ABSTRACT

Saxagliptin Clinical Trials: Evaluation of CV Risk

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RESULTS

There were no indications of increased risk of CV events:
- In monotherapy or SU based combination therapy; in patients treated with saxagliptin plus SU; in patients treated with saxagliptin plus TZDs; in patients treated with saxagliptin monotherapy plus MET. In the phase 2b/3 pooled population, there was no evidence of increased CV risk with saxagliptin treatment compared to placebo.

METHODOLOGY

To assess saxagliptin in the phase 2b/3 clinical trials, low major adverse cardiac events were defined:
- A major adverse cardiac event was defined as any of the following events: myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass graft surgery, cerebrovascular disease, acute peripheral vascular disease, sudden death, and other unexpected deaths, including deaths due to cardiovascular causes.
- The primary endpoint of the Saxagliptin in Acute Cardiovascular Disease and Diabetes (SAXA) study was the time to the first occurrence of major adverse cardiac event after randomization to saxagliptin 2.5 mg or 10 mg or placebo.

Figures 1-7: Process for Identifying Acute CV Events and MACE

Table 1:cox-Hazard Ratios for Major Adverse Cardiovascular Events in Saxagliptin vs Placebo

Table 2:Risk Factors in Addition to T2D

Table 3:Frequency of End Points

Table 4:Incidence Rate for MACE in Subgroups Expected to Be at Higher Risk

Figures 8-10: Stratifed Analyses of MACE and Acute CV Events

Figures 11-13: Time to Event of First MACE

Figures 14-16: Time to Death of Patients

CVD Events

Patients at Risk

Control

All SAXA

Control

All SAXA

Control

All SAXA

Control

All SAXA

Cardiovascular Safety Summary and Conclusions

- Saxagliptin is safe and effective in patients with T2D.
- Saxagliptin is not associated with an increased risk of CV events.
- Saxagliptin is safe in patients with T2D and a history of CV disease.

REFERENCE


2010 Australian Diabetes Society and Australian Diabetes Educators Association Annual Scientific Meeting, 1-3 September, Sydney, NSW