td>
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<tr>
<td><strong>Pipeline</strong></td>
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<tr>
<td>(e.g. FXI portfolio, Eliapixant)</td>
<td>(e.g. GFR Exon20 inhib., ATR)</td>
<td>(e.g. TTCs)</td>
<td>(e.g. BD&amp;L)</td>
</tr>
<tr>
<td>C&amp;GT platform expected to deliver significant sales contributions from ~2025 onwards</td>
<td>&gt;25 BD&amp;L-transactions signed in 2020</td>
<td>Enhanced focus on external innovation to replenish pipeline</td>
<td></td>
</tr>
</tbody>
</table>

1 In collaboration with Merck & Co. Inc., Kenilworth, NJ, USA
2 In collaboration with Orion Corporation
Kerendia is addressing an area of high unmet medical need

Diabetes wasn’t a big deal to me. The problem was that it killed my kidneys and I didn’t know.

CKD in T2D patient

Chronic Kidney Disease in Type-2-Diabetes

- 160 mio patients globally
- Shortens life expectancy by 16 years
- #1 cause for dialysis / transplants

Wen CP, et al. Kidney Int. 2017
Finerenone Investor Webinar // November 2021
## Multiple unmet needs exist in cardio-renal disease

37 Million people in the US estimated to have CKD

<table>
<thead>
<tr>
<th>Patient needs</th>
<th>HCP needs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CKD with T2D carries 3x risk of CV death and is #1 cause of ESRD</strong></td>
<td><strong>71% of HCP confirm strong unmet need despite SOC</strong></td>
</tr>
<tr>
<td><strong>Over 50% of CKD patients progress to stages 3 &amp; 4</strong></td>
<td><strong>~70% of HCPs confirm need to go beyond risk factor management with a kidney dedicated treatment to delay CKD progression</strong></td>
</tr>
<tr>
<td><strong>Patients need simple/easy to take medications with manageable side-effect burden</strong></td>
<td><strong>Therapeutics with clinical utility across a broad spectrum of patients</strong></td>
</tr>
</tbody>
</table>

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Bayer market research

// Finerenone Investor Webinar // November 2021
The Phase III trial program for Finerenone in CKD/T2D yields clinical advantage

- Largest clinical program in CKD/T2D
- Broad spectrum of disease progression

Clinical Advantage
- MOA known by Physicians
- Physician Advantage: Familiarity

13,171 Patients

- Pooled data
- FIDELITY confirms cardio-renal benefits

7,437 Patients
- FIGARO-DKD expands into earlier stage of CKD/T2D

5,734 Patients
- FIDELIO-DKD with high-risk patients with CKD/T2D


// Finerenone Investor Webinar // November 2021
FIDELITY is a large, prespecified pooled analysis of FIDELIO-DKD and FIGARO-DKD

13,171 patients randomized across the CKD/T2D continuum

Key eligibility criteria

- **T2D**
- **CKD**
- On maximized single **RASi**
- Serum [K⁺] ≤4.8 mmol/l
- **X** Symptomatic HFrEF

### UACR (mg/g)

<table>
<thead>
<tr>
<th>eGFR (ml/min/1.73 m²)</th>
<th>0–29</th>
<th>30–299</th>
<th>≥300–≤5000</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥90</td>
<td>Green</td>
<td>Yellow</td>
<td>Moderate</td>
</tr>
<tr>
<td>60–89</td>
<td>Yellow</td>
<td>Red</td>
<td>High</td>
</tr>
<tr>
<td>45–59</td>
<td>Yellow</td>
<td>Red</td>
<td>Very High</td>
</tr>
<tr>
<td>30–44</td>
<td>Red</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15–29</td>
<td>Red</td>
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</table>

**Low risk / no CKD**

**Moderately increased risk**

**High risk**

**Very high risk**

**Patient population in FIDELITY**

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**Broad disease spectrum**

Robust data in both early disease and late disease

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**CV Composite**

Time to CV death, non-fatal MI, non-fatal stroke, or hospitalization for HF

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**57% eGFR kidney composite**

Time to kidney failure, sustained ≥57% decrease in eGFR from baseline, or renal death

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**General remarks:**

- CKD = eGFR <60 ml/min/1.73 m² and/or UACR >30 mg/g for more than 3 months
- Risk of adverse outcomes in patients with CKD/T2D increases as eGFR falls and UACR rises
The FIDELITY program for Finerenone enrolled more early-stage patients than other contemporary trials in CKD/T2D

