Farxiga’s DAPA-CKD trial at ESC

Conference call for investors and analysts
Forward-looking statements disclaimer

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Agenda for today’s conference call

1. Introduction by Pascal Soriot
2. Presentation by Prof. Hiddo L. Heerspink
3. Q&A
Presenters

Pascal Soriot
Executive Director and
Chief Executive Officer

Hiddo L. Heerspink
Professor Clinical Trials and Personalized Medicine
University Medical Center Groningen

Available for Q&A

David Wheeler
Professor of Kidney Medicine
University College London

Ruud Dobber
Executive Vice President
BioPharmaceuticals Business Unit

Mene Pangalos
Executive Vice President
BioPharmaceuticals R&D

Elisabeth Björk
Senior Vice President
Late CVRM

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Professor of Kidney Medicine
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Elisabeth Björk
Senior Vice President
Late CVRM
Farxiga continues to deliver

DAPA-CKD yet another important milestone
Follows successful US launch in heart failure

- **2018**: Positive DECLARE data in a broad patient population with *type-2 diabetes*
- **2019**: Ground breaking results in *heart failure* (HFrEF) patients with and without type-2 diabetes
- **2020**: Unprecedented data in *chronic kidney disease* (CKD) in patients with and without type-2 diabetes. First SGLT2 inhibitor to show positive data in a broad CKD population

*Future data readouts:*
- **2021**: Additional *heart failure* data: DELIVER (HFpEF)
- **2021+**: Combination data including AZD9977 combo
CKD is currently highly underdiagnosed with significant morbidity & mortality

- Increase awareness
- Expand early diagnosis
- Transform CKD management

CKD - low awareness and many undiagnosed patients

- 1 in 10 people around the world is living with CKD¹
- Most adults (90%) with CKD in the US do not know they have it²
- Only ~12% of Stage 3 CKD patients are diagnosed in the US³
- Overall Medicare costs for people with CKD were over $84 billion in the US in 2017⁴

Sources:
Innovative, complementary CVRM portfolio

**Diabetes**
- **farxiga** (dapagliflozin)
- **BRILINTA** ticagrelor tablets

**Heart Failure**
- **farxiga** (dapagliflozin)
- **LOKELMA**
  - *Enabling effective treatment for HF*

**Cardiovascular**
- **farxiga** (dapagliflozin)
- **BRILINTA** ticagrelor tablets

**Kidney Disease**
- **farxiga** (dapagliflozin)
- **ROxadustat**

**Pipeline includes:**
- cotadutide (GLP-1/glucagon co-agonist) NASH
- AZD4831 (MPO inhibitor) HFpEF
- AZD5718 (FLAP inhibitor) CAD
- AZD9977 + Farxiga (MCR modulator/SGLT2) HFrEF with CKD
- AZD2693 (PNPLA3 inhibitor) NASH

1. Glucagon-like peptide-1
2. Non-alcoholic steatohepatitis
3. Myeloperoxidase
4. Heart failure with preserved ejection fraction
5. 5-Lipoxygenase activating protein
6. Mineralocorticoid receptor
Dapagliflozin in Patients with Chronic Kidney Disease
DAPA-CKD

Hiddo L. Heerspink
Department of Clinical Pharmacy and Pharmacology
University Medical Center Groningen
Disclosures

• HJLH is a consultant for AbbVie, AstraZeneca, Bayer, Boehringer Ingelheim, Chinook, CSL Pharma, Gilead, Janssen, Merck, Mundi Pharma, Mitsubishi Tanabe, Novo Nordisk, and Retrophin. He has received research support from Abbvie, AstraZeneca, Boehringer Ingelheim and Janssen.
Rationale for the DAPA-CKD trial

- Chronic kidney disease (CKD) is an important contributor to cardiovascular (CV) morbidity, all-cause mortality and diminished quality of life\(^1\)

- Until recently, the only classes of medication specifically proven to slow progression of CKD were ACE inhibitors or ARBs

