EMPA-REG OUTCOME® trial design Fact Sheet

**Introduction**

Approximately one in two people with diabetes worldwide dies due to cardiovascular (CV) disease, making it the leading cause of death in this population. The relationship between diabetes and CV disease is complex; diabetes is a risk factor for CV disease and conditions such as high blood pressure and obesity, that are more common in people with diabetes, are also risk factors for CV disease.

Given the association between CV disease and diabetes, studies to establish the CV safety profile of new diabetes treatments are highly important. The EMPA-REG OUTCOME® trial, was a long-term clinical trial which investigated CV outcomes for Jardiance® (empagliflozin) in more than 7,000 adults with T2D at high risk for CV events.

**Trial design**

EMPA-REG OUTCOME® was a multicentre, randomised, double-blind, placebo-controlled trial. The study was designed to assess the effect of Jardiance® (empagliflozin) (10mg or 25mg once daily) added to standard of care compared with placebo added to standard of care on CV events in adults with T2D at high risk of CV events and with less than optimised blood glucose control. The study was designed to first test for non-inferiority and then for superiority.

Zinman et al. Cardiovas Diabetol 2014; 13:102
Standard of care comprised glucose lowering agents and CV drugs (including antihypertensive and lipid lowering agents).

**Primary endpoint:**
Time to first occurrence of CV death, heart attack (non-fatal myocardial infarction) or non-fatal stroke.\(^3\)

**Key secondary endpoints:**
Time to first occurrence of CV death, heart attack (non-fatal myocardial infarction), non-fatal stroke or hospitalisation for unstable angina pectoris.\(^3\)

**Key inclusion criteria:**\(^3\)
- Less than optimised glycaemic control
- High risk of CV events

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**Study population\(^3\)**

<table>
<thead>
<tr>
<th>Region</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>North America / Western Pacific</td>
<td>~20%</td>
</tr>
<tr>
<td>Europe</td>
<td>~41%</td>
</tr>
<tr>
<td>Asia</td>
<td>~19%</td>
</tr>
<tr>
<td>Latin America</td>
<td>~15%</td>
</tr>
<tr>
<td>Africa</td>
<td>~4%</td>
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The trial took place in 590 clinical sites in 42 countries with 7,020 participants and was observed for a median duration of 3.1 years

**Mean age of 63 years**
- 9 percent were ≥75 years

**Time since diagnosis:**
- ≤5yrs in 18 percent
- >10yrs in 57 percent

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**References**