Robust data in patients EARLY in CKD/T2D progression

Earlier/broader CKD/T2D patient population than SGLT-2i which were mainly tested in higher-risk/late-stage patients

Clinical Advantage

MOA known by Physicians

Physician Advantage: Familiarity

No. of CKD/T2D-patients (Total trial participants)

Baseline Albuminuria/UACR (mg/g)

<table>
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<tr>
<th>CKD/T2D Progression</th>
<th>30-300</th>
<th>&gt;300</th>
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<td>Finerenone (FIDELITY)</td>
<td>4.099</td>
<td></td>
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<td>Canagliflozin (CREDENCE)</td>
<td>496</td>
<td></td>
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<td>308</td>
<td></td>
</tr>
<tr>
<td>Finerenone (FIDELITY)</td>
<td>8.692</td>
<td></td>
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<tr>
<td>Canagliflozin (CREDENCE)</td>
<td>3.874</td>
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<td>2.906</td>
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Perkovic V. et al., N Engl J Med 2019
Wheeler DC et al., Nephrol Dial Transplant. 2020
Agarwal, R. et al., data presented at ESC 2021
Early-stage patients represent the majority of the prevalent CKD/T2D patient population

Robust data in patients EARLY in CKD/T2D progression

Earlier/broader CKD/T2D patient population than SGLT-2i which were mainly tested in higher-risk/late-stage patients

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56% of prevalent US patient population with 30-300

Perkovic V. et al., N Engl J Med 2019
Wheeler DC et al., Nephrol Dial Transplant. 2020
Agarwal, R. et al., data presented at ESC 2021

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Finerenone provides heart and kidney protection in patients with mild to severe CKD and T2D

Key results of the FIDELITY pooled analysis

**Clinical Advantage**
- MOA known by Physicians
- Physician Advantage: Familiarity

**Composite CV Outcome**
- Relative risk reduction compared to placebo
  - HR = 0.86
  - (95% CI 0.78-0.95), p=0.0018
  - NNT 46
  - -14%

**Composite Kidney Outcome**
- Relative risk reduction compared to placebo
  - HR = 0.77
  - (95% CI 0.67-0.88), p=0.0002
  - NNT 59
  - -23%

**[K+] Hyperkalemia**
- ~1% placebo adjusted permanent discontinuations due to hyperkalemia
- Permanent discontinuations (%)
  - Placebo: 0.6
  - Finerenone: 1.7

Agarwal, R. et al., data presented at ESC 2021
Finerenone with cardio-renal endpoint risk reduction comparable to Canagliflozin when trial differences are considered

FIDELIO-DKD “CREDENCE-like” post-hoc analysis

<table>
<thead>
<tr>
<th></th>
<th>Finerenone</th>
<th>Finerenone&lt;sup&gt;3&lt;/sup&gt;</th>
<th>Canagliflozin&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reduction in cardio-renal endpoint risk</strong>&lt;sup&gt;1&lt;/sup&gt;</td>
<td>-26%</td>
<td>-28%</td>
<td>-30%</td>
</tr>
<tr>
<td><strong>HR = 0.74</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(95% CI 0.63-0.87)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>p=0.0003</strong></td>
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• Post-hoc analysis of FIDELIO-DKD

• Patient inclusion criteria adjusted to those of the CREDENCE trial with canagliflozin
  - UACR >300 - 5,000 mg/g
  - eGFR 30 - <90 ml/min/1.73m²

• Cardio-renal endpoint definition equivalent to CREDENCE trial
  - Composite of kidney failure, eGFR decrease of >57% from baseline for ≥ 4 weeks or renal or cardiovascular death vs. placebo

• 81% of patients included in FIDELIO-DKD were eligible for analysis

Agarwal R. et al, AHJ (242) 2021
1) No head-to-head trials available
3) Calculated analysis, adjusted for history of heart failure

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Kerendia provides mechanistical continuity for the treatment of cardio-renal diseases

RAAS overactivation is a key driver of cardio-renal diseases

ACEi/ARBs have been the gold-standard for treatment for decades

Kerendia MOA intensifies RAAS inhibition via targeting MRA

Mechanistic Continuity

RAAS Inhibition via MRA pathway

ACE inhibitors
ARBs

+ ACEi/ARBs
RAASi-intensification is accomplished with Kerendia on top of ACEi/ARBs