- Sodium glucose cotransporter 2 (SGLT2) inhibitors, including dapagliflozin, have shown favorable effects on CV and kidney outcomes in large clinical trials in patients with type 2 diabetes\(^2\)\(^-\)\(^5\)

- The DAPA-HF trial showed that dapagliflozin reduced the risk of worsening heart failure or death from CV causes, independently of the presence of diabetes\(^6\)

- We hypothesized that dapagliflozin could also preserve kidney function and improve outcomes in people with chronic kidney disease, independently of the presence of diabetes

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Objectives

- To assess whether treatment with dapagliflozin, compared with placebo, reduced the risk of renal and CV events in people with CKD with or without type 2 diabetes, and who are receiving standard of care including a maximum tolerated dose of an ACE inhibitor or ARB

• **Primary outcome**
  - Composite outcome of sustained ≥50% eGFR decline, ESKD, renal or CV death

• **Secondary outcomes (in hierarchical order)**
  - Composite outcome of sustained ≥50% eGFR decline, ESKD or renal death
  - CV death or hospitalizations for heart failure
  - All-cause mortality

Study Design

Key inclusion criteria:
• ≥18 years of age
• eGFR 25 to 75 mL/min/1.73m²
• UACR 200 to 5000 mg/g (22.6 to 565 mg/mmol)
• Stable maximum tolerated labelled dose of ACEi or ARB for ≥4 weeks (if not contraindicated)

Key exclusion criteria:
• Type 1 diabetes
• Polycystic kidney disease, lupus nephritis, ANCA-associated vasculitis
• Immunosuppressive therapy within 6 months prior to enrollment

Matching Placebo once daily

Screening

Randomization (1:1)

−2 W
Day 0
2 W
2 M
4 M
8 M

Visits every 4 months

Dapagliflozin 10 mg once daily

Study End Date
Study Closure Visit

Within 6 weeks

Outcome analysis based on Cox proportional hazard model stratified by type 2 diabetes and UACR and adjusted for eGFR

ANCA, anti-neutrophil cytoplasmic antibody; ITT, intention-to-treat; UACR, urinary albumin-to-creatinine ratio.

DAPA-CKD: 21 countries, 386 sites, 4304 participants

North America:
Canada (n=280)
United States (n=533)

Latin America:
Argentina (n=235)
Brazil (n=302)
Mexico (n=154)
Peru (n=221)

Western Europe:
Denmark (n=45)
Germany (n=138)
Spain (n=260)
Sweden (n=40)
UK (n=60)

Eastern Europe:
Hungary (n=140)
Poland (n=103)
Russia (n=255)
Ukraine (n=192)

Asia:
China (n=210)
India (n=201)
Japan (n=244)
Philippines (n=115)
South Korea (n=294)
Vietnam (n=282)
After a regular review meeting, the Independent DMC recommended on 26 March that the trial be stopped due to overwhelming efficacy, based on 408 primary endpoint events (60% of planned events).
Patient disposition

7517 participants enrolled

4304 participants randomized to treatment

3213 participants not randomized

Dapagliflozin 10 mg
N=2152

- 3 participants did not receive study drug
- 274 participants discontinued study drug
- 2142 (99.5%) participants completed the study
- 10 participants discontinued study

Placebo
N=2152

- 3 participants did not receive study drug
- 309 participants discontinued study drug
- 2147 (99.8%) participants completed the study
- 5 participants discontinued study