- In Kerendia – Bayer has accomplished what many have tried and failed to do for the last 25 years
- RAASi-intensification through Kerendia continues the long RAAS-centric treatment history
- Clinical implications from FIDELITY:
  - Addresses the unmet need/residual risk for patients
  - Decreases risk without significant increase in overall AE’s
  - Manageable hyperkalemia
  - Potential for earlier treatment of CKD/T2D

Mentz R.J. et al, Int J Cardiol 2013
Kerendia addresses familiarity of physicians with established mode of action

Mechanistic Continuity

- Well-entrenched historical paradigm may position Kerendia as front-line therapy
- Established pathophysiological pathway via MR antagonism
- Demonstrated positive treatment outcomes
- Leverages known MOA of MRAs

RAAS Inhibition

ACE inhibitors
ARBs

RAAS Inhibition via MRA pathway

Clinical Advantage

MOA known by Physicians

Physician Advantage: Familiarity
FDA approved Kerendia with a broad label recognizing the renal and cardiovascular outcomes in FIDELIO-DKD

**US-Indication**  
Indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

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**Clinical Data**  
Based on FIDELIO-DKD

**Efficacy**  
Full reflection of the main components of the primary renal and the key sec. cardiovascular composite endpoints

**Safety**  
Favorable benefit-to-risk ratio with hyperkalemia the only risk factor mentioned in the warnings and precautions section of the US-label
Strong commitment to a broad availability to the cardio-renal potential of Kerendia

Peak sales potential > EUR 1bn

- Filed 11/2020 (EU)
- Filed 2/2021 (China)
- Launched (US)
Significant investment to tap into a targeted portion of the US primary care market with Kerendia

**Strategy**
- Early focus on Nephrologists, Endocrinologists, select Cardiologists and targeted General Physicians
- Breath of disease stages covered in the phase III program should facilitate adoption into earlier stages of CKD with T2D

**Organization**
- Built commercial organization with >500 reps promoting Kerendia
- Organization with substantial expertise in the field
- Strong digital and medical education engagement during Covid

**Access**
- Early payor wins and coverage with key plans
- Access programs (copay card program, free-trial program) in place
Life-cycle management for Finerenone into non-diabetic CKD and into heart failure

**Non-diabetic CKD**

CKD attributable to causes such as hypertension or chronic glomerulonephritis

Reported cases of ESRD (US)

![Chart showing 39% Diabetes, 60% other causes](image)

**Heart Failure**

Targeting HF with a left ventricular ejection fraction of ≥40% (HFpEF).

HF patient population by left ventricular ejection fraction

![Chart showing 53% EF ≥40% (HFpEF), 47% EF <40% (HFrEF)](image)


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Kerendia sets the stage for a long-term cardio-renal vision and targets to deliver blockbuster potential

Unmet Needs

Need for RAASi intensification
Need for earlier use in disease progression
Need for disease modification and outcomes

Kidney Dedicated

Establish Kerendia as the next gen RAASi for CKD/T2D

CardioRenal Disease Modifier

Heart failure (HFpEF)
Non-diabetic CKD

Phase III studies:

FINEARTS-HF (2024E)
FiND-CKD (2025E)

Dates indicate primary trial completion according to clinicaltrials.gov

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Christian Rommel, Head of R&D, Pharmaceuticals
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Abbreviations

ACEi  Angiotensin converting enzyme inhibitor
AE   Adverse event
ARB  Angiotensin receptor blocker
BD&L Business development and licensing
CI   Confidence interval
CKD  Chronic kidney disease
CV   Cardiovascular
DKD  Diabetic kidney disease
EF   Ejection fraction
eGFR Estimated glomerular filtration rate
ESRD End-stage renal disease
HCP  Healthcare provider
HF   Heart failure
HFrEF Heart failure with reduced ejection fraction
HK   Hyperkalemia
HR   Hazard ratio
LoE  Loss of exclusivity
MOA Mode of action
MR   Mineralocorticoid receptor
MRA  Mineralocorticoid receptor antagonist
NNT  Number needed to treat
PSP  Peak sales potential
RAAS Renin-angiotensin-aldosteron system
RASi Renin-angiotensin-system inhibition/inhibitor
SGLT-2i Sodium-glucose-cotransporter 2 inhibitor
SOC  Standard of care
T2D  Type-2-diabetes
UACR Urine albumin-to-creatinine ratio
WH  Women’s health