4299 (99.9%) vital status known; 4289 (99.7%) completed study

## Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Dapagliflozin (N=2152)</th>
<th>Placebo (N=2152)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean</td>
<td>62</td>
<td>62</td>
</tr>
<tr>
<td>Sex, female, %</td>
<td>33</td>
<td>33</td>
</tr>
<tr>
<td>Race, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>52</td>
<td>54</td>
</tr>
<tr>
<td>Black or African-American</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Asian</td>
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<td>33</td>
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<tr>
<td>Other</td>
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<td>8</td>
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<tr>
<td>Type 2 diabetes, %</td>
<td>68</td>
<td>67</td>
</tr>
<tr>
<td>Systolic blood pressure, mmHg, mean</td>
<td>137</td>
<td>137</td>
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<tr>
<td>eGFR, mL/min/1.73m², mean</td>
<td>43</td>
<td>43</td>
</tr>
<tr>
<td>UACR, mg/g, median</td>
<td>965</td>
<td>934</td>
</tr>
<tr>
<td>ACEi or ARB, %</td>
<td>97</td>
<td>97</td>
</tr>
</tbody>
</table>

Primary outcome:
Sustained ≥50% eGFR decline, ESKD, renal or CV death

Hazard ratio, 0.61 (95% CI, 0.51–0.72)
p=0.000000028
NNT=19

Secondary outcome:
Sustained ≥50% eGFR decline, ESKD, renal death

Hazard ratio, 0.56 (95% CI, 0.45–0.68)
p=0.000000018

243 Events
Placebo

142 Events
Dapagliflozin

No. at Risk
Dapagliflozin 2152 2001 1955 1898 1841 1701 1288 831 309
Placebo 2152 1993 1936 1858 1791 1664 1232 774 270
Chronic dialysis, kidney transplantation, renal death

Hazard ratio, 0.66 (95% CI, 0.49–0.90) p=0.0072

- Placebo: 103 Events
- Dapagliflozin: 71 Events

No. at Risk
Summary of the primary outcome and its components

<table>
<thead>
<tr>
<th>Event</th>
<th>Dapagliflozin events</th>
<th>Placebo events</th>
<th>Hazard Ratio (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary composite endpoint</td>
<td>197</td>
<td>312</td>
<td>0.61 (0.51, 0.72)</td>
<td>0.000000028</td>
</tr>
<tr>
<td>≥50% eGFR decline</td>
<td>112</td>
<td>201</td>
<td>0.53 (0.42, 0.67)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>ESKD</td>
<td>109</td>
<td>161</td>
<td>0.64 (0.50, 0.82)</td>
<td>0.0004</td>
</tr>
<tr>
<td>eGFR &lt;15 mL/min/1.73m²</td>
<td>84</td>
<td>120</td>
<td>0.67 (0.51, 0.88)</td>
<td>0.0045</td>
</tr>
<tr>
<td>Chronic dialysis</td>
<td>68</td>
<td>99</td>
<td>0.66 (0.48, 0.90)</td>
<td>0.0080</td>
</tr>
<tr>
<td>Transplantation</td>
<td>3</td>
<td>8</td>
<td>0.81 (0.58, 1.12)</td>
<td>0.2029</td>
</tr>
<tr>
<td>Renal death</td>
<td>2</td>
<td>6</td>
<td>NC</td>
<td></td>
</tr>
<tr>
<td>CV death</td>
<td>65</td>
<td>80</td>
<td>NC</td>
<td></td>
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NC, not calculable
## Primary outcome – pre-specified subgroup analysis

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Dapagliflozin events</th>
<th>Placebo events</th>
<th>Hazard Ratio (95% CI)</th>
<th>p-value interaction</th>
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</thead>
<tbody>
<tr>
<td>All patients</td>
<td>197</td>
<td>312</td>
<td>0.61 (0.51, 0.72)</td>
<td>0.24</td>
</tr>
<tr>
<td>With type 2 diabetes</td>
<td>152</td>
<td>229</td>
<td>0.64 (0.52, 0.79)</td>
<td></td>
</tr>
<tr>
<td>Without type 2 diabetes</td>
<td>45</td>
<td>83</td>
<td>0.50 (0.35, 0.72)</td>
<td>0.24</td>
</tr>
<tr>
<td>UACR ≤1000 mg/g</td>
<td>44</td>
<td>84</td>
<td>0.54 (0.37, 0.77)</td>
<td></td>
</tr>
<tr>
<td>UACR &gt;1000 mg/g</td>
<td>153</td>
<td>228</td>
<td>0.62 (0.50, 0.76)</td>
<td>0.52</td>
</tr>
<tr>
<td>eGFR &lt;45 mL/min/1.73m²</td>
<td>152</td>
<td>217</td>
<td>0.63 (0.51, 0.78)</td>
<td></td>
</tr>
<tr>
<td>eGFR ≥45 mL/min/1.73m²</td>
<td>45</td>
<td>95</td>
<td>0.49 (0.34, 0.69)</td>
<td>0.22</td>
</tr>
</tbody>
</table>
### Primary outcome – pre-specified subgroup analysis

<table>
<thead>
<tr>
<th></th>
<th>Dapagliflozin events</th>
<th>Placebo events</th>
<th>Hazard ratio (95% CI)</th>
<th>p-value interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All patients</strong></td>
<td>197</td>
<td>312</td>
<td>0.61 (0.51, 0.72)</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤65 years</td>
<td>122</td>
<td>191</td>
<td>0.64 (0.51, 0.80)</td>
<td>0.53</td>
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<tr>
<td>&gt;65 years</td>
<td>75</td>
<td>121</td>
<td>0.58 (0.43, 0.77)</td>
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</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>126</td>
<td>209</td>
<td>0.57 (0.46, 0.72)</td>
<td>0.50</td>
</tr>
<tr>
<td>Female</td>
<td>71</td>
<td>103</td>
<td>0.65 (0.48, 0.88)</td>
<td></td>
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<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>White</td>
<td>110</td>
<td>174</td>
<td>0.62 (0.49, 0.79)</td>
<td>0.68</td>
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<tr>
<td>Black</td>
<td>7</td>
<td>14</td>
<td>0.33 (0.13, 0.81)</td>
<td></td>
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<tr>
<td>Asian</td>
<td>53</td>
<td>77</td>
<td>0.66 (0.46, 0.93)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>27</td>
<td>47</td>
<td>0.54 (0.33, 0.86)</td>
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</tr>
<tr>
<td><strong>Region</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asia</td>
<td>50</td>
<td>69</td>
<td>0.70 (0.48, 1.00)</td>
<td></td>
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<tr>
<td>Europe</td>
<td>57</td>
<td>89</td>
<td>0.60 (0.43, 0.85)</td>
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<tr>
<td>North America</td>
<td>35</td>
<td>69</td>
<td>0.51 (0.34, 0.76)</td>
<td></td>
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<tr>
<td>Latin America</td>
<td>55</td>
<td>85</td>
<td>0.61 (0.43, 0.86)</td>
<td>0.77</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>With type 2 diabetes</td>
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<td></td>
</tr>
<tr>
<td><strong>eGFR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;45 mL/min/1.73m²</td>
<td>152</td>
<td>217</td>
<td>0.63 (0.51, 0.78)</td>
<td>0.22</td>
</tr>
<tr>
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<td>45</td>
<td>95</td>
<td>0.49 (0.34, 0.69)</td>
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</tr>
<tr>
<td><strong>UACR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤1000 mg/g</td>
<td>44</td>
<td>84</td>
<td>0.54 (0.37, 0.77)</td>
<td>0.52</td>
</tr>
<tr>
<td>&gt;1000 mg/g</td>
<td>153</td>
<td>228</td>
<td>0.62 (0.50, 0.76)</td>
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<tr>
<td><strong>SBP</strong></td>
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<tr>
<td>≤130 mmHg</td>
<td>46</td>
<td>96</td>
<td>0.44 (0.31, 0.63)</td>
<td>0.04</td>
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<tr>
<td>&gt;130 mmHg</td>
<td>151</td>
<td>216</td>
<td>0.68 (0.56, 0.84)</td>
<td></td>
</tr>
</tbody>
</table>

Secondary outcome: CV death or heart failure hospitalization

Hazard ratio, 0.71 (95% CI, 0.55–0.92)  
*p=0.0089*

138 Events
100 Events

Placebo
Dapagliflozin

<table>
<thead>
<tr>
<th>Months since Randomization</th>
<th>Hazard ratio, 0.71 (95% CI, 0.55–0.92)</th>
<th><em>p=0.0089</em></th>
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<tbody>
<tr>
<td>0</td>
<td>10.0</td>
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<tr>
<td>4</td>
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<td>8</td>
<td>6.0</td>
<td></td>
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<tr>
<td>12</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>2.0</td>
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<tr>
<td>20</td>
<td>4.0</td>
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<td>24</td>
<td>6.0</td>
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<tr>
<td>32</td>
<td>10.0</td>
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</table>

No. at Risk

Dapagliflozin
Placebo

<table>
<thead>
<tr>
<th>Months since Randomization</th>
<th>No. at Risk (Dapagliflozin)</th>
<th>No. at Risk (Placebo)</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>2152</td>
<td>2152</td>
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<tr>
<td>4</td>
<td>2035</td>
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<td>16</td>
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<td>36</td>
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<td>40</td>
<td>976</td>
<td>976</td>
</tr>
<tr>
<td>44</td>
<td>360</td>
<td>360</td>
</tr>
</tbody>
</table>

Secondary outcome: All-cause mortality

Hazard ratio, 0.69 (95% CI, 0.53–0.88)  
P=0.0035

## Safety

<table>
<thead>
<tr>
<th>Safety outcomes*, n (%)</th>
<th>Dapagliflozin (N=2149)</th>
<th>Placebo (N=2149)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinuation of study drug</td>
<td>274 (12.8)</td>
<td>309 (14.4)</td>
</tr>
<tr>
<td>Discontinuation due to adverse event</td>
<td>118 (5.5)</td>
<td>123 (5.7)</td>
</tr>
<tr>
<td>Any serious adverse event</td>
<td>633 (29.5)</td>
<td>729 (33.9)</td>
</tr>
<tr>
<td><strong>Adverse events of interest</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amputation†</td>
<td>35 (1.6)</td>
<td>39 (1.8)</td>
</tr>
<tr>
<td>Any definite or probable diabetic ketoacidosis</td>
<td>0</td>
<td>2 (0.1)</td>
</tr>
<tr>
<td>Fracture‡</td>
<td>85 (4.0)</td>
<td>69 (3.2)</td>
</tr>
<tr>
<td>Renal related adverse event‡</td>
<td>155 (7.2)</td>
<td>188 (8.7)</td>
</tr>
<tr>
<td>Major hypoglycaemia§</td>
<td>14 (0.7)</td>
<td>28 (1.3)</td>
</tr>
<tr>
<td>Volume depletion‡</td>
<td>127 (5.9)</td>
<td>90 (4.2)</td>
</tr>
<tr>
<td>Serious adverse events of volume depletion</td>
<td>22 (1.0)</td>
<td>18 (0.8)</td>
</tr>
</tbody>
</table>

*Safety outcomes reported in participants on and off treatment; †surgical or spontaneous/non-surgical amputation, excluding amputation due to trauma; ‡based on pre-defined list of preferred terms; §AE with the following criteria confirmed by the investigator: i) symptoms of severe impairment in consciousness or behaviour, ii) need of external assistance, iii) intervention to treat hypoglycaemia, iv) prompt recovery of acute symptoms following the intervention

Conclusion

- In patients with CKD, with and without type 2 diabetes, dapagliflozin compared to placebo:
  - Reduced the risk of kidney failure
  - Reduced the risk of death from CV causes or hospitalization for heart failure
  - Prolonged survival

- Dapagliflozin was well tolerated, in keeping with its established safety profile
Thank You

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Marc A. Pfeffer, Stuart Pocock, Karl Swedberg, Jean L. Rouleau, Nishi Chaturvedi, Peter Ivanovich, Andrew S. Levey, and Heidi Christ-Schmidt

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Q&A
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